NEVADA STATE
BOARD OF PHARMACY

BOARD MEETING

December 4 - 5, 2024

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

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

1

Nevada State Board of Pharmacy

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

Date Posted: November 13, 2024

AGENDA

◈ PUBLIC NOTICE ◈

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

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

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

Please Note:

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

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

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

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

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

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

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

◈ CONSENT AGENDA ◈

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

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

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

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

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

Background Check Not Required by Law.

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

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

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

H. McKesseon Medical Surgical, Inc – Suwanee, GA

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

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

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

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

M. Auburn Pharmaceutical, LLC – Rochester Hills, MI
N. Auburn Pharmaceutical, LLC – Salt Lake City, UT
O. Smith Drug Company – Paragould, AR

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

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

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

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

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

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

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

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

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

QQ. The Medicine Shoppe LTC Pharmacy – Las Vegas, NV

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

RR. Wedgewood Pharmacy, LLC – San Jose, CA

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

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

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

UU. ASAP Pharmacy – Orland Park, IL
VV. Cascade Specialty Pharmacy – Poulsbo, WA
WW. Costco Pharmacy #1710 – Madison, WI
XX. Cotttrill's Pharmacy, Inc – Orchard Park, NY
YY. Fertility Pharmacy of America, LP – Nashville, TN
ZZ. Pantherx Specialty Pharmac – Collierville, TN
AAA. RARX II, LLC – Nashville, TN
BBB. Roman Health Pharmacy – Buffalo Grove, IL
CCC. Strive Pharmacy Missouri, LLC –Fenton, MO
DDD. Triad Rx, Inc – Daphne, AL
EEE. TrustedmedRx, LLC – Boca Raton, FL
FFF. UrgentMedRx, LLC – Boca Raton, FL

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

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

GGG. Stephanie Andersson
HHH. Kara Balduzzi

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

III.Prosthetic Center of Excellence – Las Vegas, NV

◈ REGULAR AGENDA ◈

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

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

B. Mee Han	(22-185-CS-B-S)
C. Yuko Sweatt	(22-214-CS-S)
D. Partell Pharmacy	(23-239-PH-S)
E. Jeffrey Lang	(23-239-RPH-S)
F. Matthew Dikin	(23-482-CS-S)
G. DeeFlat Pharmacy	(24-282-PH-O)
H. Thu Thi Phuong Vo	(24-282-RPH-O)
I. Laughlin Pharmacy & Wellness Center	(24-289-PH-S)
J. Youjin Seo	(24-289-RPH-A-S)
K. Thu Thi Phuong Vo	(24-289-RPH-B-S)
L. Safe Chain Solutions	(24-356-WH-O)
M. John Katzen	(24-389-CS-S)
N. Jon Siems	(24-390-CS-S)
O. Matthew Okeke	(19-013-CS-S)
P. Jack Thomas Jr	(22-187-CS-S)
Q. Wilson Bernales	(23-015-CS-S)
R. Marcy Hanson	(24-193-RPH-S)
S. Xu Zhang	(24-196-RPH-S)
T. Orthopedic Motion, Inc	(24-281-MP-S)
U. John Devilbiss	(24-243-RPH-S)

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

    A. Heath DeHart
    B. Nova Specialty Pharmacy

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

    A. Complete Care Pharmacy – Las Vegas, NV
    B. Laughlin Pharmacy – Laughlin, NV

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

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

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

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

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

A. Corstasis USA LLC – Henderson, NV – Background Check Not Required
B. Stericycle, Inc – McCarran, NV – Background Check Not Required

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

A. Jonathan Joel Runion
B. John Venocchi
C. Sherman Washington
D. Shouping Li
E. Victor Jimenez Banuel
F. William Clark

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

A. Nicholas Dipirro
B. Thomas Lynch

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

◈ WORKSHOP ◈

Thursday, December 5, 2024 – 9:00 am

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

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

B. **Amendment to the Nevada Administrative Code ("NAC") 639.742.** The proposed amendments relate to removing the requirement that Dispensing Practitioners must personally dispense at a facility and provide other matters properly relating thereto. The change would allow Dispensing Practitioners to mail prescriptions to individual patients in their care as allowed by the Center for Medicare and Medicaid Services.

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

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

16. Executive Secretary Report:

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

17. Date and Location of Next Scheduled Board Meeting:

    January 15-16, 2025 – Las Vegas, NV

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

19. Adjournment

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

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

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

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

2

3

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206, Reno, NV 89521
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
Email: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

MINUTES

October 16-17, 2024

BOARD MEETING

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, October 16, 2024, at 9:00 am. The meeting will continue Thursday, October 17, 2024, at 9:00 am if necessary or until the Board concludes its business. Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

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

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

Board Members Present:

Helen Park	Krystal Freitas	Wayne Mitchell	Richard Tomasso
Adam Porath	Jade Jacobo	Gener Tejero	

Board Staff Present:

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

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

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

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

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

2. Public Comment October 16, 2024, 9:04 AM

There was no public comment.

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

Board Action:

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

Second: Wayne Mitchell

Action: Passed unanimously.

◈ CONSENT AGENDA ◈

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

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

A. Omnis Medical Services, LLC – Jersey City, NJ
B. Philips RS North America LLC – Murrysville, PA

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

Background Check Not Required by Law.

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

C. Becton, Dickinson & Co. – San Diego, CA

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

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

D. AngioDynamics, Inc – Queensbury, NY
E. BridgeBio Pharma, Inc – Palo Alto, CA
F. Citius Oncology, Inc – Cranford, NJ
G. Cranbury Pharmaceuticals, LLC – Monmouth Junction, NJ
H. Crinetics Pharmaceuticals – San Diego, CA
I. Day One Biopharmaceuticals, Inc – Brisbane, CA
J. Stryker Sales, LLC – Porage, MI
K. Stryker Spine – Allendale, NJ
L. Welch Allyn, Inc – Milwaukee, WI

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

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

M. DHL Supply Chain – Southaven, MS
N. Fisher BioServices, Inc – Frederick, MD

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

O. Ambu, Inc – Columbia, MD
P. Auburn Pharmaceuticals, LLC – Rochester Hills, MI
Q. Averitas Pharma, Inc – Morristown, NJ
R. Cosette Pharmaceuticals, NC Laboratories, LLC – Lincolnton, NC
S. Deciphera Pharmaceuticals, LLC – Waltham, MA
T. DeVilbiss Healthcare – Somerset, PA
U. Dexcel Pharma USA – Parsippany, NJ
V. Endo USA, Inc – Malvern, PA
W. Hu-Friedy Mfg Co, LLC – Des Plains, IL
X. International Medical Industries, Inc – Pampano Beach, FL
Y. Inovo Inc – Lehigh Acres, FL
Z. Messer LLC – City of Industry, CA
AA. Tris Pharma, Inc – Monmouth Junction, NJ

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

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

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

BB. Fisher BioServices, Inc – Rockville, MD
CC. HN Pharma, Inc – Sylmar, CA

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

DD. ER at Aliante – North Las Vegas, NV
EE. ER at Skye Canyon – Las Vegas, NV
FF. ER at Skye Hills – Las Vegas, NV
GG. Lyfe Pharmacy 2 – Las Vegas, NV

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

HH. Olive Tree Compounding Pharmacy – Rio Rancho, NM
II. Valescent Pharmaceuticals, Inc – Centennial, CO
JJ. Vital Care of Albuquerque – Albuquerque, NM

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

KK. AIDS Healthcare Foundation – Fort Lauderdale, FL
LL. Blend Labs, Rx, LLC – South Richmond Hill, NY
MM. Brigent – Calabasas, CA
NN. CoAssist Pharmacy, LLC – Orlando, FL
OO. CoverMyMeds Pharmacy – Louisville, KY
PP. CoverMyMeds Pharmacy – Columbus, OH
QQ. CoverMyMeds Pharmacy – Memphis, TN
RR. CoverMyMeds Pharmacy – Irving, TX
SS. Jase Pharmacy – West Jordan, UT
TT. Kroger Specialty Pharmacy – Garden Grove, CA
UU. Kroger Specialty Pharmacy – Lake Mary, FL
VV. Orsini Pharmaceutical Services, LLC – Columbus, OH
WW. Stellus Rx, LLC – Plano, TX
XX. Village Fertility Pharmacy, LLC – Waltham, MA

YY. Walgreens Gene & Cell Services #21574 – Pittsburgh, PA

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

ZZ. Hualapai Ambulatory Surgery Center, LLC – Las Vegas, NV

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

AAA. Eagle Pharma Outsourcing – Hoover, AL

David Wuest, Executive Secretary for Nevada Board of Pharmacy, stated that item 4L has been withdrawn, item 4P has requested to table their application, and item 4U was only a name change and will be reported to the Board in the December meeting.

Board Action:

Motion: Jade Jacobo moved to approve the Consent Agenda with the exception of the Agenda Item 4IL, 4P and 4U.

Second: Wayne Mitchell

Action: Passed unanimously.

◈ REGULAR AGENDA ◈

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

I. Sam Zand (21-229-CS-A-S)

Bridget Kelly appeared as counsel on behalf of Sam Zand.

Brett Kandt, General Counsel for the Nevada State Board of Pharmacy, prosecuted the case alleging that the respondent permitted unauthorized access of his credentials with the PMP database, and failed to check MyRx report regularly as required by Nevada law.

Mr. Kandt presented a proposed Stipulation and Order for Case No. 21-229-CS-A-S for the Board's consideration.

The proposed stipulated penalties for Sam Zand, Certificate of Registration No. CS22466, are the following:

Respondent as the holder of Certificate of Registration No. CS22466 is placed on probation for a period of one (1) year with public reprimand; Respondent fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs.

Board discussion ensued.

Board Action:

Motion: Wayne Mitchell moved to approve the Stipulation and Order for Sam Zand as presented by Mr. Kandt.

Second: Jade Jacobo

Action: Passed unanimously.

P. Heather Nicole Zamzow (22-004-CS-S)

Heather Zamzow, DVM, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that Dr. Zamzow wrote a prescription for buprenorphine, a Schedule III controlled substance, when she did not hold an active DEA registration.

Mr. Zunino presented a proposed Stipulation and Order for Case No. 22-004-CS-S for the Board's consideration.

The proposed stipulated penalties for Heather Nicole Zamzow, Certificate of Registration No. CS09628, are the following: 1) that Dr. Zamzow's certificate of registration to prescribe controlled substances be revoked, with an allowance to petition for reinstatement after 1 year or when Dr. Zamzow obtains a DEA registration number, whichever is later; 2) that Dr. Zamzow pay a $5,000 fine for the violations; and; 3) that Dr. Zamzow pay $500 to partially reimburse the Board for recoverable attorney fees and costs incurred in investigating and prosecuting this matter. The fine and attorney's fees and costs are to be paid by April 30, 2025.

Board discussion ensued.

Board Action:

Motion: Wayne Mitchell moved to approve the Stipulation and Order for Heather Nicole Zamzow as presented by Mr. Zunino.

Second: Krystal Freitas

Action: Passed unanimously.

B.	Douglas Thomas	(19-105-CS-A-S)
C.	Anna Melisa Lopez-Sanglay	(19-105-CS-B-S)
D.	Susan Smith	(19-105-CS-C-S)
E.	Jordan Spoon	(19-105-CS-D-S)
F.	Vanessa Benes	(19-105-CS-E-S)
G.	Christine Crovetti	(19-105-CS-F-S)

President Park recused herself from this matter due to her personal relationship with Dr. Thomas and Thomas Dermatology.

Marie Ellerton appeared as counsel on behalf of respondents.

Douglas Thomas, Anna Melisa Lopez-Sanglay, Susan Smith, Jordan Spoon, Vanessa Benes, and Christine Crovetti were sworn in by Jade Jacobo prior to answering questions and offering testimony.

Brett Kandt, General Counsel for the Nevada State Board of Pharmacy, prosecuted the case against the respondents alleging that Thomas Dermatology was dispensing prescriptions without a valid dispensing registration for all dispensing practitioners.

Mr. Kandt presented a proposed Stipulation and Order for Case No. 19-105-CS-A-S for the Board's consideration. Per the proposed stipulation, all causes of action against Lopez-Sanglay, Smith, Spoon, Benes and Crovetti, as set forth in Counts 1, 2, 3 and 5, Paragraphs 10, 11, 12 and 14 of the Accusation, are hereby DISMISSED pursuant to NRS 622A.320(4). Lopez-Sanglay, Smith, Spoon, Benes and Crovetti shall each accept this Stipulation and Order as a WARNING against dispensing prescriptions for controlled substances or dangerous drugs to patients without a valid dispensing practitioner registration.

The proposed stipulated penalties for Douglas Thomas, Certificate of Registration Nos. CS06503, PD00297, and PD27397, are the following:

Respondent Thomas' Certificate of Registration Nos. CS06503, PD00297, and PD27397 are suspended for a period of one year. The suspensions are stayed subject to the following conditions: 1) a public reprimand; 2) Respondent fined $8,000 for the violations; and 3) Respondent assessed $3,000 in attorney's fees and costs.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Stipulation and Orders for Douglas Thomas, Anna Melisa Lopez-Sanglay, Susan smith, Jordan Spoon, Vanessa Benes, and Christine Crovetti, as presented by Mr. Kandt.

Second: Richard Tomasso

Action: Passed unanimously.

A. Mihreteab Tesema (19-049-RPH-S)

Brett Kandt, General Counsel for Nevada State Board of Pharmacy, reported that the respondent had come into compliance and requested that the Board vacate the show cause hearing.

President Park vacated the Order to Show Cause against Mihreteab Tesema.

J. Marie Michelle Stevens (21-229-CS-B-S)

Brett Kandt, General Counsel for Nevada State Board of Pharmacy reported that the respondent had come into compliance and requested that the Board vacate the show cause hearing.

President Park vacated the Order to Show Cause for Marie Michelle Stevens.

H. Vincent Nalbone (21-109-CS-S)

Bridget Kelly appeared as counsel on behalf of Vincent Nalbone.

Brett Kandt, General Counsel for Nevada State Board of Pharmacy, prosecuted the case alleging that Dr. Nalbone issued prescriptions under the names of his staff to obtain controlled substances for general office administration.

Mr. Kandt presented a proposed Stipulation and Order for Case No. 21-109-CS-S for the Board's consideration.

The proposed stipulated penalties for Vincent Nalbone, Certificate of Registration No. CS08907, are the following: Respondent as the holder of Certificate of Registration No. CS08907 is placed on probation for a period of one year with public reprimand; Respondent fined $2,500 for the violations; assessed $1,000 in attorney fees and costs; and Respondent's practice subject quarterly inspections, not to exceed $500 per inspection.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Order for Vincent Nalbone as presented by Mr. Kandt.

Second: Krystal Freitas

Action: Passed unanimously.

S.	Walgreens Pharmacy #6424	(23-310-PH-S)
T.	Sanette Severance	(23-310-RPH-S)

William Stilling appeared as counsel on behalf of Walgreen's Pharmacy #6424 and Sanette Severance.

Sanette Severance appeared and was sworn in by President Park prior to answering questions and offering testimony.

Gener Tejero disclosed that he has a business relationship with William Stilling but he can participate in this matter fairly and without bias.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that Dr. Severance failed to communicate matters which would enhance therapy through drugs to patient concerning his prescription.

Mr. Zunino presented a proposed Stipulation and Order for the Board's consideration.

Mr. Zunino commented that Count Two is dismissed in the Accusation.

The proposed stipulated penalties for Walgreens Pharmacy #6424, Pharmacy License No. PH01628, are the following: 1) pay $750 fine for the violations; and 2) pay $500 to partially reimburse the Board for recoverable attorney fees and costs incurred investigating and prosecuting this matter.

The proposed stipulated penalties for Sanette Severance, Certificate of Registration No. 20772, are the following: 1) pay $750 fine for the violations; and 2) pay $500 to partially reimburse the Board for recoverable attorney fees and costs incurred investigating and prosecuting this matter.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Orders for Walgreens Pharmacy #6424 and Sanette Severance as presented by Mr. Zunino.

Second: Krystal Freitas

Action: Passed unanimously.

L. Robert Feingold (23-118-CS-S)

Craig Perry appeared as counsel on behalf of Robert Feingold.

Brett Kandt, General Counsel for the Nevada State Board of Pharmacy, prosecuted the case against Dr. Feingold alleging unlawfully issued prescriptions; failed to put into practice all necessary policies and procedures to maintain the security of the drug inventory in the course of operating Advance Medical; failed to keep and maintain a complete, accurate and readily retrievable records accounting for all controlled substances and dangerous drugs; and failed to query the PMP database both prior to issuing and upon dispensing controlled substance prescriptions..

Mr. Kandt presented a proposed Stipulation and Order for Case No. 23-118-CS-S for the Board's consideration.

The proposed stipulated penalties for Robert Feingold, Certificate of Registration Nos. CS15741, CS18837, CS28864, PD15741 and PD27479, are the following: Certificate of Registration Nos. CS154741, CS18837, CS28864, PD15741, and PD27479 are revoked. The revocations are stayed, and Respondent is placed on probation for a period of three (3) years subject to the following conditions: 1) a public reprimand; 2) Respondent fined $13,000 for the violations; and 3) assessed $3,000 in attorney's fees and costs.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Order for Robert Feingold as presented by Mr. Kandt.

Second: Wayne Mitchell

Action: Passed unanimously.

V. Prosthetic Center of Excellence (24-263-MP-S)

Thomas Hartman, Senior Vice President and General Counsel for Prosthetic Center of Excellence, appeared on behalf of the respondent.

Gustaf Vanderdonck, General Counsel for the Nevada State Board of Pharmacy, prosecuted the case against Prosthetic Center of Excellence alleging that the respondent failed to notify the Board of the change of ownership or of the departure of its facility administrator in a timely matter.

Mr. Vanderdonck presented a proposed Stipulation and Orders for Case Nos. 24-263-MP-S for the Board's consideration.

The proposed stipulated penalties for Prosthetic Center of Excellence, License No. MP00109, are the following: 1) pay a $2,000 fine for the violations; and 2) pay $500 to partially reimburse the Board for recoverable attorney fees and costs incurred investigating and prosecuting this matter.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Stipulation and Order for Prosthetic Center of Excellence as presented by Mr. Vanderdonck.

Second: Jade Jacobo

Action: Passed unanimously.

M. Jason Dazley (23-266-CS-A-S)

Jason Dazley appeared and was sworn in by President Park prior to answering questions and offering testimony.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Dr. Dazley alleging that as medical director of Prime IV, Dazley permitted registered nurses (RNs), paramedics, Advanced Emergency Medical Technicians (AEMTS) and/or Emergency Medical Technicians (EMTS) to independently access, possess and administer dangerous drugs, without direct practitioner supervision..

Mr. Kandt presented a proposed Stipulation and Order for Case No. 23-266-CS-A-S for the Board's consideration.

The proposed stipulated penalties for Jason Dazley, Certificate of Registration No. CS25977, are the following: Respondent as the holder of Certificate of Registration No. CS25977 i s placed on probation for a period of one year with public reprimand; Respondent fined $2,500 for the violations; and assessed $1,000 in attorney fees and costs.

Board discussion ensued.

Board Action:

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

Second: Jade Jacobo

Action: Passed unanimously.

Q. Anneleisa Gail McDonald (22-069-CS-S)

No representative was present on behalf of Anneleisa McDonald.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that Ms. McDonald failed to disclose on her October 21, 2022 renewal application that she was disciplined by the Nevada Board of Nursing.

Erin Miller and Jessette Phaynarikone, Board Coordination for the Nevada State Board of Pharmacy, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Mr. Zunino questioned Ms. Miller and Ms. Phaynarikone on their positions at the Nevada Board of Pharmacy and what their responsibilities include.

Mr. Zunino questioned Ms. Miller on serving the Accusation upon Ms. McDonald.

Mr. Zunino questioned Ms. Phaynarikone on serving the Notice of Hearing upon Ms. McDonald.

Mr. Zunino commented that he called and emailed the respondent regarding this Accusation and Notice of Hearing with no response. He would like to proceed with a default hearing.

Mr. Zunino requested the Board find that Ms. McDonald was adequately and properly noticed of the hearing.

Board Action:

Motion: President Park moved that Ms. McDonald was adequately and properly noticed of the hearing.

Second: Adam Porath

Action: Passed unanimously.

Mr. Zunino requested the Board to make Findings of Fact consistent with paragraphs 3-11 of the Accusation.

Board Action:

Motion: President Park moved to make Findings of Fact consistent with paragraphs 3-11 of the accusation.

Second: Jade Jacobo

Action: Passed unanimously.

Mr. Zunino requested the Board to make Conclusions of Law consistent with paragraphs 12-18 of the Accusation.

Board Action:

Motion: Jade Jacobo moved to make Conclusions of Law consistent with paragraphs 12-18 in the Accusation.

Second: Krystal Freitas

Action: Passed unanimously.

Mr. Zunino requested the Board to make the Findings of Culpability consistent with paragraphs 19-27 of the accusation.

Board Action:

Motion: Jade Jacobo moved to find Ms. McDonald guilty of Count One and Count Two consistent with paragraphs 19-27 of the Accusation.

Second: Krystal Freitas

Action: Passed unanimously.

Mr. Zunino recommended the proposed discipline against Anneleisa McDonald's , Certificate of Registration No. CS30357, as the following: 1) Certificate of Registration No. CS30357 will be revoked with an allowance to petition for reinstatement after one (1) year; and 2) pay $687.67 to partially reimburse the Board for recoverable attorney fees and costs incurred in investigating and prosecuting this matter.

Board Action:

Motion: Jade Jacobo moved to revoke Anneleisa McDonald's Certificate of Registration No. CS30357 for a period of one (1) year, effective immediately.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to award attorney's fees and costs of $687.67 on the basis that they were reasonable, necessary, and actually incurred.

Second: Krystal Freitas

Action: Passed unanimously.

K. Cristy O'Connell (23-090-CS-S)

J. Malcolm Devoy appeared as counsel on behalf of Cristy O'Connell.

Brett Kandt, General Counsel for the Nevada State Board of Pharmacy, prosecuted the case against Dr. O'Connell alleging that the practitioner issued prescriptions under the name of specific patients to obtain controlled substances for general office administration.

Mr. Kandt presented a proposed Stipulation and Order for Case No. 23-090-CS-S for the Board's consideration.

The proposed stipulated penalties for Cristy O'Connell, Certificate of Registration No. CS25857, are the following:
Respondent as the holder of Certificate of Registration No. CS25857 is placed on probation for a period of one year with public reprimand; Respondent fined $2500 for the violations; assessed $1000.00 in attorney's fees and costs; and Respondent's practice subject to quarterly inspections Respondent's expense, not to exceed $500 per inspection.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Stipulation and Order for Cristy O'Connell as presented by Mr. Kandt.

Second: Krystal Freitas

Action: Passed unanimously.

N. Archway Apothecary (23-441-PH-O)

Gener Tejero disclosed that he has a business relationship with William Stilling but he can participate fairly and without bias.

William Stilling appeared as counsel for Archway Apothecary.

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

Brett Kandt, General Counsel for the Nevada State Board of Pharmacy, prosecuted the case against Archway Apothecary, charged with engaging in unprofessional conduct as detailed in the California State Board of Pharmacy's Order entered in Case No 7175..

Mr. Kandt presented a proposed Stipulation and Order for Case No. 23-441-PH-O for the Board's consideration.

The proposed stipulated penalties for Archway Apothecary, Pharmacy License No. PH04307, are the following: 1) Pharmacy License No. PH04307 will be suspended until November 30, 2025, concurrent with the California Board of Pharmacy action; the suspension is stayed, and Archway Apothecary is placed on probation subject to the following terms: 1) Respondent shall notify the Board of any change in status of their probation with the California State Board of Pharmacy in that case; and 2) Respondent assessed $1,000 in attorney's fees and costs.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Order for Archway Apothecary as presented by Mr. Kandt.

Second: Adam Porath

Action: Passed unanimously.

U. Jodi Sabala (24-221-PTT-N)

No representative was present on behalf of Jodi Sabala.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging Ms. Sabala diverted several controlled substance tablets for personal use. He would like to continue with a default hearing.

Mr. Zunino called Jessette Phaynarikone as a witness.

Jessette Phaynarikone, Board Coordination, appeared and was still sworn from a previous matter.

Mr. Zunino questioned Ms. Phaynarikone on the serving of the Accusation and the Notice of Hearing.

Mr. Zunino requested President Park to admit Exhibits 1-4 into the record.

President Park admitted Exhibits 1-4 into the record.

Mr. Zunino requested the Board to find that Ms. Sabala was adequately and properly noticed of the hearing.

Board Action:

Motion: Jade Jacobo moved to find that Ms. Sabala was adequately and properly noticed of the hearing.

Second: Adam Porath

Action: Passed unanimously.

Mr. Zunino requested the Board to make Findings of Fact consistent with paragraphs 3-7 of the Accusation.

Board Action:

Motion: Jade Jacobo moved to make Findings of Fact consistent with paragraphs 3-7 of the Accusation.

Second: Adam Porath

Action: Passed unanimously.

Mr. Zunino requested the Board to make Conclusions of Law consistent with paragraphs 8-12 of the Accusation.

Board Action:

Motion: Jade Jacobo moved to make Conclusions of Law consistent with paragraphs 8-12 in the Accusation.

Second: Adam Porath

Action: Passed unanimously.

Mr. Zunino requested the Board to make Findings of Culpability consistent with paragraphs 13-18 of the Accusation.

Board Action:

Motion: Jade Jacobo moved to find Ms. Sabala guilty of Count One, Count Two, and Count 3 consistent with paragraphs 13-18 of the accusation.

Second: Adam Porath

Action: Passed unanimously.

Mr. Zunino recommended the proposed discipline against Ms. Sabala, Certificate of Registration No. PT24955, as the following: 1) Certificate of Registration No. PT24955 will be revoked for a period of at least one (1) year; and 2) pay $545.30 to partially reimburse the Board for recoverable attorney fees and costs incurred in investigating and prosecuting this matter.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to revoke Ms. Sabala's Certificate of Registration No. PT24955, effective immediately, with an allowance to petition for reinstatement after 2 years.

Second: Helen Park

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to award the attorney's fees and costs of $545.36 on the basis that they were reasonable, necessary, and actually incurred.

Second: Adam Porath

Action: Passed unanimously.

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

This matter was continued.

R. Jack Thomas, Jr (22-187-CS-S)

This matter was continued.

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

This matter was continued.

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

A. OxyGo

Blaine King, representative for OxyGo, appeared and was sworn in prior to answering questions and offering testimony.

Gustaf Vanderdonck, General Counsel for Nevada State Board of Pharmacy, gave a brief overview of the Citation and Fine appeal.

Mr. King provided a statement to the Board.

Mr. Vanderdonck called Monica Segedy as a witness.

Monica Segedy, Board Investigator for the Nevada Board of Pharmacy, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Vanderdonck questioned Ms. Segedy on her position with the Nevada State Board of Pharmacy, her investigation of the case, and Exhibit 1.

Mr. Vanderdonck requested that Exhibit 1 be entered into the record.

President Park admitted Exhibit 1 into record.

Mr. Vanderdonck questioned Ms. Segedy on Exhibit 2.

Mr. Vanderdonck requested that Exhibit 2 be entered into the record.

President Park admitted Exhibit 2 into record.

Board discussion ensued.

Mr. Vanderdonck and Mr. King gave their closing statement.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to uphold the $5,000 Fine for OxyGo.

Second: Richard Tomasso

Action: Passed unanimously.

17. General Counsel Report

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

18. Executive Secretary Report:

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

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

7. Application for Rehearing and Reinstatement pursuant to NRS 639.252 from American Wellness Pharmacy, Case No. 23-063-PH-S. **(FOR POSSIBLE ACTION)**

Richard Tomasso disclosed that he received information on this case after the last hearing and will recuse himself from this matter.

Kimberly Maxton-Rushton appeared as counsel for American Wellness Pharmacy.

Eytan Klepach, Co-Owner, and George Maiorano, Co-Owner, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case and gave a brief background on the events that occurred, and respondent's request for an amendment to 8(C) of the Stipulation and Order.

Ms. Maxton-Rushton asked the Board to amend Section 8(C) of the Stipulation and Order and provided the actions taken by American Wellness Pharmacy to remedy Board's concerns.

Board discussion ensued.

Jade Jacobo was excused from the meeting at 2:02PM.

Jade Jacobo returned to the meeting at 2:11PM.

Todd Weiss, Deputy Attorney General for the Attorney General's office, provided counseling on what the next step would be for the Board in this matter.

President Park commented that Jade Jacobo was excused from the meeting at 2:37PM.

Mr. Weiss clarified that the Board would need to vote on the motion to either grant or deny the rehearing as provided by statute, prior to reviewing or discussing any amendments that would be made to section 8(C) of the signed stipulation.

Board discussion ensued.

President Park noted that Jade Jacobo left the meeting at 2:37PM.

Board Action:

Motion: President Park moved to grant the rehearing for section 8(C) for American Wellness Pharmacy's previous Stipulation.

Second: Adam Porath

Aye: Porath, Park, Freitas
Nay: Tejero, Mitchell

Action: Motion passed (Tomasso recused).

Mr. Kandt gave an overview of the amendment to section 8(C) of the original stipulation.

Ms. Maxton Rushton shared what additional amendments the Respondents were willing to add to their stipulation.

Board discussion ensued.

David Wuest, Executive Secretary of the Nevada Board of Pharmacy, read the proposed amendments to section 8(C) of the original Stipulation and Order.

Ms. Maxton-Rushton stated that the Respondents are in agreement with the proposed amendments to section 8(C) but wanted to propose that the Pharmacist in Charge and the designated person would be the only two people required to complete the sterile compound training, being that they would be the only individuals who would be participating in sterile compounding until the remainder of staff completed their sterile compounding training.

Mr. Wuest read into record the proposed amendments to section 8(C) of the Stipulation and Order for Case No. 23-063-PH-S for the Board's consideration.

The proposed amendments to section 8(C) for American Wellness Pharmacy, Pharmacy License No. PH02705, are the following: Prior to resuming sterile compounding, American Wellness Pharmacy shall; 1) Respondent shall generate and send written notice to patients for products that were mislabeled with inaccurate beyond use dates in the two (2) years prior to the date of the Order and offer a refund to patients. The form of notification is subject to approval by Board staff, and Respondent must submit the list to Board staff; 2) the Managing Pharmacist, Designated Person, and Sterile Compounding Personnel shall complete USP Implementation Training, CORE Compounding Training and Sterility Assurance Training courses through accredited vendor PCCA, and documentation of completion shall be provided to Board staff; 3) the Managing Pharmacist and Designated Person shall complete all CE modules comprised of all Sterile Compounding Training Schedule through Critical Point, and documentation of completion shall be provided to Board staff; 4) upon completion of above amendments, Respondent shall be subject to an inspection by Board staff prior to resuming sterile compounding; inspection shall count towards one of the quarterly inspections required in original Stipulation; 5) each pharmacist and pharmaceutical technician shall also complete the USP Implementation Training, CORE Compounding Training and Sterility Assurance Training courses through accredited vendor PCCA, and documentation of completion shall be provided to Board staff prior to engaging in sterile compounding; and 6) Respondent shall have two (2) additional inspections complete by the National Association of Boards of Pharmacy (NABP) during the probationary period, with results sent to Board staff.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the amendments to section 8C of the original Stipulation and Order in Case No. 23-063-PH-S.

Second: Krystal Freitas

Action: Passed unanimously (Tomasso recused).

18. Executive Secretary Report:

Monica Moazez, Assistant General Counsel for Nevada Board of Pharmacy, shared an advisory that the Nevada Board of Pharmacy had received reports of scam calls of individuals impersonating Board members and Board staff. A notice was uploaded to the Nevada Board of Pharmacy website.

Mr. Wuest noted the change made to the Board meeting calendar for 2025.

15. Pursuant to NAC 639.256, Walgreens Corporation is requesting approval of its Program of Training for Pharmaceutical Technicians. **(FOR BOARD ACTION)**

Victoria Kroger, Manager of Walgreens' Pharmacy Affairs, appeared and gave an overview of Walgreens' Program of Training for Pharmaceutical Technicians for the Board's approval.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve Walgreen's request to approve their Program of Training for Pharmaceutical Technicians.

Second: Wayne Mitchell

Action: Passed unanimously.

8. Application for Pharmacist Registration Reinstatement – Appearance **(FOR POSSIBLE ACTION)**

   A. Daniel Hays

Daniel Hays appeared and was sworn in by President Park prior to answering questions and offering testimony.

David Wuest, Executive Secretary for the Nevada Board of Pharmacy, gave a brief overview of what had occurred since Mr. Hays was last before the Board.

Board discussion ensued.

Board Action:

Motion: President Park moved to have Daniel Hays' license remain in an "Inactive" status until June 23, 2026 and would need to appear before the Board if he ever would like to activate his license to practice in Nevada after June 23, 2026.

Second: Wayne Mitchell

Action: Passed unanimously.

Public comment October 16, 2024, at 4:22PM

There was no public comment.

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

Board Members Present:

Helen Park	Krystal Freitas	Wayne Mitchell	Richard Tomasso
Adam Porath	Gener Tejero	Jade Jacobo	

Board Staff Present:

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

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

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

Call to Order and Roll Call – Establishment of Quorum

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

Public Comment October 17, 2024, 9:04 AM

Danilo Jaravata appeared and notified the Board that he was present for his appearance today.

◈ WORKSHOP ◈

Thursday, October 17, 2024 – 9:00 am

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

    A. **Amendment to the Nevada Administrative Code ("NAC") 639**. The proposed amendments relate to the licensing requirements for facilities for treatment with narcotics and provide other matters properly relating thereto.

Darla Zarley, PMP Administrator for the Nevada Board of Pharmacy, presented the background on the amendment to the Nevada Administrative Code NAC 639. Ms. Zarley outlined the specific changes that would be made with this amendment.

Brett Kandt, General Counsel for Nevada Board of Pharmacy, gave additional notes on the amendments being made to the administrative code and noted that there is a typo in the proposed regulation that will need to be updated.

David Wuest, Executive Secretary for Nevada Board of Pharmacy, gave a brief background on what occurred before this amendment was proposed.

President Park opened the floor for public comment.

Stephanie Cook, NV State Opioid Treatment Authority, appeared and commented that she appreciated working with Board staff on the proposed regulation amendment.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to adopt the amendments for the licensing requirements for facilities.

Second: Wayne Mitchell

Action: Passed unanimously.

◈ PUBLIC HEARING ◈

Thursday, October 17, 2024 – 9:00 am

18. Notice of Proposed Regulation Public Hearing Pursuant to NRS 233B.061(2)

(FOR POSSIBLE ACTION)

A. **Amendment to Nevada Administrative Code NAC 639.748.** The proposed amendments revises the requirements concerning the documentation an employee of a pharmacy must obtain from a person before dispensing a controlled substance pursuant to a lawful prescription to the person. (LCB File No. R189-24)

David Wuest, Executive Secretary for Nevada Board of Pharmacy, gave a brief overview of the background of the proposed regulation.

President Park opened the floor for public comment.

There was no public comment.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve LCB File No. R189-24 as presented by Board staff.

Second: Krystal Freitas

Action: Passed unanimously.

16. Discussion on Audit by Casey Neilon Pursuant to NRS 218G.400 for Fiscal Year Ending June 30, 2024 – **(FOR POSSIBLE ACTION)**

David Wuest, Executive Secretary for the Nevada Board of Pharmacy, explained why the outside audit was completed.

Kiran Bains, Finance Manager for the Nevada Board of Pharmacy, gave a brief overview of the financial audit and addressed the background of changes had been made in order to become more compliant during the audit this year.

9. Application for Nevada Ambulatory Surgery Center License (NAC 639.4992) - Appearance (**FOR POSSIBLE ACTION)**

A. Saguaro Surgical Center, LLC – Las Vegas, NV

Mary Grear, Consultant Pharmacist, Nicola Spirtos, Temporary Chief Medical Officer, and Kathleen Krueger, Administrator, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Joe Dodge, Inspector for Nevada Board of Pharmacy, gave a brief background of the application and asked if all partners of the surgical center would be providing surgical services, what type of surgeries will be performed, and if they planned on getting accredited. Dr. Dodge also asked Ms. Grear how many locations that she was currently contracted in Nevada, how many pharmacists she employs, and how often they visit surgery centers.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve Saguaro Surgical Center's Ambulatory Surgery Center License.

Second: Adam Porath

Action: Passed unanimously.

B. Vegas Ambulatory Surgery Center LLC – Las Vegas, NV

Mary Grear, Consultant Pharmacist, appeared on behalf of the applicants and was still sworn in from a previous matter.

Thomas Meagher, Consultant Nurse, and George Tan, Physician, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Joe Dodge, Inspector for Nevada Board of Pharmacy, gave a brief background of the application and asked Dr. Tan if he has ever owned a surgery center before, if Ivy Tan will be the Director of Nursing at the facility, what days the surgery center will be operating, and what type of surgeries would be done at the facility.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve Vegas Ambulatory Surgery Center's Ambulatory Surgery Center License.

Second: Jade Jacobo

Action: Passed unanimously.

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

A. AHCS Well Care – Reno, NV
B. AHCS Well Care – Las Vegas, NV

Christopher Smith, Senior Counsel, and Thomas Lan, VP of Compliance and Risk Management, appeared, and Mr. Lan was sworn in by President Park prior to answering questions and offering testimony.

Gustaf Vanderdonck, General Counsel for Nevada Board of Pharmacy, gave a brief background of the application and asked what would occur with the ownership change, if any staff changes would be made, and verified that there were no disclosures.

President Park asked Mr. Tan to confirm the change in Managing Pharmacists for both locations.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve ownership and name change for AHCS Well Care for both locations.

Second: Adam Porath

Action: Passed unanimously.

C. Vegas Specialty Pharmacy – Las Vegas, NV

Hashim Nawaz, Pharmacist, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Monica Moazez, Assistant General Counsel for the Nevada Board of Pharmacy, asked Dr. Nawaz if he had ever owned a pharmacy, his past work experience, how long he had been doing the supervisory role at his current location, and if he planned to hire pharmacy technicians at his location. Ms. Moazez asked Dr. Nawaz to verify if he planned to open this location as a retail pharmacy selling only dangerous drugs and controlled substances, and if he had any experience in nonsterile compounding.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Nevada Pharmacy License for Vegas Specialty Pharmacy, subject to a favorable inspection.

Second: Krystal Freitas

Action: Passed unanimously.

Jade Jacobo left the meeting at 10:20AM.

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

E. Hann's Pharmacy – Fairfax, VA

Kristen Souders, Owner and Pharmacist in Charge, Morgan Hennington, Pharmacist, and Mary Buckley, Pharmacist, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Gustaf Vanderdonck, General Counsel for Nevada Board of Pharmacy, gave a brief background of the application, and for them to explain the disclosure on the application of the discipline from the Virginia Board of Pharmacy.

Jade Jacobo returned to the meeting at 10:23AM.

Mr. Vanderdonck asked Dr. Souders of her sterile compounding experience she had, what training they have planned for the staff who would be doing sterile compounding, if they had been following the updated USP guidelines, how they planned to ship their products, and to explain the inspection completed by NABP.

Adam Porath commented that the application did not state that they were going to be doing dangerous drugs along with controlled substances.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Out-of-State Pharmacy License for Hann's Pharmacy, pending discussion with Joe Dodge on sterile compounding.

Second: Jade Jacobo

Action: Passed unanimously.

F. Omniscript Pharmacy, LLC – Phoenix, AZ

Kristine Lowe, Pharmacist in Charge, and Matt Potter, Lab Director, appeared and were sworn in by President Park prior to answering questions and offering testimony.

David Wuest, Executive Secretary for Nevada Board of Pharmacy, gave a brief background of the application and asked the respondents about the business plan they have for Nevada, for the applicants to walk through the disclosures from the Arizona Board of Pharmacy, and if there would be any changes to the sterile compounding process with the name change.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Out-of-State Pharmacy License for Hann's Pharmacy, pending the review of the sterile compounding questionnaire by Joe Dodge.

Second: Krystal Freitas

Action: Passed unanimously.

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

    C. Steven Michael Brown

Bridget Kelly appeared as counsel on behalf of Steven Michael Brown.

Steven Brown appeared was sworn in by President Park prior to answering questions and offering testimony.

Ms. Kelly requested that the Board go into a closed session on behalf of Dr. Brown.

Board Action:

Motion: President Park moved to go into closed session.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

Motion: President Park moved to go into open session.

Second: Jade Jacobo

Action: Passed unanimously.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the controlled substance registration for Dr. Brown.

Second: Adam Porath

Action: Passed unanimously.

E. Victoria Orr

Victoria Orr appeared and was sworn in by President Park prior to answering questions and offering testimony.

David Wuest, Executive Secretary of Nevada Board of Pharmacy, gave a brief background on the application and asked her to go into detail on the disclosure listed on her application.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the controlled substance registration for Victoria Orr.

Second: Gener Tejero

Action: Passed unanimously.

A. Danilo Jaravata

Danilo Jaravata appeared and was sworn in by President Park prior to answering questions and offering testimony.

David Wuest, Executive Secretary for Nevada Board of Pharmacy, gave a brief overview of the application and asked Dr. Jaravata to confirm whether he planned to prescribe Schedule I drugs, as he marked it on his application. Mr. Wuest also asked Dr. Jaravata to explain the disclosure on his application, and whether he is aware of the PMP program and its laws in Nevada.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the controlled substance registration for Danilo Jaravata, pending an update to remove Schedule I from his application and with the need to complete a two (2) hour training on PMP with Board staff.

Second: Krystal Freitas

Action: Passed unanimously.

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

A. BioMatrix Specialty Pharmacy – Van Nuys, CA
B. BioMatrix Specialty Pharmacy – Plantation, FL
C. BioMatrix Specialty Pharmacy – Garnet Valley, PA
D. BioMatrix Specialty Pharmacy – Bartlett, TN

Allison Croft, Pharmacist in Charge – PA, Jessica Caballero, Pharmacist in Charge – FL, Lacy Burns, Pharmacist in Charge – TN, Diana Badaross, Pharmacist in Charge - CA, Dana Proum, Pharmacist in Charge - NV, Morgan Harber, Chief Administrative Officer and Designated Representative for BioMatrix Specialty Pharmacy, and Robyn Hansen, Regulatory Compliance Consultant, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Jade Jacobo returned to the meeting at 1:09PM.

Monica Moazez, Assistant General Counsel for Nevada Board of Pharmacy, gave a brief overview of the ownership change applications for all locations, and asked whether there were any policy changes with the change of ownership. Ms. Moazez asked whether the California location would be dealing with dangerous drugs only, and to further explain the disclosures listed on the California application.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the ownership changes for BioMatrix Specialty Pharmacy for all locations.

Second: Adam Porath

Action: Passed unanimously.

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

A. Save Life's Durable Medical Equipment Supply – Las Vegas, NV

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

Monica Moazez, Assistant General Counsel for Nevada Board of Pharmacy, gave a brief overview of the application and asked Mr. Ejiofor what experience he has with medical supplies, what medical devices and products he plans to sell at the location, and how many days a week he planned to be open.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve name and ownership change for Save Live's Durable Medical Equipment Supply.

Second: Adam Porath

Action: Passed unanimously.

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

D. Valerie Drnovsek

Valerie Drnovsek appeared and was sworn in by President Park prior to answering questions and offering testimony.

Gregory Zunino, Senior General Counsel for Nevada Board of Pharmacy, gave a brief overview of the application and asked Dr. Drnovsek if she will only be practicing in Nevada and not participating in any telemedicine, and to detail what occurred in her disclosure.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the controlled substance registration for Dr. Drnovsek, as long as she continued treatment with Dr. Chase and NVBOP would receive quarterly reports through November 27, 2028.

Second: Gener Tejero

Action: Passed unanimously.

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

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

This matter was continued.

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

    B. John Vennochi

This matter was continued.

21. Date and Location of Next Scheduled Board Meeting:

    December 4-5, 2024 – Las Vegas, NV

22. Public Comment

President Park opened the floor for public comment.

There was no public comment.

23. Adjournment

DRAFT

4

4A

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: ABC Home Medical Supply, Inc.

MDEG Physical Address: 1720 N Greenville Ave

City: Richardson State: TX Zip: 75081-1808

Mailing Address (if different from physical address): 1660 SW Saint Lucie West Blvd, STE 200

City: Port Saint Lucie State: FL Zip: 34986-1965

Telephone: 972-279-9090 Website: www.abc-med.com

Email: credentialing@abc-med.com

Name of MDEG Administrator (NAC 639.694): Deborah Teel

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

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 9am - 3:30pm	■ Tue: 9am - 3:30pm	■ Wed: 9am - 3:30pm	■ Thurs: 9am - 3:30pm	■ Fri: 9am - 3:30pm
☐ Sat: Closed	☐ Sun: Closed	☐ Holidays:		

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

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

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

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

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

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Texas

Parent Company (if any): ABC Medical Holdings, Inc.

Corporation/Organization Name: ABC Home Medical Supply, Inc.

Mailing Address: 1660 SW Saint Lucie West Blvd, STE 200

City: Port Saint Lucie State: FL Zip: 34986-1965

Telephone: 866-897-8588 Email: credentialing@abc-med.com

Contact Person Name: Emily M. Vestal

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Emily M. Vestal President and Director

Print Name of Authorized Person Submitting Application

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

August 15, 2024

Date

Board Use Only	Date Received: 9/4/24	Amount: $500-cc

ABC medical
Adapt. Believe. Compete.

main: 866.897.8588
fax: 877.785.7396
www.abc-med.com
1660 SW Saint Lucie West Blvd, Ste 200
Port Saint Lucie, FL 34986

List of Medicare and Medicaid Enrollments

ABC Home Medical Supply, Inc.
[redacted] W Terra Cotta Ave, [redacted]
Crystal Lake, IL 60014-3401
Tax ID: 51-0443844
NPI: 1932667516

Enrollment:	Provider Number:	Effective Date:
Medicare PTAN	4738970006	02-15-2021
Illinois Medicaid	510443844003	05-27-2022
Wisconsin Medicaid	100261304	12-18-2023

ABC Home Medical Supply, Inc.
1720 N. Greenville Ave
Richardson, TX 75081
Tax ID: 51-0443844
NPI: 1477534717

Enrollment:	Provider Number:	Effective Date:
Medicare PTAN	4738970001	09/06/2023
Alabama Medicaid	009934613	03/01/2015
Arizona Medicaid	040637	07/09/2013
Arkansas Medicaid	158660716	01/05/2005
Colorado Medicaid	31389015	09/16/2016
District of Columbia Medicaid	095735900	05/13/2015
Georgia Medicaid	982216402C	11/01/2016
Idaho Medicaid	1477534717	02/19/2010
Illinois Medicaid	510443844002	07/15/2012
Indiana Medicaid	200972330A	12/01/2009
Iowa Medicaid	0401401	07/11/2008
Kentucky Medicaid	7100202210	05/15/2012
Louisiana Medicaid	1333042	07/01/2005
Maine Medicaid	1477534717	07/01/2012
Maryland Medicaid	413700100	06/25/2014
Michigan Medicaid	5338606	01/01/2008
Minnesota Medicaid	1477534717	12/28/2015
Mississippi Medicaid	07956061	05/04/2015
Montana Medicaid	1477534717	03/22/2010
Nebraska Medicaid	10025992900	07/01/2014
New Hampshire Medicaid	3141165	12/07/2021
New Mexico Medicaid	69584567	01/13/2006
Ohio Medicaid	2622746	02/02/2006

Pursuant to 45 C.F.R 164.504 (d), Twenty Second Company Inc. hereby designates itself and its subsidiaries; ABC Medical Holdings, Inc., ABC Home Medical Supply, Inc., Southeast Medical Inc., MrMed Supply Co., Inc., Freestate Medical Supply, M.K Associates, Inc., and Arkansas Medical Supply to be known as "the affiliates" and from time to time, as a single covered entity, solely for the purposes of the above referenced regulations.

ABC medical
Adapt. Believe. Compete.

main: 866.897.8588
fax: 877.785.7396
www.abc-med.com
1660 SW Saint Lucie West Blvd, Ste 200
Port Saint Lucie, FL 34986

Oklahoma Medicaid	200061970A	03/13/2014
Oregon Medicaid	500783869	09/01/2020
Pennsylvania Medicaid	1015431740004	04/26/2013
Rhode Island Medicaid	1477534717	08/02/2022
South Dakota Medicaid	1477534717	12/22/2016
Tennessee Medicaid	1523283	09/06/2003
Texas Medicaid	1598120-01	09/22/2003
Utah Medicaid	1014147	02/02/2006
Vermont Medicaid	30015033450001	07/29/2022
Virginia Medicaid	30015128060001	10/22/2007
Washington Medicaid	1060360	03/01/2007
West Virginia Medicaid	220060001	01/31/2022
Wisconsin Medicaid	41571000	02/18/2016
Wyoming Medicaid	135141900	05/13/2013

ABC Home Medical Supply, Inc.
[redacted] Interplex Drive, [redacted]
Feasterville Trevose, PA 19053
Tax ID: 51-0443844
NPI: 1760757934

Enrollment:	Provider Number:	Effective Date:
Medicare PTAN	4738970002	08/06/2012
Delaware Medicaid	250696458	01/06/2023
New Jersey Medicaid	0742465	08/13/2020
Pennsylvania Medicaid	101543174-0007	07/27/2022

ABC Home Medical Supply, Inc.
[redacted] S Alton Way, [redacted]
Centennial, CO 80112-2313
Tax ID: 51-0443844
NPI: 1831545565

Enrollment:	Provider Number:	Effective Date:
Medicare PTAN	4738970005	10/03/2016
Colorado Medicaid	19155107	11/10/2016
Kansas Medicaid	200362700B	03/16/2020

Pursuant to 45 C.F.R.164.504 (d), Twenty Second Company Inc., hereby designates itself and its subsidiaries; ABC Medical Holdings, Inc., ABC Home Medical Supply, Inc., Southeast Medical, Inc., MHMed Supply Co., Inc., Freestate Medical Supply, M.K Associates Inc., and Arkansas Medical Supply to be known as "the affiliates" and from time to time as a single covered entity, solely for the purposes of the above referenced regulations.

ABC medical
Adapt. Believe. Compete.

main: 866.897.8588
fax: 877.785.7396
www.abc-med.com
1660 SW Saint Lucie West Blvd, Ste 200
Port Saint Lucie, FL 34986

ABC Home Medical Supply, Inc.
[redacted]SW Saint Lucie West Blvd, Ste [redacted]
Port Saint Lucie, FL 34986
Tax ID: 51-0443844
NPI: 1417217951

Enrollment:	Provider Number:	Effective Date:
Medicare PTAN	4738970003	08/08/2012
Florida Medicaid	114650200	06/24/2022

ABC Home Medical Supply, Inc.
[redacted] 15th Street NW, [redacted]
New Brighton, MN 55112
Tax ID: 51-0443844
NPI: 1427051531

Enrollment:	Provider Number:	Effective Date:
Medicare PTAN	4738970007	03/18/2024

Southeast Medical, Inc. dba ABC Home Medical Supply, Inc.
[redacted]N Main St, [redacted]
Clayton, GA 30525
Tax ID: 20-51-32648
NPI: 1427081934

Enrollment:	Provider Number:	Effective Date:
Medicare PTAN	5783880001	11-18-2016
Georgia Medicaid	893-856-568A	01-01-2000
Georgia Medicaid Waiver	893-856-568B	11-01-2016
North Carolina Medicaid	7705428	10-15-2012
South Carolina Medicaid	DE2802	09-01-2005
South Carolina Medicaid Waiver	EN2129-CLTC	11-01-2011

Southeast Medical, Inc. dba ABC Home Medical Supply, Inc.
[redacted]S Cedar Ave
South Pittsburg, TN 37380
Tax ID: 20-5132648
NPI: 1972962132

Enrollment:	Provider Number:	Effective Date:
Medicare PTAN	5783880003	05-10-2016
Tennessee Medicaid	Q021745	06-01-2016

Pursuant to 45 C.F.R 164.504 (d), Twenty Second Company Inc. hereby designates itself and its subsidiaries; ABC Medical Holdings, Inc., ABC Home Medical Supply, Inc., Southeast Medical Inc., Mi-Med Supply Co., Inc., Freestate Medical Supply, MLK Associates, Inc., and Arkansas Medical Supply to be known as "the affiliates" and from time to time, as a single covered entity, solely for the purposes of the above referenced regulations.

ABC medical
Adapt. Believe. Compete.

main: 866.897.8588
fax: 877.785.7396
www.abc-med.com
1660 SW Saint Lucie West Blvd, Ste 200
Port Saint Lucie, FL 34986

Southeast Medical, Inc. dba ABC Home Medical Supply, Inc.
[redacted] University Blvd
Tuscaloosa, AL 35401
Tax ID: 20-5132648
NPI: 1508394339

Enrollment:	Provider Number:	Effective Date:
Medicare PTAN	5783880004	10-02-2017
Alabama Medicaid	242843	08-01-2018
Mississippi Medicaid	08836851	12-21-2020

Pursuant to 45 C.F.R 164.504 (d), Twenty Second Company Inc. hereby designates itself and its subsidiaries; ABC Medical Holdings, Inc., ABC Home Medical Supply, Inc., Southeast Medical Inc., McMed Supply Co., Inc., Freestate Medical Supply, MLK Associates, Inc., and Arkansas Medical Supply to be known as "the affiliates" and from time to time, as a single covered entity, solely for the purposes of the above referenced regulations.

ABC medical
Adapt. Believe. Compete.

main: 866.897.8588
fax: 877.785.7396
www.abc-med.com
1660 SW Saint Lucie West Blvd, Ste 200
Port Saint Lucie, FL 34986

List of Officers and Directors

ABC Home Medical Supply, Inc.

Name:	Title:	Ownership Percent:	Shareholder:
Emily M. Vestal	President and Director	0%	No
Patrick C. Noble	Vice President, Chief Financial Officer, and Director	0%	No
Lise M. Heroux	Secretary	0%	No
Timothy B. Finnerty	Director	0%	No

Pursuant to 45 C.F.R 164.504 (d), Twenty Second Company Inc., hereby designates itself and its subsidiaries; ABC Medical Holdings, Inc., ABC Home Medical Supply, Inc., Southeast Medical, Inc., Mi-Med Supply Co., Inc., Freestate Medical Supply, MLK Associates, Inc., and Arkansas Medical Supply to be known as "the affiliates" and from time to time, as a single covered entity, solely for the purposes of the above referenced regulations.

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

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Articles of Incorporation for ABC Home Medical Supply, Inc. (file number 800169395), a Domestic For-Profit Corporation, was filed in this office on February 03, 2003.

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

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on March 27, 2024.

Jane Nelson
Secretary of State

01-300 (Rev.7-12/18)

TEXAS SALES AND USE TAX PERMIT

This permit is not transferable, and this side must be prominently displayed in your place of business.

Retailers: A seller may NOT accept a copy of this permit in lieu of a properly completed exemption or resale certificate. A certificate is necessary to document why tax is not collected on a sale.

You must obtain a new permit if there is a change of ownership, location, or business location name.

TAXPAYER NAME, BUSINESS LOCATION NAME, and PHYSICAL LOCATION

ABC HOME MEDICAL SUPPLY, INC.

ABC HOME MEDICAL SUPPLY, INC.
1720 N GREENVILLE AVE
RICHARDSON TX 75081-1808
DALLAS COUNTY

NAICS CODE: [redacted] DESCRIPTION ON NEXT LINE:

Wholesale Trade Agents and Brokers

WE SHOW THIS BUSINESS IN THE FOLLOWING LOCAL SALES TAX AUTHORITIES:

CITY: RICHARDSON EFF: 10/12/2012
TRANSIT: DALLAS MTA EFF: 10/12/2012

Type of permit	SALES AND USE TAX
Taxpayer number	[redacted]
Location number	00003
First business date of location	10/12/2012

Susan Combs
Comptroller of Public Accounts

You may need to collect sales and/or use tax for other local taxing authorities depending on your type of business. For additional information, see "Collecting Local Sales and Use Tax" section on the back of this document.

If you have any questions regarding sales tax, visit our website at www.window.state.tx.us or call us at 1-800-252-5555 or 512-463-4600.

Detach here and prominently display your permit only. Retain the portion below for your records.

01-300-P4

Is the Information Printed on this Permit Correct?

The information printed on your permit is public information. It must be accurate and current. If there is an error, make corrections on the form below. Enter the correct information for incorrect items only. Detach the form and mail it to:

Comptroller of Public Accounts
111 E. 17th Street
Austin, TX 78774-0100

More helpful information about your permit is on the back of this document.

Texas Sales and Use Tax Permit Corrections Form

Taxpayer name shown on the permit: ABC HOME MEDICAL SUPPLY, INC.

Taxpayer number shown on the permit: [redacted]

Location number shown on the permit: [redacted]

If you need to make changes to your local sales tax authorities or to the NAICS code printed on your permit, see information on the back of this form.

Correct business location name •

Correct business location (no P.O. Box or directions accepted) •

City • | State | ZIP code | County

Correct taxpayer name • | Daytime phone *(Area code and number)*

Correct mailing address •

City • | State | ZIP code | Federal Employer Identification Number

If you are **no longer in business**, enter the date of your last business transaction. _____

sign here ▸ Taxpayer or authorized agent | Date

000000065
0057

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

ABC HOME MEDICAL SUPPLY. INC.
1660 SW SAINT LUCIE WEST BLVD STE 200
PORT SAINT LUCIE FL 34986

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

ABC HOME MEDICAL SUPPLY INC

1720 N GREENVILLE AVE
RICHARDSON, TX 75081

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

DEVICE DISTRIBUTOR

License # 1000858
Expires: February 5, 2026

NON-TRANSFERABLE

Commissioner

513820

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
02/21/2024

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

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

PRODUCER Willis Towers Watson Midwest, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	CONTACT NAME: Willis Towers Watson Certificate Center PHONE (A/C, No, Ext): 1-877-945-7378 FAX (A/C, No): 1-888-467-2378 E-MAIL ADDRESS: certificates@willis.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : Federal Insurance Company	20281
INSURED ABC Home Medical Supply, Inc. 1660 SW Saint Lucie West Blvd Ste 200 Port Saint Lucie, FL 34986	INSURER B : Ironshore Specialty Insurance Company	25445
	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** W32693434 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			3588-49-18	10/01/2023	10/01/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ $ $ $ $ $	1,000,000 1,000,000 10,000 1,000,000 2,000,000
	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $	
A	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $			7819-48-29	10/01/2023	10/01/2024	EACH OCCURRENCE AGGREGATE	$ $	1,000,000 1,000,000
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A					PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $	
B	Excess Liability (Ironshore) Claims Made			HC7CACDCDE003	10/01/2023	10/01/2024	Each Occurrence Aggregate		$1,000,000 $1,000,000

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

This Voids and Replaces Previously Issued Certificate Dated 02/16/2024 WITH ID: W32681936.

SEE ATTACHED

CERTIFICATE HOLDER

ABC Home Medical Supply, Inc.
Five Interplex Dr, Suite 201
Feasterville Trevose, PA 19053-6968

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

© 1988-2016 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: _____

LOC #: _____

ADDITIONAL REMARKS SCHEDULE

AGENCY Willis Towers Watson Midwest, Inc.	NAMED INSURED ABC Home Medical Supply, Inc. 1660 SW Saint Lucie West Blvd Ste 200 Port Saint Lucie, FL 34986
POLICY NUMBER See Page 1	
CARRIER See Page 1 / NAIC CODE See Page 1	EFFECTIVE DATE: See Page 1

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Re: 1660 St. Lucie West Blvd Ste 200 Port St. Lucie, Fl 34986; 1720 N. Greenville Ave., Richardson, TX 75081; 7302 S. Alton Way, Unit 4k, Centennial, CO 80112; 651 W. Terra Cotta Ave, Ste 221, Crystal Lake, IL 60014-3401

INSURER AFFORDING COVERAGE: Federal Insurance Company NAIC#: 20281

POLICY NUMBER: 3588-49-17 EFF DATE: 10/01/2023 EXP DATE: 10/01/2024

TYPE OF INSURANCE:	LIMIT DESCRIPTION:	LIMIT AMOUNT:
Product Liability (Claims Made)	Occurence	$10,000,000
Retroactive Date 1/1/86	Aggregate:	$10,000,000
	SIR - Each Event:	$250,000

© 2008 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

SR ID: 25461549 BATCH: 3343235 CERT: W32693434

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG ABC Home Medical Supply, Inc. MDEG License # (if applicable) _____

Physical Address 1720 N Greenville Ave

City Richardson State TX Zip 75081-1808

Mailing Address (if different from physical address) 1660 SW Saint Lucie West Blvd, Ste 200

City Port Saint Lucie State FL Zip 34986-1965

Telephone 972-279-9090 Website www.abc-med.com

Licensing Company Email credentialing@abc-med.com

Section 2: Personal Information

First Deborah Middle _____ Last Teel

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

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

Mailing Address [redacted] Greenville Ave

City Richardson State TX Zip 75081-1808

Telephone [redacted] Email [redacted]

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

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

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

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

School Name			From - To (MM/YY – MM/YY)	
North Mesquite High School			08/76-05/80	
Address		City	State	Zip
18201 LBF Freeway		Mesquite	TX	75150
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
N/A				
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
N/A				
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
N/A				
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
N/A				
Address		City	State	Zip
Diploma/Degree obtained, if any				

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/13 - Current	[redacted] Jock Lane	Wylie	TX	75098
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
ABC Home Medical Supply, Inc.			06/22 - Current
Business Address	**City**	**State**	**Zip**
1720 N Greenville Ave	Richardson	TX	75081
Phone	**Title**	**Number of Employed Hours**	
972-279-9090	Office Administrator / Audit and Appeal Specialist	40 Weekly	
Description of Duties			
Office administration, ordering office supplies, audit and appeals.			

Business Name			From - To (MM/YY – MM/YY)
Fresenlys Medical			09/21 - 06/22
Business Address	**City**	**State**	**Zip**
2201 W Plano Pkwy	Plano	TX	75075
Phone	**Title**	**Number of Employed Hours**	
972-231-0320	Patient Account Representative	40 Weekly	
Description of Duties			
Billing of all claims via electronic/paper claim forms and resolving any rejections.			

Business Name			From - To (MM/YY – MM/YY)
AIS Healthcare			07/20 - 09/21
Business Address	**City**	**State**	**Zip**
18451 Dallas Pkwy	Dallas	TX	75287
Phone	**Title**	**Number of Employed Hours**	
877-443-4006	Collector	40 Weekly	
Description of Duties			
Collections of Account Balances			

Business Name			From - To (MM/YY – MM/YY)
Apple Home Medical Supplies			05/19 - 07/20
Business Address	**City**	**State**	**Zip**
500 Industrial Dr #500	Richardson	TX	75081
Phone	**Title**	**Number of Employed Hours**	
972-699-9511	Billing / AR Collections	40 Weekly	
Description of Duties			
Confirming orders for patients, entering orders into the company software and collecting outstanding balances.			

Business Name			From - To (MM/YY – MM/YY)
Inogen Oxygen			11/15 - 03/18
Business Address	**City**	**State**	**Zip**
600 Shiloh Rd	Plano	TX	75074
Phone	**Title**	**Number of Employed Hours**	
972-616-6500	CMN Billing	40 Weekly	
Description of Duties			
Accounts receivable collections and obtaining physical orders for supplies.			

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Deborah Teel

Original Signature (electronic, copies or stamps not accepted)

8/12/24

Date

I, Deborah Teel, **certify that as the MDEG Administrator for**

ABC Home Medical Supply, Inc.,

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

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

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

Deborah Teel

Print Name (First, Last)

Deborah Teel

Original Signature (electronic, copies or stamps not accepted)

8/12/24

Date

Board Use Only	Date Received: 8/14/24

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler ABC Home Medical Supply, Inc.

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

Physical Address 1720 Greenville Ave

City Richardson State TX Zip 75081-1808

Mailing Address (if different from physical address) 1660 SW Saint Lucie West Blvd, STE 200

City Port Saint Lucie State FL Zip 34986-1965

Telephone 972-279-9090 Website www.abc-med.com

Licensing Company Email credentialing@abc-med.com

Section 2: Personal Information

First Deborah Middle _____ Last Teel

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

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

Mailing Address [redacted] Greenville Ave

City Richardson State TX Zip 75081-1808

Telephone [redacted] Email [redacted]

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

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

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

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

School Name			From - To (MM/YY – MM/YY)	
North Mesquite High School			08/76 - 05/80	
Address		City	State	Zip
18201 LBF Freeway		Mesquite	TX	75150
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
N/A				
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
N/A				
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
N/A				
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
N/A				
Address		City	State	Zip
Diploma/Degree obtained, if any				

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/13 - Current	[redacted]Jock Lane	Wylie	TX	75098
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				

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

Business Name			From - To (MM/YY – MM/YY)
ABC Home Medical Supply, Inc.			06/22 - Current
Business Address	**City**	**State**	**Zip**
1720 N Greenville Ave	Richardson	TX	75081
Phone	**Title**		
972-279-9090	Office Administrator / Audit and Appeal Specialist		

Description of Duties

Office administration, ordering office supplies, audit and appeals.

Business Name			From - To (MM/YY – MM/YY)
Fresenlys Medical			09/21 - 06/22
Business Address	**City**	**State**	**Zip**
2201 W Plano Pkwy	Plano	TX	75075
Phone	**Title**		
972-231-0320	Patient Account Representative		

Description of Duties

Billing of all claims via electronic/paper claim forms and resolving any rejections.

Business Name			From - To (MM/YY – MM/YY)
AIS Healthcare			07/20 - 09/21
Business Address	**City**	**State**	**Zip**
18451 Dallas Pkwy	Dallas	TX	75287
Phone	**Title**		
877-443-4006	Collector		

Description of Duties

Collections of Account Balances

Business Name			From - To (MM/YY – MM/YY)
Apple Home Medical Supplies			05/19 - 07/20
Business Address	**City**	**State**	**Zip**
500 Industrial Dr #500	Richardson	TX	75081
Phone	**Title**		
972-699-9511	Billing / AR Collections		

Description of Duties

Confirming orders for patients, entering orders into the company software and collecting outstanding balances.

Business Name			From - To (MM/YY – MM/YY)
Inogen Oxygen			11/15 - 03/18
Business Address	**City**	**State**	**Zip**
600 Shiloh Rd	Plano	TX	75074
Phone	**Title**		
972-616-6500	CMN Billing		

Description of Duties

Accounts receivable collections and obtaining physical orders for supplies.

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Deborah Tell

Original Signature (electronic, copies or stamps not accepted)

8/12/24

Date

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

Deborah Teel

Print Name (First, Last)

Deborah Teel

Original Signature (electronic, copies or stamps not accepted)

8/12/24

Date

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

State of Texas, ss. County of Dallas

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

Deborah Teel

Original Signature

8/12/2024

Date

Subscribed and Sworn to before me this 12th day of August, 2024

Nora F. Jackson

Notary Public Signature

NORA F. JACKSON
Notary Public, State of Texas
Comm. Expires 09-14-2024
Notary ID 5059045

(Seal)

Debbie Teel
Wylie, TX 75098
[redacted]

EXPERIENCE & ACCOMPLISHMENTS

BOOKKEEPING & ACCOUNTING

- Operated under general supervision in performing a broad range of duties related to financial business transactions such as accounts payable, accounts receivable, payroll, expense reimbursement, disbursements, receipts, sales and use tax, and/or employee benefits.

- Verify, sort, post, and check claims, bills, invoices, vouchers, and other financial data.
- Post journal or voucher entries, reconcile accounts, and closes ledgers.
- Ensure that entries are complete, accurate, logical, and auditable.
- Reconcile bank and financial statements and reports.
- Ensure quality customer service by responding to e-mails and phone calls.
- Research customer inquiries.
- Ensure adherence to laws and regulations. Maintain records and files.

DME/INTAKE/INSURANCE VERIFICATIONS/COLLECTIONS

- Ensures the billing of all claims via electronic or paper to Medicare, Medicaid, and Private Insurance payers are being submitted accurately and timely in accordance with billing procedures, this includes resolving any rejections involving payer file errors.
- Verifies and evaluates insurance benefits to determine the policy's compatibility with services.
- Obtains all required authorizations timely to bill claims to the insurance payers.

- Verifies billing accounts with accounts receivable ledger to ensure that all payments are accounted for and properly posted.
- Makes calls to troubleshoot payment discrepancies and establish resolution.
- Documents, in detail, phone calls, phone number, person spoken to, and call details on a consistent basis. (Who, What, When, Where & Why)
- Consistently maximums reimbursement of claims.
- Resolves issues that created a denial within 5 days of receipt of denial.
- Collect payments for outstanding open accounts receivable balances.

- Gathers, prepares, and submits required information and/or documentation to appeal claim denials/Audits.
- Uses appropriate write off reason code(s) for writing off balances that are deemed uncollectible.
- Verifies and evaluates insurance benefits to determine the policy's compatibility with services.
- Collection processes which include contract analysis, reimbursement, denial management, appeals and resolving billing-related issues with insurance companies or other responsible party for services rendered.

RELATED SKILLS

QuickBooks Pro
Microsoft Office
Peachtree
Brightree
CPR+
Medforce
CRM
Salesforce
Medact
Waystar
Availity

EMPLOYMENT HISTORY

2022-Present	Audit & Appeals Specialist	ABC Home Medical Supply,
2021-2022	Patient Account Rep	Fresenius Medical
2020-2021	AR Collections	AIS Healthcare Dallas, TX
2019-2020	Billing/AR/Collections/CSR	Apple Home Medical Richardson
2015-2018	Patient Billing Advocate	Inogen Oxygen, Richardson, TX
2014-2015	Pap compliance/CSR/Pap supplies	SPC Home Medical Richardson

4B

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
☐ New MDEG ■ Ownership Change* ☐ Name Change* ☐ Location Change*	* If making a change, provide current license number: M P00365	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: EBI, LLC

MDEG Physical Address: 1 Gatehall Drive, Suite 303

City: Parsippany State: NJ Zip: 07054

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 800-526-2579 Website: www.highridgemedical.com

Email: payer.relations@highridgemedical.com

Name of MDEG Administrator (NAC 639.694): Vincent Binetti

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

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8:30am-5:00p	■ Tue: 8:30am-5:00p	■ Wed: 8:30am-5:00p	■ Thurs: 8:30am-5:00p	■ Fri: 8:30am-5:00p
☐ Sat:	☐ Sun:	☐ Holidays:		

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

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

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

Name: N/A -No Owners are a Health Professional Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): ZEB Parent, LP

Corporation/Organization Name: EBI, LLC

Mailing Address: 1450 Brickell Avenue, 31st Floor

City: Miami State: FL Zip: 33131

Telephone: [redacted] Email: vincent.binetti@highridgemedical.com

Contact Person Name: Vincent Binetti

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Vincent Binetti

Print Name of Authorized Person Submitting Application

[redacted]

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

8-27-2024

Date

Board Use Only	Date Received: 9/16/24	Amount: 500/CC

EBI Medicaid Provider Numbers

State	Provider Number
ARIZONA	[redacted]
COLORADO	[redacted]
DIST OF COLUMBIA	[redacted]
DELAWARE	[redacted]
FLORIDA	[redacted]
GEORGIA	[redacted]
IDAHO	[redacted]
ILLINOIS	[redacted]
INDIANA	[redacted]
IOWA	[redacted]
KENTUCKY	[redacted]
LOUISIANA	[redacted]
MAINE	[redacted]
MARYLAND	[redacted]
MASSACHUSETTS	[redacted]
MICHIGAN	[redacted]
MISSISSIPPI	[redacted]
MISSOURI	[redacted]
MONTANA	[redacted]
NEBRASKA	[redacted]
NEVADA	[redacted]
NEW HAMPSHIRE	[redacted]
NEW JERSEY	[redacted]
NEW MEXICO	[redacted]
NEW YORK	[redacted]
NORTH CAROLINA	[redacted]
OHIO	[redacted]
OKLAHOMA	[redacted]
OREGON	[redacted]
PENNSYLVANIA	[redacted]
PUERTO RICO	[redacted]
RHODE ISLAND	[redacted]
SOUTH CAROLINA	[redacted]
TEXAS	[redacted]
TENNESSEE	[redacted]
VIRGINIA	[redacted]
WASHINGTON	[redacted]
WEST VIRGINIA	[redacted]
WISCONSIN	[redacted]
WYOMING	[redacted]

EBI License Numbers

State	Name of License/Registration	License/Registration #
Alabama	Home Medical Equipment Services Provider Permit	[redacted]
Arizona	Non-Rx Retailer Category II Permit	
Arkansas	Supplier of Medical Equipment License	
California	Home Medical Device Retail Registration	
California	Home Medical Device Retail Registration	
Connecticut	Wholesaler of Drugs, Cosmetics and Medical Devices Registration	
Florida	Home Medical Equipment Provider License	
Idaho	Durable Medical Equipment Outlet Registration	
Illinois	Home Medical Equipment and Services Provider	
Indiana	Home Medical Equipment Service Provider License	
Idaho	Durable Medical Equipment Outlet Registration	
Iowa	Durable Medical Distributor License	
Kansas	Durable Medical Equipment Permit	
Kentucky	Home Medical Equipment License	
Louisiana	Distributor of Legend Drugs or Legend Devices	
Louisiana	Durable Medical Equipment Permit	
Maryland	Residential Service Agency License	
Michigan	Manufacturer and Wholesaler License	
Mississippi	Medical Equipment Supplier Permit	
Montana	Wholesale Drug Distributor	
Nevada	Medical Devices Equipment & Gas License	
New Hampshire	Limited Retail Drug Distributors License	
New Jersey	Drug and Medical Device Certificate of Registration	
North Carolina	Device and Medical Equipment Dispensing Permit	
North Dakota	Durable Medical Equipment Distributor License	
Ohio	Respiratory Care Board HME Registration	
Oklahoma	DME Supplier	
Oregon	Medical Device, Equipment & Gas Outlet - Class C Registration	
Pennsylvania	Drug & Device Registration	
South Carolina	Non-Resident Medical Gas-Legend Device Permit	
Utah	Pharmacy Class E Business License	
Virginia	Non-resident Medical Equipment Supplier Permit	

State of Indiana
Office of the Secretary of State

CERTIFICATE OF EXISTENCE

To Whom These Presents Come, Greeting:

I, DIEGO MORALES, Secretary of State of Indiana, do hereby certify that I am, by virtue of the laws of the State of Indiana, the custodian of the corporate records and the proper official to execute this certificate.

I further certify that records of this office disclose that

EBI, LLC

duly filed the requisite documents to commence business activities under the laws of the State of Indiana on May 24, 1999, and was in existence or authorized to transact business in the State of Indiana on July 29, 2024.

I further certify this Domestic Limited Liability Company has filed its most recent report required by Indiana law with the Secretary of State, or is not yet required to file such report, and that no notice of withdrawal, dissolution, or expiration has been filed or taken place. All fees, taxes, interest, and penalties owed to Indiana by the domestic or foreign entity and collected by the Secretary of State have been paid.



In Witness Whereof, I have caused to be affixed my signature and the seal of the State of Indiana, at the City of Indianapolis, July 29, 2024

Diego Morales

DIEGO MORALES
SECRETARY OF STATE

LP99050044 / 20243887871

All certificates should be validated here: https://bsd.sos.in.gov/ValidateCertificate

Expires on August 28, 2024.

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0749932

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

1 GATEHALL DR, STE 303 PARSIPPANY, NJ 07054-

Reg. No.
5002755

EBI, LLC
1 GATEHALL DR, STE 303
PARSIPPANY, NJ 07054-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2025

Establishment Copy

Board of Managers

Name	Home Address	Title/Position
Glen Andrew Kashuba	[redacted]Rachael Ave Madison, NJ 07940	CEO
Vincent Binetti	[redacted]Webster Ave, Township of Washington NJ	Chief Financial Officer and GM
Frank Aversa	[redacted]iewcrest Dr. Venture, CA 93003	Manager, Payer Relations and Contracting

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 5/1/2024

4/1/2025

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

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

PRODUCER Lockton Companies 1185 Avenue of the Americas, Suite 2010 New York NY 10036 646-572-7300	CONTACT NAME: PHONE (A/C, No, Ext): FAX (A/C, No): E-MAIL ADDRESS:
INSURED 1541500 ZEB Parent, LP Westmoor Center Building 6 10225 Westmoor Drive Westminster CO 80021	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Federal Insurance Company — 20281 INSURER B : Chubb Custom Insurance Company — 38989 INSURER C : INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** 20541062 **REVISION NUMBER:** XXXXXXX

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY PRO-JECT LOC OTHER:	Y	N	3608-55-48	4/1/2024	4/1/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG 	$ $1,000,000 $ $1,000,000 $ $10,000 $ $1,000,000 $ $2,000,000 $ XXXXXXX $
A	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY X HIRED AUTOS ONLY SCHEDULED AUTOS X NON-OWNED AUTOS ONLY	N	N	7364-08-57	4/1/2024	4/1/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) Deductible	$ $1,000,000 $ XXXXXXX $ XXXXXXX $ XXXXXXX $ $1,000
A	X UMBRELLA LIAB OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $	N	N	5672-10-65	4/1/2024	4/1/2025	EACH OCCURRENCE AGGREGATE 	$ $10,000,000 $ $10,000,000 $ XXXXXXX
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A	N	7184-08-06	4/1/2024	4/1/2025	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $1,000,000 $ $1,000,000 $ $1,000,000
B	Products/ Professional Liability	N	N	36085547	4/1/2024	4/1/2025	Aggregate $10,000,000 Per Claim $10,000,000 Retention $1,000,000	

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

EBI, LLC is included as Additional Insured with respects to the General Liability policy as required by written contract.

CERTIFICATE HOLDER

20541062
EBI, LLC
1 Gatehall Drive, Suite 303
Parsippany, NJ NJ 07054

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

© 1988-2015 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site EBI, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) P00365

Physical Address 1 Gatehall Drive, Suite 303

City Parsippany State NJ Zip 07054

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-526-2579 Website www.highridgemedical.com

Licensing Company Email payer.relations@highridgemedical.com

Section 2: Personal Information

First Vincent Middle _____ Last Binetti

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

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

Mailing Address [redacted] Webster Ave

City Township of Washington State NJ Zip 07676-5238

Telephone [redacted] Email [redacted]

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Saint Peter's University		1990-1996	
Address	**City**	**State**	**Zip**
2641 John F. Kennedy Blvd	Jersey City	NJ	07306
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Ridgefield Park High School		1981-1985	
Address	**City**	**State**	**Zip**
1 Ozzie Nelson Dr	Ridgefield Park	NJ	07660
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1/2002 - Present	[redacted] Webster Ave	Township of Washington	NJ	07676
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
EBI, LLC			4/2016 - Present	
Business Address		**City**	**State**	**Zip**
1 Gatehall Drive, Suite 303		Parsippany	NJ	07054
Phone	**Title**			
800-526-2579	Chief Operating Officer, VP and General Manager			
Description of Duties				
Responsibilities include but not limited to managing all Sales, Marketing, R&D, Manufacturing, Finance, and all supporting functions of the Bone Healing Business.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

8-27-2024
Date

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

Vincent Binetti

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8-27-2024

Date

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

State of New Jersey, ss. County of Union

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

Original Signature

8-27-2024

Date

Subscribed and Sworn to before me this 27 day of August.

Notary Public Signature

CAROL A SALAZAR
Notary Public, State of New Jersey
My Commission Expires
February 02, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG EBI, LLC MDEG License # (if applicable) P00365

Physical Address 1 Gatehall Drive, Suite 303

City Parsippany State NJ Zip 07054

Mailing Address (if different from physical address)

City State Zip

Telephone 800-526-2579 Website www.highridgemedical.com

Licensing Company Email payer.relations@highridgemedical.com

Section 2: Personal Information

First Vincent Middle Last Binetti

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

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

Mailing Address [redacted] Webster Ave

City Township of Washington State NJ Zip 07676-5238

Telephone [redacted] Email [redacted]

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Saint Peter's University		1990-1996	
Address	**City**	**State**	**Zip**
2641 John F. Kennedy Blvd	Jersey City	NJ	07306
Diploma/Degree obtained, if any			
Bachelor of Science (BS) in Accounting			

School Name		From - To (MM/YY – MM/YY)	
Ridgefield Park High School		1981-1985	
Address	**City**	**State**	**Zip**
1 Ozzie Nelson Dr	Ridgefield Park	NJ	07660
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1/2002 - Present	[redacted] Webster Ave	Township of Washington	NJ	07676
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
EBI, LLC			4/2016 - Present
Business Address	**City**	**State**	**Zip**
1 Gatehall Drive, Suite 303	Parsippany	NJ	07054
Phone	**Title**	**Number of Employed Hours**	
800-526-2579	VP and General Manager	16,640	
Description of Duties			
Responsibilities include but not limited to managing all Sales, Marketing, R&D, Manufacturing, Finance, and all supporting functions of the Bone Healing Business.			

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

8-27-2024
Date

I, Vincent Binetti, **certify that as the MDEG Administrator for**

EBI, LLC,

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

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

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

Vincent Binetti

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8-27-2024

Date

Board Use Only	Date Received:

HIGHRIDGE

EBI, LLC

July 8, 2024

Attention: Provider Relations
Provider Name: EBI, LLC
Tax Identification Number: [redacted]
NPI Number: [redacted]

Please be advised that we had a recent change in our great grandparent company and will continue to operate under the same name, EBI, LLC with no direct modification to the company. The ownership change is effective immediately and each entity listed in the chart below is owned by the entity immediately preceding it.

ZEB Parent, LP
[redacted]
1450 Brickell Avenue, 31st Floor, Miami, Florida 33131

ZEB Intermediate LLC
[redacted]
1450 Brickell Avenue, 31st Floor, Miami, Florida 33131

ZEB Buyer LLC
[redacted]
1450 Brickell Avenue, 31st Floor, Miami, Florida 33131

Zimmer Biomet Spine, Inc. d/b/a Highridge Medical, LLC
[redacted]
10225 Westmoor Drive, Westminster, CO 80021

Electro-Biology, LLC
[redacted]
1 Gatehall Drive, Suite 303, Parsippany, NJ 07054

EBI Holdings, LLC
[redacted]
1 Gatehall Drive, Suite 303, Parsippany, NJ 07054

EBI Medical Systems, LLC
[redacted]
1 Gatehall Drive, Suite 303, Parsippany, NJ 07054

EBI, LLC
[redacted]
1 Gatehall Drive, Suite 303 Parsippany, NJ 07054

Sincerely,

Vincent Binetti
VP & General Manager
Vincent.Binetti@highridgemedical.com

Disclosure of Ownership

Organizational Structure

EBI, LLC
[redacted]
1 Gatehall Drive, Suite 303
Parsippany, NJ 07054

EBI, LLC [redacted]) is an indirectly owned subsidiary of ZEB Parent, LP ([redacted].

Enclosed is the organizational structure of wholly-owned subsidiaries of ZEB Parent, LP that includes EBI, LLC. Each entity listed on the chart is owned by the entity immediately preceding it.

Sincerely,

Frank Aversa
Manager, Payer Relations and Contracting
EBI, LLC
Mobile: [redacted]
Fax: 973-607-3033
[redacted]

Organizational Structure

ZEB Parent, LP

[redacted]

1450 Brickell Avenue, 31st Floor
Miami, Florida 33131

ZEB Intermediate LLC

[redacted]

1450 Brickell Avenue, 31st Floor
Miami, Florida 33131

ZEB Buyer LLC

[redacted]

1450 Brickell Avenue, 31st Floor
Miami, Florida 33131

Zimmer Biomet Spine, Inc. d/b/a Highridge Medical, LLC

[redacted]

10225 Westmoor Drive
Westminster, CO 80021

Electro-Biology, LLC

[redacted]

1 Gatehall Drive, Suite 303
Parsippany, NJ 07054-4514

EBI Holdings, LLC

[redacted]

1 Gatehall Drive, Suite 303
Parsippany, NJ 07054-4514

EBI Medical Systems, LLC

[redacted]

1 Gatehall Drive, Suite 303
Parsippany, NJ 07054-4514

EBI, LLC

[redacted]

1 Gatehall Drive, Suite 303
Parsippany, NJ 07054-4514

4C

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Firefly Supply LLC

MDEG Physical Address: 2500 Leaphart Rd, Suite H

City: West Columbia State: SC Zip: 29169

Mailing Address (if different from physical address): 135 Duryea Road, E-355

City: Melville State: NY Zip: 11747

Telephone: 631-843-5500 Website: www.fireflysupply.com

Email: licensure@henryschein.com

Name of MDEG Administrator (NAC 639.694): Matthew Longman

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

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 7 am - 4 pm	■ Tue: 7 am - 4 pm	■ Wed: 7 am - 4 pm	■ Thurs: 7 am- 4 pm	■ Fri: 7 am - 4 pm
☐ Sat:	☐ Sun:	☐ Holidays:		

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

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

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

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

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

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware (State of Formation)

Parent Company (if any): Firefly Holdco LLC

Corporation/Organization Name: Firefly Supply LLC

Mailing Address: 135 Duryea Rd, E-355

City: Melville State: NY Zip: 11747

Telephone: 631-843-5500 Email: licensure@henryschein.com

Contact Person Name: Jennifer Cunningham

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

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

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

Matthew Longman

Print Name of Authorized Person Submitting Application

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

10/9/24

Date

Board Use Only	Date Received: 10/14/24	Amount: $500-ck 0081947077

Corporate Directors and Officers
Firefly Supply LLC
[redacted]

Parent Company
Firefly Holdco LLC
[redacted]

State of Formation
Delaware

Directors

Mark Hillebrandt
Ciprian Tamas
Michael Ettinger

Officers

Mark Hillebrandt	Vice President
Ciprian Tamas	Vice President
Matthew Longman	Vice President
Robert Ponzo	Vice President, Corporate Tax
Michael Amodio	Vice President and Treasure
Jennifer Ferrero	Secretary

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "FIREFLY SUPPLY LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SIXTH DAY OF AUGUST, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "FIREFLY SUPPLY LLC" WAS FORMED ON THE THIRTIETH DAY OF SEPTEMBER, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

3778724 8300

SR# 20243514585

Authentication: 204242889

Date: 08-26-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

South Carolina
Department of Labor, Licensing and Regulation

Board of Pharmacy

110 Centerview Drive
Post Office Box 11927
Columbia, SC 29211-1927
Phone: (803) 896-4700
FAX: (803) 896-4596

Henry D. McMaster
Governor

Emily H. Farr
Director

www.llronline.com/POL/Pharmacy

August 14, 2024

Pamela Griffin
Henry Schein
US Regulatory Compliance

Dear Pamela Griffin,

Per your email request dated August 14, 2024, this letter states that the South Carolina Board of Pharmacy does not issue a permit for OTC Drugs and OTC devices. A home state inspection will not be conducted since permitting is not required.

Sincerely,

Stephanie Calhoun

Stephanie Calhoun
Program Coordinator I

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 08/22/2024

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

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

PRODUCER	CONTACT NAME:	
Aon Risk Services Northeast, Inc. New York NY Office One Liberty Plaza 165 Broadway, Suite 3201 New York NY 10006 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Henry Schein, Inc., Subsidiaries & Affiliates 135 Duryea Road Melville NY 11747 USA	INSURER A: Berkshire Hathaway Specialty Ins Company	22276
	INSURER B: QBE Specialty Insurance Company	11515
	INSURER C: Liberty Insurance Corporation	42404
	INSURER D: Liberty Mutual Fire Ins Co	23035
	INSURER E: ProAssurance Specialty Insurance Company	17400
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570107764698 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
D	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY [ ] PRO-JECT [X] LOC OTHER:			TB2621093363034	06/01/2024	06/01/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $100,000 $5,000 $1,000,000 $5,000,000 Excluded
D	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			AS2-621-093363-044	06/01/2024	06/01/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$2,000,000
C	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION			TH7621093363074	06/01/2024	06/01/2025	EACH OCCURRENCE AGGREGATE	$5,000,000 $5,000,000
C C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [N] N/A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			WA762D093363014 AOS WC7621093363024 WI	06/01/2024 06/01/2024	06/01/2025 06/01/2025	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	 $1,000,000 $1,000,000 $1,000,000
E	Products Liability			N24NY380027 Claims Made	06/01/2024	06/01/2025	Each Occurrence Aggregate	$10,000,000 $10,000,000

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

Evidence of Insurance.

CERTIFICATE HOLDER

Henry Schein, Inc.
and its Subsidiary and Affiliated
Companies
135 Duryea Road
Melville NY 11747 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast, Inc.

Holder Identifier : EOC

Certificate No : 570107764698

©1988-2015 ACORD CORPORATION. All rights reserved.

AGENCY CUSTOMER ID: 570000025511
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Henry Schein, Inc.,
POLICY NUMBER: See Certificate Number: 570107764698	
CARRIER: See Certificate Number: 570107764698 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

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

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER	
INSURER	
INSURER	
INSURER	

ADDITIONAL POLICIES If a policy below does not include limit information, refer to the corresponding policy on the ACORD certificate form for policy limits.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	OTHER							
B	E&O - Miscellaneous Professional-Primary			130003732 Cyber Liab/Tech& E&O SIR applies per policy terms & conditions	12/01/2023	12/01/2024	Limit of Liability	$10,000,000
A	Fiduciary Liability - Primary			47EPC31399303 Fiduciary Liability SIR applies per policy terms & conditions	11/01/2023	11/01/2024	Aggregate Limit	$10,000,000

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

AGENCY CUSTOMER ID: 570000025511
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Henry Schein, Inc.,
POLICY NUMBER	
See Certificate Number: 570107764698	
CARRIER / NAIC CODE	EFFECTIVE DATE:
See Certificate Number: 570107764698	

ADDITIONAL REMARKS

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

Named Insureds

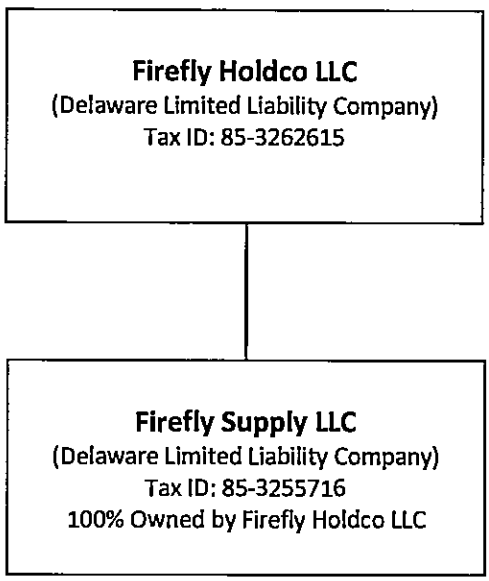
Henry Schein, Inc.
Ace Surgical Supply Company, Inc.
All Star Orthodontics
BIOHORIZONS IMPLANT SYSTEMS, INC.
Camlog
Dental Instrument Sales & Service, LLC
Dentrix Dental Systems
Exan Enterprises
G.I.V. Inc.
General Injectibles & Vaccines, Inc.
HF Acquisition Co. LLC
Hand Piece Parts & Repair, Inc.
Henry Schein and Schvadent
Henry Schein Dental, Inc.
Henry Schein Global Sourcing, Inc.
Henry Schein Medical
Henry Schein Practice Solutions
Henry Schein, Supply
HealthFirst
Henry Schein MSO, LLC
Impromed, LLC.
Insource, Inc.
Ortho Organizers, Inc.
Ortho Technology, Inc.
RXWORKS, INC.
Southern Anesthesia & Surgical Inc.
The Custom Milling Center, Inc.
Zahn Dental Company, Inc.
Zahn/Darby Lab
Edge Endo
North American Rescue LLC and NAR Medical Depot, LLC
NAR Training LLC
Lighthouse 360, Inc.
Hayes Handpiece Franchises, Inc.
Henry Schein One, LLC
US Endodontics
TDSC, Inc.
NAR Medical Depot LLC
Prism Medical Products - 12.31.20
Sesame Communications
eAssist Inc.
eAssist Publishing LLC
Midway Dental Supply LLC
Ace Southern Surgical Solutions
ORTHO2 LLC
Shield HealthCare - 10/2/23
Dental Practice Transitions
Vulcan Custom Dental
AEP MPE Holdings, LLC
Firefly Supply LLC

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

Ownership Information
(in lieu of Personal History Application)

Firefly Supply LLC was formed as a Limited Liability Company with the Secretary of State of Delaware on 09/30/2020.

Firefly Holdco LLC is a sole member of Firefly Supply LLC. Firefly Holdco LLC was formed as a Limited Liability Company with the Secretary of State of Delaware on 09/30/2020.


Firefly Holdco LLC
(Delaware Limited Liability Company)
Tax ID: 85-3262615
Firefly Supply LLC
(Delaware Limited Liability Company)
Tax ID: 85-3255716
100% Owned by Firefly Holdco LLC

Ownership Information
(in lieu of Personal History Application)

Firefly Supply LLC was formed as a Limited Liability Company with the Secretary of State of Delaware on 09/30/2020. Firefly Supply LLC is a sole member of and 100% owned by Firefly Holdco LLC.

Firefly Holdco LLC was formed as a Limited Liability Company with the Secretary of State of Delaware on 09/30/2020.

South Carolina
Department of Labor, Licensing and Regulation

Board of Pharmacy

110 Centerview Drive
Post Office Box 11927
Columbia, SC 29211-1927
Phone: (803) 896-4700
FAX: (803) 896-4596

Henry D. McMaster
Governor

Emily H. Farr
Director

www.llronline.com/POL/Pharmacy

August 14, 2024

Pamela Griffin
Henry Schein
US Regulatory Compliance

Dear Pamela Griffin,

Per your email request dated August 14, 2024, this letter states that the South Carolina Board of Pharmacy does not issue a permit for OTC Drugs and OTC devices. A home state inspection will not be conducted since permitting is not required.

Sincerely,

Stephanie Calhoun

Stephanie Calhoun
Program Coordinator I

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Firefly Supply LLC MDEG License # (if applicable) _____

Physical Address 2500 Leaphart Rd, Suite H

City West Columbia State SC Zip 29169

Mailing Address (if different from physical address) [redacted]Duryea Road, [redacted]

City Melville State NY Zip 11747

Telephone 631-843-5500 Website www.fireflysupply.com

Licensing Company Email licensure@henryschein.com

Section 2: Personal Information

First Matthew Middle Edward Last Longman

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

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

Mailing Address [redacted]Marina Rd, Unit [redacted]

City Irmo State SC Zip 29063

Telephone [redacted] Email [redacted]

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
University of South Carolina		08/2017 - 05/2019	
Address	**City**	**State**	**Zip**
1244 Blossom Street, Suite 106	Columbia	SC	29208
Diploma/Degree obtained, if any			
Master in Business Administration			

School Name		From - To (MM/YY – MM/YY)	
University of South Carolina		08/2001 - 05/2006	
Address	**City**	**State**	**Zip**
1244 Blossom Street, Suite 106	Columbia	SC	29208
Diploma/Degree obtained, if any			
Bachelor of Science and Marketing			

School Name		From - To (MM/YY – MM/YY)	
Dutch Fork High School		08/1997 - 05/2001	
Address	**City**	**State**	**Zip**
1400 Old Tamah Rd	Irmo	SC	29063
Diploma/Degree obtained, if any			
Diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2023 - Present	[redacted] Marina Rd. Unit [redacted]	Irmo	SC	29063
03/2010 - 06/2023	[redacted] Village Well Ct.	Chapin	SC	29036

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

Business Name			From - To (MM/YY – MM/YY)	
Firefly Supply LLC			06/2024 - Present	
Business Address		**City**	**State**	**Zip**
1 Southern Ct		West Columbia	SC	29169
Phone	**Title**		**Number of Employed Hours**	
803-318-4144	General Manager 3rd Party Marketplaces / VP		712	
Description of Duties				
General Manager overseeing the daily operations of sales, marketing, and distribution.				

Business Name			From - To (MM/YY – MM/YY)	
Southern Anesthesia & Surgical, Inc.			05/2018 - 06/2024	
Business Address		**City**	**State**	**Zip**
1 Southern Ct		West Columbia	SC	29169
Phone	**Title**		**Number of Employed Hours**	
800-624-5926	VP of		12,072	
Description of Duties				
Managed the ecommerce business, medical business and equipment business.				

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

10/9/24
Date

I, Matthew Longman, **certify that as the MDEG Administrator for**

Firefly Supply LLC,

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

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

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

Matthew Longman
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/9/24
Date

Board Use Only	Date Received:

4D

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
☐ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
■ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M P00234	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Nationwide Medical, Inc.

MDEG Physical Address: 5230 Las Virgenes Road STE 105

City: Calabasas State: CA Zip: 91302

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 818-338-3500 Website: www.nationwidemedical.com

Email: boliver@nationwidemedical.com

Name of MDEG Administrator (NAC 639.694): David Siegel

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	■ Medical Gases**
☐ Pharmacies[a]	■ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	■ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: David Siegel
	Telephone: 818-338-3522

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8am - 5pm	■ Tue: 8am - 5pm	■ Wed: 8am - 5pm	■ Thurs: 8am - 5pm	■ Fri: 8am - 5pm
☐ Sat: N/A	☐ Sun: N/A	☐ Holidays: N/A		

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

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Medicare PTAN - 5567030001

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

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

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): NWI Acquisitions, Inc.

Corporation/Organization Name: Nationwide Medical, Inc.

Mailing Address: 5230 Las Virgenes Road STE 105

City: Calabasas State: CA Zip: 91302

Telephone: 818-338-3500 Email: boliver@nationwidemedical.com

Contact Person Name: Brian Oliver

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

David Siegel

Print Name of Authorized Person Submitting Application

D S

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

9-26-24

Date

Board Use Only	Date Received: 10/2/24	Amount: $500-CC

SECRETARY OF STATE



CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporation soles, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify, that the following is a list of all organizational documents on file in this office for

NATIONWIDE MEDICAL, INC.

Organizational Documents on File	Filing Date
Articles of Incorporation	08/19/2002

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, NATIONWIDE MEDICAL, INC., as a DOMESTIC CORPORATION (78) duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 08/19/2002, and is in good standing in this state.

SECRETARY OF STATE

STATE OF NEVADA

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 05/01/2024

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202405014612501
You may verify this certificate online at http://www.nvsos.gov

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

HOME MEDICAL DEVICE RETAIL LICENSE

Nationwide Medical Inc
5230 Las Virgenes Rd Suite # 105
Calabasas, CA 91302

LICENSE NUMBER: 118751
EXPIRATION DATE: 4/19/2025*

The person named herein is licensed to operate a Home Medical Device Retail Facility through the expiration date of this license. This annual license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee shall be responsible for assuring compliance with all requirements of this article pertaining to Home Medical Device Retail Facilities.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-8500

0129

Printed: 3/21/2024

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 11/15/2023

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

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

PRODUCER	CONTACT NAME: Lillian Chen
UWIB Risk, Inc. 228 Pearl St. FL. 2 Franklin TN 37064	PHONE (A/C, No, Ext): (626) 397-4700 FAX (A/C, No): (626) 683-7682 E-MAIL ADDRESS: lillian@uwib.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A: Benchmark Insurance Company	41394
INSURER B: Technology Insurance Co	42376
INSURER C:	
INSURER D:	
INSURER E:	
INSURER F:	

INSURED: Nationwide Medical, Inc., 5230 Las Virgenes Road, Suite 105, Calabasas CA 91302

COVERAGES **CERTIFICATE NUMBER:** CL23111514660 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	☒ COMMERCIAL GENERAL LIABILITY ☐ CLAIMS-MADE ☒ OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: ☒ POLICY ☐ PRO-JECT ☐ LOC OTHER:			D1023G59366	11/17/2023	11/17/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 100,000 $ 10,000 $ 1,000,000 $ 3,000,000 $ 3,000,000
	AUTOMOBILE LIABILITY ☐ ANY AUTO ☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS ☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ Included $ $ $ $
A	☐ UMBRELLA LIAB ☒ OCCUR ☒ EXCESS LIAB ☐ CLAIMS-MADE DED ☒ RETENTION $ 0			UM102359376	11/17/2023	11/17/2024	EACH OCCURRENCE AGGREGATE	$ 5,000,000 $ 5,000,000 $
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N ☐ If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		TWC4334153	11/17/2023	11/17/2024	☒ PER STATUTE ☐ OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
A	Medical Professional Liability			D1023G59366	11/17/2023	11/17/2024	Each Occurrence	$1,000,000

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

Certificate holder is named as Additional Insured as respects the operations of the named insured, if required by written contract.

CERTIFICATE HOLDER

Evidence of Insurance Coverage

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

© 1988-2015 ACORD CORPORATION. All rights reserved.

Nationwide Medical®

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

September 26, 2024

Sent via UPS Overnight

Re: Nationwide Medical, Inc. - Stock Sale

Nevada State Board of Pharmacy Medical Devices, Equipment and Gases license: MP00234

Ladies and Gentlemen:

Enclosed is an application for a change in the ownership of Nationwide Medical, Inc. (the "Company"). The Company operates in California and provides durable medical equipment to patients across the United States.

On or about October 31st, 2024, the Company intends to undergo a merger through which the Company will remain intact, but 100% of the Company will be owned by NWI Acquisitions, Inc. [redacted].

There will be no significant changes in the Company's operations or its management team as a result of this transaction. David Siegel will remain the CEO, and the Company will continue to operate at the same location and under the same Federal Tax ID Number and NPI.

We are happy to answer any questions that you have regarding the transaction or the ownership structure of the Company. Should you require additional documentation or information, please contact me at ([redacted] or via email at [redacted]

Sincerely,

Brian Oliver, CHC
Chief Compliance Officer
Nationwide Medical, Inc.

Nationwide Medical, Inc. Corporate Officers

Name and Title	Address	SSN & DOB	Contact info
David Siegel, CEO	[redacted] Dean Martin Drive Unit [redacted] Las Vegas, NV 89103	[redacted]	([redacted] [redacted]

Business Address:
Nationwide Medical, Inc.
5230 Las Virgenes Road STE 105
Calabasas, CA 91302

Nationwide Medical, Inc. Ownership (New Ownership)

Name and Title	Address	TIN	Ownership %	Contact info
NWI Acquisitions, Inc., Owner	[redacted] Burton Hills Blvd. Nashville, TN 37215	[redacted]	100	[redacted]

Business Address:
Nationwide Medical, Inc.
5230 Las Virgenes Road STE 105
Calabasas, CA 91302

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Nationwide Medical, Inc. MDEG License # (if applicable) MP00234

Physical Address 5230 Las Virgenes Road STE 105

City Calabasas State CA Zip 91302

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 818-338-3500 Website www.nationwidemedical.com

Licensing Company Email boliver@nationwidemedical.com

Section 2: Personal Information

First Brian Middle Rick Last Oliver

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

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

Mailing Address [redacted] Catarina Drive

City Westlake Village State CA Zip 91362

Telephone [redacted] Email [redacted]

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Antioch High School		06/92 - 06/95	
Address	**City**	**State**	**Zip**
700 West 18th Street	Antioch	CA	94509
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
UC Berkeley		08/95 - 06/98	
Address	**City**	**State**	**Zip**
University Ave and Oxford Street	Berkeley	CA	94720
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Cal State Northridge University		08/03 - 06/06	
Address	**City**	**State**	**Zip**
18111 Nordhoff St	Northridge	CA	91330
Diploma/Degree obtained, if any			
Bachelors Degree			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/07 - Current	[redacted] Catarina Drive	Westlake Village	CA	91362
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
Nationwide Medical, Inc.			03/03- Current
Business Address	**City**	**State**	**Zip**
5230 Las Virgenes Road STE 105	Calabasas	CA	91302
Phone	**Title**	**Number of Employed Hours**	
818-338-3522	Chief Compliance Officer	75,000+	

Description of Duties

Oversees the company compliance program, internal auditing and monitoring as well as the and company's adherence to regulatory requirements and industry standards. Develop policies and procedures and contuct staff training.

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

Description of Duties

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

Description of Duties

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

Description of Duties

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

Description of Duties

Continue on next page if additional space is needed.

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

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

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

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

Provide explanation below:

BQ

Original Signature (electronic, copies or stamps not accepted)

10/4/24

Date

I, Brian Oliver, **certify that as the MDEG Administrator for**

Nationwide Medical, Inc.,

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

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

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

Brian Oliver

Print Name (First, Last)

BO

Original Signature (electronic, copies or stamps not accepted)

10/4/24

Date

Board Use Only	Date Received:

4E

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: JETLENSES INC DBA VERSE MEDICAL

MDEG Physical Address: 158 W 27TH STREET, FLOOR 10

City: NEW YORK State: NY Zip: 10001

Mailing Address (if different from physical address): SAME AS ABOVE

City: _____ State: _____ Zip: _____

Telephone: 833-518-1613 Website: https://versemedical.com/

Email: DANIELLE@VERSEMEDICAL.COM

Name of MDEG Administrator (NAC 639.694): DHAIVAT PANDYA

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

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 10am-6pm	■ Tue: 10am-6pm	■ Wed: 10am-6pm	■ Thurs: 10am-6pm	■ Fri: 10am-6pm
☐ Sat:	☐ Sun:	☐ Holidays:		

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

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))	
MEDICARE PTAN: 8028770001	IOWA STATE MEDICAID: 1033796016
MICHIGAN STATE MEDICAID: 1033796016	NEW MEXICO-HMO: 86286838
VIRGINIA STATE MEDICAID: 3001749850002	
WISCONSON STATE MEDICAID: 1033796016	

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

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Deleware

Parent Company (if any): N/A

Corporation/Organization Name: JETLENSES INC DBA VERSE MEDICAL

Mailing Address: 158 W 27TH STREET, FLOOR 10

City: NEW YORK State: NY Zip: 10001

Telephone: 833-518-1613 Email: DANIELLE@VERSEMEDICAL.COM

Contact Person Name: DANIELLE WATIMAR

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

DHAIVAT N. PANDYA

Print Name of Authorized Person Submitting Application

Dhaivat Pandya

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

08/08/2024

Date

Board Use Only	Date Received: 8/9/24	Amount: $500-cc

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "JETLENSES INC" IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWELFTH DAY OF AUGUST, A.D. 2024.

Jeffrey W. Bullock, Secretary of State

6833727 8300

SR# 20241173175

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203232276

Date: 08-12-24

MISSISSIPPI

Board of Pharmacy

Permit #
18493 / 11.1

Medical Equipment Supplier

JETLENSES INC
DBA Verse Medical
37 W 20TH ST
STE 801
New York, NY 10011

Permit Holder:
Dhaivat N Pandya

This permit is not transferable or assignable.

Issued: 06/19/2024
Renewed: 06/19/2024
Expires: 06/30/2025

Susa McCoy
Executive Director

Mississippi Board of Pharmacy | 6360 I-55 North | Suite 400 | Jackson, MS 39211
Phone: 601-899-8880 | Fax: 601-899-8851

NORTH CAROLINA BOARD OF PHARMACY

DME PERMIT
(ORIGINAL)

This is to Certify

JETLENSES INC
doing business as
VERSE MEDICAL

Address **37 W 20Th Ave Ste 801** City **New York, NY**

Is Registered as a
DME

As Required by G.S. 90-85.21,
The Number of Said Permit Being:

Issued **06/25/2024** **03197**

North Carolina Board of Pharmacy

Executive Director

TO BE CONSIPCUOUSLY
DISPLAYED IN
MAIN LOBBY OF DME

THIS PERMIT IS NOT TRANSFERABLE IT MUST BE RENEWED BY JANUARY 1ST OF EACH YEAR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 05/28/2024
Receipt Number: 2024174358
Receipt Amount $: 100.00

Medical Gas - Durable Medical Equipment

PERMIT NO	EXPIRES
C002445	10/31/2025

Issued to :

JETLENSES INC
Dhaivat Pandya
37 W 20TH ST STE 801
NEW YORK, NY 10011

JETLENSES INC
37 W 20TH ST STE 801
NEW YORK, NY 10011

Kam Gandhi
EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : Dhaivat Pandya
LICENSE NUMBER : C002445
EXPIRES : 10/31/2025

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.

- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

Public Protection Cabinet

Department of Professional Licensing

This Document is an official verification of license by the Commonwealth of Kentucky

8/21/2024 2:48:13 PM

Board Name : Kentucky Board of Durable Medical Equipment Suppliers						
License Type : Home Medical Equipment and Services Provider						
Name	Legacy Number	License Number	Disciplinary Actions	Status	Issue Date	Expiration Date
JetLenses Inc. 37 W. 20th St., Ste. 801 New York, NY 10011		[redacted]	No	Active	12/15/2022 12:00:00 AM	9/30/2025 12:00:00 AM

Dealer in Products for the Disabled License

Business Name:
JETLENSES INC

DBA/Trade Name:
VERSE MEDICAL

Business Address:
37 W 20TH ST STE 801
NEW YORK, NY 10011-3716

License Number: [redacted]

Issued: 02/28/2023 **Expires:** 03/15/2025

6765-2023-RDPD

New York City Department of Consumer and Worker Protection
42 Broadway, New York, NY 10004

For complaints, contact:
311 | nyc.gov/dcwp

NYC **Consumer and Worker Protection**

Eric L. Adams
Mayor

Vilda Vera Mayuga
Commissioner

0150

New York State Department of Taxation and Finance

Certificate of Authority

Identification number

82-5060467

(Use this number on all returns and correspondence)

VALIDATED

7/26/2024

Dept of Tax and Finance

JETLENSES INC
VERSE MEDICAL
158 W 27TH ST FL 10
NEW YORK NY 10001-6216

is authorized to collect sales and use taxes under Articles 28 and 29 of the New York State Tax Law.

Nontransferable

This certificate must be prominently displayed at your place of business.
Fraudulent or other improper use of this certificate will cause it to be revoked.
The certificate may not be photocopied or reproduced.

4020109100098

1DB8 - 2092200 P0000018 - 01

DTF-17-A (11/14)

Dealer in Products for the Disabled License

Business Name:
JETLENSES INC

DBA/Trade Name:
VERSE MEDICAL

Business Address:
37 W 20TH ST STE 801
NEW YORK, NY 10011-3716

License Number: [redacted]

Issued: 02/28/2023 **Expires:** 03/15/2025

For complaints, contact:
311 | nyc.gov/dcwp

6765-2023-RDPD

New York City Department of Consumer and Worker Protection
42 Broadway, New York, NY 10004

NYC Consumer and Worker Protection

Eric L. Adams
Mayor

Vilda Vera Mayuga
Commissioner

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
07/02/2024

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

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

PRODUCER	CONTACT NAME:	
Millennial Specialty Insurance LLC dba Founder Shield 4211 West Boy Scout Blvd, Suite 800 Tampa, Florida, 33607	PHONE (A/C No. Ext): 646-854-1058	FAX (A/C No):
	E-MAIL ADDRESS:coi@foundershield.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : Hartford Underwriters Ins Co (Hartford)	30104
INSURED	INSURER B : At-Bay Specialty Insurance Company	
JetLenses Inc 158 West 27th Street, Floor 10 New York, New York, 10001	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES CERTIFICATE NUMBER: REVISION NUMBER:

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	COMMERCIAL GENERAL LIABILITY CLAIMS MADE ✓ OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: ✓ POLICY PROJECT LOC OTHER			10SBAAT3LJM	07/15/2024	07/15/2025	EACH OCCURRENCE	$1,000,000.00
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000.00
							MED EXP (Any one person)	$10,000.00
							PERSONAL & ADV INJURY	$1,000,000.00
							GENERAL AGGREGATE	$2,000,000.00
							PRODUCTS - COMP/OP AGG	$2,000,000.00
A	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY SCHEDULED ✓ HIRED AUTOS ONLY ✓ NON-OWNED AUTOS ONLY			10SBAAT3LJM	07/15/2024	07/15/2025	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000.00
							BODILY INJURY (Per person)	
							BODILY INJURY (Per accident)	
							PROPERTY DAMAGE (Per accident)	
A	✓ UMBRELLA LIAB EXCESS LIAB ✓ OCCUR CLAIMS-MADE			10SBAAT3LJM	07/15/2024	07/15/2025	Each occurence	$4,000,000.00
							Aggregate	$4,000,000.00
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYP ROPRIETOR/PARTNER/EXECUTIV OFFICER/MEMBER EXCLUDED? Y/N N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A					PER STATUTE OTHER	
							E.L. EACH ACCIDEN	
							E.L. DISEASE - EA EMPLOYEE	
							E.L. DISEASE - POLICY LIMIT	
B	Cyber Liability			AB-6698675-01	05/07/2024	05/07/2025	$ 100,000 per occ $100,000 in agg	
A	Property			10SBAAT3LJM	07/15/2024	07/15/2025	$ 3000000.00 BPP $1,000 deductible	

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

CERTIFICATE HOLDER

Evidence Only

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

© 1988-2016 ACORD CORPORATION. All rights reserved.

ADDITIONAL REMARKS SCHEDULE

Intermediary	Insured
Policy Number	
Insurer	Effective Date

ADDITIONAL REMARKS

This Additional Remarks form is a schedule to ACORD form,

Form Number:						Form Title JetLenses Inc - Evidence Only COI	
INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS
		[redacted]	[redacted]				

© 1988-2016 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

TRANSMISSION VERIFICATION REPORT

TIME : 08/15/2024 10:41AM
NAME :
FAX :
TEL :
SER.# : U64646D3F145085

DATE,TIME	03/22 05:16PM
FAX NO./NAME	davidgregg@versemedical.com
DURATION	00:00:00
PAGE(S)	00
RESULT	NG
MODE	COLOR 200 DPI eML

NG: POOR LINE CONDITION / OUT OF MEMORY

TRANSMISSION VERIFICATION REPORT

TIME : 08/15/2024 10:41AM
NAME :
FAX :
TEL :
SER.# : U64646D3F145085

DATE,TIME	03/22 05:16PM
FAX NO./NAME	davidgregg@versemedical.com
DURATION	00:00:00
PAGE(S)	00
RESULT	NG
MODE	COLOR 200 DPI eML

NG: POOR LINE CONDITION / OUT OF MEMORY

Name	Role	EIN	Current Issued Ownership/Stockholdings	Address (for owners only)	DOB
Chetan Puttagunta	Owner, Managing Employee, Officer, CEO		39.41%	[redacted]	[redacted]
Sapphire Fund III, L.P.	Owner	[redacted]	13.89%		
Sapphire Venture Fund III, L.P.	Owner	88-2817349	10.63%		
AVF II, L.P.	Owner	[redacted]	8.24%		
Bartlett Ventures II, LP	Owner	86-4007775	5.02%		
YC30, L.P.	Owner	[redacted]	4.45%	535 Pioneer Way Mountain View, CA 94041	
Webb Investment Network Fund, L.P.	Owner	[redacted]	3.08%	780 Market Street, Ste. 700 San Francisco, CA 94103	
Headline US VI, LP	Owner	84-2636074	2.73%	101 Montgomery Street, Ste. 200 San Francisco, CA 94129	
ACVC Fund I LP	Owner	[redacted]	1.53%	2261 Market Street, Ste. 20011 San Francisco, CA 94114	
Wayfinder Ventures, LP	Owner	[redacted]	1.26%	548 Market Street, PMB 44351 San Francisco, CA 94104	
Abeele Capital Fund I, LP	Owner	[redacted]	1.24%	1257 3rd Street, Floor 3 Santa Monica, CA 90401	
Nitin Pandya	Owner		1.11%	158 W 27th St Fl 10, New York, NY 10001 6216	
FounderDuli ZF LLC	Owner	[redacted]	0.78%	257 Kearny Street, Ste. 404 San Francisco, CA 94108	
James Everingham	Owner		0.73%	158 W 27th St Fl 10, New York, NY 10001 6216	
AME Cloud Ventures, LP	Owner	87-1353846	0.55%	4200 Portage Ave Palo Alto, CA 94306	
Paul Graham	Owner		0.54%	158 W 27th St Fl 10, New York, NY 10001 6216	
Paul Buchheit	Owner		0.45%	158 W 27th St Fl 10, New York, NY 10001 6216	
SOMA CAPITAL FUND II, LP	Owner	[redacted]	0.45%	101 Mission Street, Ste. 610 San Francisco, CA 94105	
Chris Ogden	Owner		0.45%	158 W 27th St Fl 10, New York, NY 10001 6216	
IA Fund, LP - A4	Owner	[redacted]	0.37%	411 1st Ave S Seattle WA 98104	
Castle Bridge	Owner		0.36%		
22nd Street Ventures	Owner	[redacted]	0.33%	1300 22nd Street, APT 410 San Francisco, CA 94107	
Building Endeavors LLC	Owner	[redacted]	0.33%	9 Blanding Lane Belvedere Tiburon, CA 94920	
VE Fund I, a series of Riverside Ventures, LP	Owner	32-0677786	0.33%	158 W 27th St Fl 10, New York, NY 10001 6216	
Ankit Kohli	Owner		0.22%	158 W 27th St Fl 10, New York, NY 10001 6216	
The Chestnut Revocable Trust March 18, 2003	Owner		0.22%	158 W 27th St Fl 10, New York, NY 10001 6216	
Geometry Capital	Owner	[redacted]	0.17%	15 Commissioners House D Admiralty Arsenal London, England SE18 3PP	
Jonathan Pines	Owner		0.12%	158 W 27th St Fl 10, New York, NY 10001 6216	
The Schneider Trust	Owner		0.12%	158 W 27th St Fl 10, New York, NY 10001 6216	
Nicolas Baum	Owner		0.11%	158 W 27th St Fl 10, New York, NY 10001 6216	
Mungal Trust, created on March 28, 2011	Owner		0.11%	158 W 27th St Fl 10, New York, NY 10001 6216	
Adam and Jaclyn Forought Family Trust 2011	Owner		0.11%	158 W 27th St Fl 10, New York, NY 10001 6216	
The Hartz Family Revocable Trust	Owner		0.10%	158 W 27th St Fl 10, New York, NY 10001 6216	
Alex Nichols	Owner		0.08%	158 W 27th St Fl 10, New York, NY 10001 6216	
Scout VI A, LLC	Owner	[redacted]	0.06%	138 Montfort Drive Ste. 100 Dallas, TX 75240	
Harriet Manvenara Riddiford	Owner	[1]	0.04%	158 W 27th St Fl 10, New York, NY 10001 6216	
John Sayres	Owner		0.03%	158 W 27th St Fl 10, New York, NY 10001 6216	
Sundeep Ahuja	Owner	[redacted]	0.03%	158 W 27th St Fl 10, New York, NY 10001 6216	
Max Stevens	Owner		0.03%	158 W 27th St Fl 10, New York, NY 10001 6216	
Jesse Zining	Owner		0.01%	158 W 27th St Fl 10, New York, NY 10001 6216	
Nahen Parsiani	Owner		0.01%	158 W 27th St Fl 10, New York, NY 10001 6216	
Harry Oi	Owner		0.01%	158 W 27th St Fl 10, New York, NY 10001 6216	
Fast Hearing Family Revocable Trust U/T/A Dated October 10, 2014	Owner		0.01%	158 W 27th St Fl 10, New York, NY 10001 6216	
Vinay Iyengar	Owner		0%	158 W 27th St Fl 10, New York, NY 10001 6216	
Total	Owner		100%	158 W 27th St Fl 10, New York, NY 10001 6216	

Verse Medical

158 W 27th St. Floor 10
New York, NY 10001
NPI: 1033796016
versemedical.com

Jetlenses Inc. dba Verse Medical Board of Director/Officer Listing

President & CEO: Dhaivat N. Pandya
Treasurer: Dhaivat N. Pandya
Secretary: Dhaivat N. Pandya

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Jetlenses Inc dba Verse Medical MDEG License # (if applicable) _____

Physical Address 158 W 27th Street, Floor 10

City New York State NY Zip 10001

Mailing Address (if different from physical address) Same

City _____ State _____ Zip _____

Telephone 833-518-1613 Website www.versemedical.com

Licensing Company Email N/A

Section 2: Personal Information

First Dhaivat Middle Nitinrai Last Pandya

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

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

Mailing Address [redacted] W 26th Street, [redacted]

City New York State NY Zip 10001

Telephone [redacted] Email [redacted]

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Harvard University		09/15-05/18	
Address	**City**	**State**	**Zip**
Massachusetts Hall	Cambridge	MA	02138
Diploma/Degree obtained, if any			
Bachelor of Arts			

School Name		From - To (MM/YY – MM/YY)	
Appleton North High School		09/11-06/15	
Address	**City**	**State**	**Zip**
5000 N. Ballard Rd.	Appleton	WI	54913
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/23-present	[redacted]W 26th St., [redacted]	New York	NY	10001
03/19-05/23	[redacted]W 47th Street, [redacted]	New York	NY	10036
09/18-03/19	[redacted]32nd Ave[redacted]	Seattle	WA	98125
05/18-09/18	[redacted]Evandale Avenue, [redacted]	Mountain View	CA	94043
09/16-05/18	[redacted]Linnaean Street, Cambridge	Cambridge	MA	02138
09/15-09/16	[redacted]Cambridge St	Cambridge	MA	02138
11/11-19/15	[redacted]E Ashbury Drive, [redacted]	Appleton	WI	54913
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
JetLenses Inc dba Verse Medical			4/2018-present	
Business Address		**City**	**State**	**Zip**
158 W 27th St., Floor 10		New York	NY	10001
Phone	**Title**		**Number of Employed Hours**	
833-518-1613	CEO		12,480+	
Description of Duties				
CEO				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Dhaivat Pandya

Original Signature (electronic, copies or stamps not accepted)

10/08/24

Date

I, Dhaivat Nitinrai Pandya, **certify that as the MDEG Administrator for**

Jetlenses Inc dba Verse Medical,

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

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

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

Dhaivat Nitinrai Pandya

Print Name (First, Last)

Dhaivat Pandya

Original Signature (electronic, copies or stamps not accepted)

10/08/24

Date

Board Use Only	Date Received:

39.41%

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: JetLenses Inc dba Verse Medical

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

Physical Address: 158 W 27th Street, Floor 10

City: New York State: NY Zip: 10001

Mailing Address (if different from physical address): same as physical

City: State: Zip:

Telephone: 833-518-1613 Website: versemedical.com

Licensing Company Email:

Section 2: Personal Information

First: Dhaivat Middle: Nitinrai Last: Pandya

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

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

Mailing Address: [redacted] W 26th Street, [redacted]

City: New York State: NY Zip: 10001

Telephone: [redacted] Email: [redacted]

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Harvard University		09/15-05/18	
Address	**City**	**State**	**Zip**
Massachusetts Hall	Cambridge	MA	02138
Diploma/Degree obtained, if any			
Bachelor of Arts			

School Name		From - To (MM/YY – MM/YY)	
Appleton North High School		09/11-06/15	
Address	**City**	**State**	**Zip**
5000 N. Ballard Rd.	Appleton	WI	54913
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/23-present	[redacted]W 26th St., [redacted]	New York	NY	10001
03/19-05/23	[redacted]W 47th Street, [redacted]	New York	NY	10036
09/18-03/19	[redacted] 32nd Ave[redacted]	Seattle	WA	98125
05/18-09/18	[redacted]Evandale Avenue, [redacted]	Mountain View	CA	94043
09/16-05/18	[redacted] Linnaean Street, Cambridge	Cambridge	MA	02138
09/15-09/16	[redacted]Cambridge St	Cambridge	MA	02138
11/11-19/15	[redacted]E Ashbury Drive, [redacted]	Appleton	WI	54913
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
JetLenses Inc dba Verse Medical			4/2018-present
Business Address	**City**	**State**	**Zip**
158 W 27th St., Floor 10	New York	NY	10001
Phone	**Title**		
833-518-1613	CEO		

Description of Duties

CEO

Business Name			From - To (MM/YY – MM/YY)
TWO SIGMA			05/17-08/16
Business Address	**City**	**State**	**Zip**
100 Avenue of the Americas, 16th Floor	New York	NY	10013
Phone	**Title**		
212 625 5700	QUANTITATIVE RESEARCH INTERN		

Description of Duties

Analyzed financial market data using statistical techniques (linear models, PCA, etc.) to improve market beta estimation models. Used Python, Pandas, NumPy, SciPy, etc.

Business Name			From - To (MM/YY – MM/YY)
METEOR			05/16-08/16
Business Address	**City**	**State**	**Zip**
1600 Bryant St #411447	San Francisco	CA	94103
Phone	**Title**		
	CORE DEVELOPER INTERN		

Description of Duties

Meteor is a YCombinator alumni funded by A16Z, Matrix Partners and Trinity Ventures, Built a caching client for Facebook's GraphQL query language., Implemented AST-level optimizations, improved performance of cache.

Business Name			From - To (MM/YY – MM/YY)
KENSHO			09/15-01/16
Business Address	**City**	**State**	**Zip**
44 Brattle St	Cambridge	MA	02138
Phone	**Title**		
n/a- info@kensho.com	QUANTITATIVE RESEARCH INTERN		

Description of Duties

Analyzed and modeled the reconstitution effect within the Russell index using Python data analysis libraries such as Pandas, NumPy, SciPy.

Business Name			From - To (MM/YY – MM/YY)
MIT NETWORK CODING GROUP			07/14-08/14
Business Address	**City**	**State**	**Zip**
77 Massachusetts Avenue	Cambridge	MA	02139
Phone	**Title**		
617.253.3167	INFORMATION THEORY RESEARCH INTERN		

Description of Duties

Worked on research within information theory, specifically network coding., Designed algorithms and published literature on the construction of optimal cost linear network code for all networks rather than only special cases.

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

_____ _____

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

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

Dhaivat Pandya

Print Name (First, Last)

Dhaivat Pandya

Original Signature (electronic, copies or stamps not accepted)

09/18/24

Date

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

State of New York, ss. County of New York

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

Original Signature

September 18th, 2024

Date

Subscribed and Sworn to before me this 18th day of September.

Notary Public Signature

Jaden Rodriguez
Notary Public, State of New York
Reg. No. 01RO6442864
Qualified in New York County
Commission Expires October 24th, 2026

(Seal)

4F

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

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

Section 1: General Information

Facility Name: AstraZeneca Pharmaceuticals LP

Physical Address: 1800 Concord Pike

City: Wilmington State: DE Zip: 19850

Mailing Address (if different from physical address): 355 Omicron Court

City: Shepherdsville State: KY Zip: 40165

Telephone: 800-456-3669 Website: astrazeneca.com

Name of Designated Representative (DR): Sabrina Brooks

Licensing Company Email: usdruglicensing@astrazeneca.com DR Email: sabrina.brooks@astrazeneca.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies ■ Practitioners ■ Hospitals ■ Wholesalers ☐ Veterinarians ☐ Others:	■ Dangerous Drugs ☐ Controlled Substances ☐ [a]Medical devices, equipment, supplies, gases ☐ Others:	■ Manufacturer ☐ Repacker ☐ Reverse Distributor ☐ Warehouse ☐ Retail pharmacy wholesale distributor ☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	✓	
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Jun 2023	Jun 2023	DE	Wilmington	New Castle
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
1:03CR55(JJF)		United States District Court, District of Delaware		
Reason/Charge				
Conspiracy to violate the Prescription Drug Marketing Act by causing the sale of drug samples.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
AstraZeneca Pharmaceuticals LP			Lawsuit	
Name of Business/Industry/Entity				
AstraZeneca Pharmaceuticals LP				

Provide explanation below:

In June 2003, AstraZeneca Pharmaceuticals LP pleaded guilty to a one-count criminal information charging the company with conspiracy to violate the Prescription Drug Marketing Act by providing, during the time period 1993 through 1996, free samples of Zoladex to certain physicians with the understanding that these physicians would submit claims for reimbursement to Medicare.

Original Signature (electronic, copies or stamps not accepted)

15 Aug 2024
Date

Case Summary

1:03-cr-00055-JJF All Defendants USA v. Astrazeneca Pharm LP
Date filed: 06/20/2003
Date terminated: 07/01/2003
Date of last filing: 09/08/2003

Astrazeneca Pharm LP (1)
Office: Wilmington **Filed:** 06/20/2003
County: New Castle **Terminated:** 06/20/2003 **Reopened:**
Other Court Case: None

Count: 1 **Citation:** 18:371.F **Offense Level:** 4
18:371 - CONSPIRACY TO DEFRAUD THE UNITED STATES (CT. 1 - 1993 THRU 07/96)
Defendant Custody Status:
Flag: CLOSED

Plaintiff: USA **represented by** Beth Moskow-Schnoll **Phone:**(302) 252-4465
Email: moskowschnollb@ballardspahr.com

PACER Service Center			
Transaction Receipt			
07/11/2023 08:53:36			
PACER Login:	sablbrooks	**Client Code:**	
Description:	Case Summary	**Search Criteria:**	1:03-cr-00055-JJF
Billable Pages:	1	**Cost:**	0.10

Department of Justice

FOR IMMEDIATE RELEASE
FRIDAY, JUNE 20, 2003
WWW.USDOJ.GOV

CIV
(302) 573-6277

ASTRAZENECA PHARMACEUTICALS LP PLEADS GUILTY TO HEALTHCARE CRIME; COMPANY AGREES TO PAY $355 MILLION TO SETTLE CHARGES

The United States Attorney's Office for the District of Delaware, the Department of Health and Human Services Acting Principal Deputy Inspector General Dara Corrigan, Terrell L. Vermillion, Director, Office of Criminal Investigations, Food & Drug Administration, and SAIC Edward T. Bradley of the Northeast Field Office for the Defense Criminal Investigative Service announced that AstraZeneca Pharmaceuticals LP ("AstraZeneca"), a major pharmaceutical manufacturer headquartered in Wilmington, Delaware, today pleaded guilty in federal district court in Wilmington, Delaware to a healthcare crime and agreed to pay $355,000,000 to resolve criminal charges and civil liabilities in connection with its drug pricing and marketing practices with regard to Zoladex, a drug sold by AstraZeneca Pharmaceuticals LP and used primarily for the treatment of prostate cancer. The general components of the global agreement are as follows:

AstraZeneca pleaded guilty to conspiring to violate the Prescription Drug Marketing Act ("PDMA") by causing to be submitted claims for payment for the prescription of Zoladex which had been provided as free samples to urologists. This criminal conduct caused losses of $39,920,098 to Medicare, Medicaid and other federally funded insurance programs. As part of the plea agreement, AstraZeneca agreed to pay a $63,872,156 criminal fine;

AstraZeneca agreed to settle its federal civil False Claim Act liabilities and to pay the U.S. government $266,127,844 to resolve allegations that the company caused false and fraudulent claims to be filed with the Medicare, TriCare, Department of Defense and Railroad Retirement Board Medicare programs as a result of AstraZeneca's fraudulent drug pricing schemes and sales and marketing misconduct;

AstraZeneca agreed to settle its civil liabilities to the Medicaid program by paying to the United States and the states a total of $24,900,000 to resolve allegations that it caused false and fraudulent claims to be filed with the states as a result of its drug pricing and marketing misconduct and that it failed to provide the state Medicaid programs AstraZeneca's best price for those drugs as required by law. The National Association of Medicaid Fraud Control Units has reached an agreement in principle to settle the state portion of these liabilities on behalf of the state Attorneys General; and

AstraZeneca has agreed to comply with the terms of a corporate integrity agreement which ensures, among other things, that AstraZeneca will report to the Medicare and Medicaid programs the average sale price for drugs reimbursed by those programs and will promote, through internal training and other programs and policies, marketing and sales practices that are in full compliance with the law.

Zoladex is marketed by AstraZeneca primarily for the treatment of prostate cancer, as is the drug Lupron which is produced by TAP Pharmaceuticals, Inc. ("TAP"). In October 2001, TAP agreed to pay $875,000,000 to resolve civil and criminal liabilities in connection with its pricing and marketing of Lupron.

While Medicare does not pay for most drugs needed by Medicare beneficiaries, Medicare covers some drugs, such as Zoladex, that must be injected under the supervision of a physician.

In documents filed with this case, the United States alleged that from January 1991 through December 31, 2002, Astra Zeneca engaged in the following conduct involving the marketing, sale and pricing of Zoladex for the treatment of prostate cancer:

(i) Employees of AstraZeneca provided thousands of free samples of Zoladex to physicians knowing and expecting that certain of those physicians would prescribe and administer the free drug samples to their patients and thereafter bill those free samples to the patients and to Medicare, Medicaid, and other federally funded insurance programs;

(ii) In order to induce certain physicians, physicians' practices, and others to purchase Zoladex, AstraZeneca offered and paid illegal remuneration in various forms including free Zoladex, unrestricted educational grants, business assistance grants and services, travel and entertainment, consulting services, and honoraria;

(iii)Also in order to induce physicians to purchase Zoladex, AstraZeneca marketed a "Return-to-Practice" program to physicians. This Return-to-Practice program consisted of inflating the Average Wholesale Price ("AWP") used by Medicare and others for reimbursement of the drug , deeply discounting the price paid by physicians to AstraZeneca for the drug ("the discounted price"), and marketing the spread between the AWP and the discounted price to physicians as additional profit to be returned to the physician's practice from Medicare reimbursements for Zoladex;

(iv) AstraZeneca set the AWP for Zoladex at levels far higher than the majority of its physician customers actually paid for the drug. As a result, AstraZeneca's customers received reimbursement from Medicare and state Medicaid programs and others at levels significantly higher than the physicians' actual costs or the wholesalers' average price; and

(v) AstraZeneca misreported and underpaid its Medicaid rebates for Zoladex used for treatment of prostate cancer, i.e., the amounts that it owed to the states under the federal Medicaid Rebate Program. AstraZeneca was generally required on a quarterly basis to rebate to each state Medicaid program the difference between the Average Manufacturer Price ("AMP") and its "Best Price". AstraZeneca falsely reported the Best Price for Zoladex used for treatment of prostate cancer because AstraZeneca calculated its Best Prices for Zoladex without accounting for off-invoice price concessions provided in various forms including cash discounts in the form of grants, services and free goods contingent on any purchase requirement.

The investigation commenced after the filing of a civil False Claim Act suit by Douglas Durand who was employed as the Vice President of Sales for TAP Pharmaceutical Products, Inc. The civil False Claims Act allows for private individuals like Durand to file a whistleblower suit to bring the government information about wrongdoing. Where persons submit, cause others to submit, or conspire to submit false or fraudulent claims to the United States government, the government is entitled to recover treble damages and $5,500 to $11,000 for each false or fraudulent claim. If the government is successful in resolving or litigating its claims, the whistleblower may share in the recovery by receiving from 15 to 25% of the amount recovered. As part of this settlement, Durand will receive a 17% share of the civil recovery pursuant to the False Claims Act whistleblower provisions. This amounts to approximately $47.5 million.

Prior to today's guilty plea by AstraZeneca, three physicians have been charged, and two have pleaded guilty, for their role in conspiring to bill for Zoladex samples. Dr. Saad Antoun, a urologist practicing in Holmdel, New Jersey, was charged on January 15, 2002, and pleaded guilty to conspiracy on September 18, 2002. Dr. Stanley Hopkins, a urologist practicing in Boca Raton, Florida, was charged on September 30, 2002, and pleaded guilty to conspiracy on December 17, 2002. Dr. Robert Berkman, a urologist practicing in Columbus, Ohio, was charged on May 19, 2003.

"This prosecution of a pharmaceutical company demonstrates our resolve to protect federal health insurance programs when they are abused to enrich drug companies and doctors. We will pursue those whose criminal conduct imposes enormous expense on trust funds that the taxpayers fund to protect and preserve the health of our elderly, our poor, our military, and its dependents." said Associate Attorney General Robert D. McCallum, Jr. of the United States Department of Justice.

"The public has been well served by the investigators who uncovered the extent of this scheme and brought it to an end," said Commissioner of Food and Drugs Mark B. McClellan, M.D., Ph.D. "FDA will not tolerate criminal conduct that exploits patients, plunders the national treasury, and adds to the cost of health care."

"Today's settlement shows that the federal government is holding the pharmaceutical industry strictly accountable for improper conduct as well as those who conduct business with them." Department of Health and Human Services Acting Principal Deputy Inspector General Dara Corrigan stated. "The Office of Inspector General, along with our partners, will not tolerate this type of behavior, and we will continue to investigate allegations of illegal conduct concerning the pharmaceutical industry."

"Today's plea and settlement demonstrates our strong commitment to protecting the American public from corporate greed, in whatever form that it may occur", said SAC Bradley. "This commitment extends to all participants in the many healthcare systems in this country, including our brave service men and women and their dependents. This case sends a strong message to the pharmaceutical industry that fraudulent activity, such as the scheme perpetrated by AstraZeneca, will not be tolerated and will be investigated and prosecuted to the full extent of the law."

The entire amount of the nearly $64 million criminal fine paid by AstraZeneca will go to the Department of Justice's Crime Victims Fund. The Fund was established in 1984 by the Victims of Crime Act ("VOCA") and serves as a major funding source for victim services throughout the country. Victims of federal as well as state crimes are eligible to receive VOCA-funded services, and state Assistance programs use VOCA funds to provide or contract for services to victims of rape, drunk driving, child abuse, domestic violence, homicide, and other crimes.

The investigation has been conducted by the Office of Inspector General for the U.S. Department of Health and Human Services, the Office of Criminal Investigations for the Food and Drug Administration, the Defense Criminal Investigative Service and the Federal Bureau of Investigation. On the criminal side, the investigation and prosecution are being handled by Assistant U.S. Attorney Beth Moskow-Schnoll. On the civil side, the investigation and prosecution are being handled by Assistant U.S. Attorney Virginia Gibson.

Press contact: Beth Moskow-Schnoll, (302) 573-6277 x 130.

###

03-371

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Keuhne + Nagel Inc.
Address: 6005 Freeport Ave # 103 City: Memphis State: TN Zip: 38141
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): AstraZeneca PLC
Corporation Name: AstraZeneca Pharmaceuticals
Mailing Address: 355 Omicron Court
City: Shepherdsville State: KY Zip: 40165
Telephone: 502-543-5102 Email: usdruglicensing@astrazeneca.com
Contact Person Name: Shannon Grimes

Date of SEC Registration: 14Jul2000	SEC Registration Number: 333-9062	Stock Exchange Symbol: AZN

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

AstraZeneca Pharmaceuticals LP

Facility Name

Sabrina Brooks

Print Name of Authorized Person Submitting Application

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

15 Aug 2024

Date

Board Use Only	Date Received: 8/19/24	Amount: $1000-cc

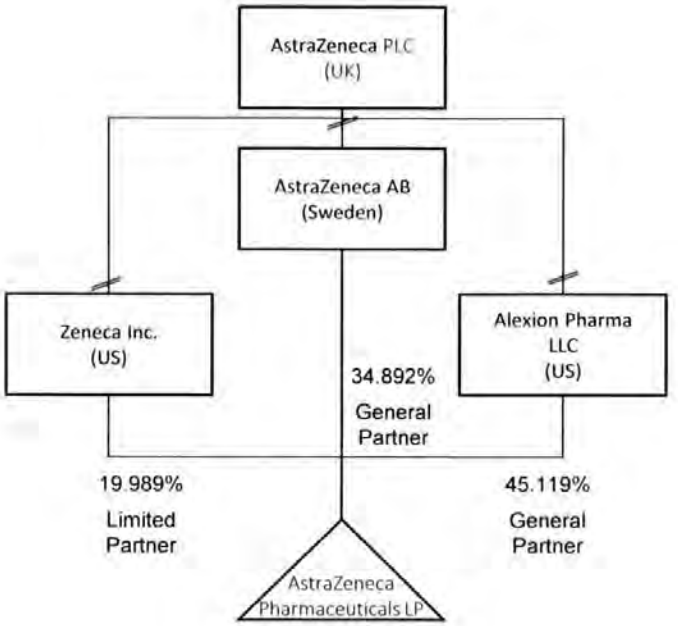
AstraZeneca Pharmaceuticals LP Officers

AZPLP Officers

Name	Title	Business Address	Business Phone	Email
Andrew Wirths	SVP Supply, Americas	[redacted] Gaithersburg, MD 20878	[redacted]	andrew.wirths@astrazeneca.com
David E. White	Treasurer	[redacted] Wilmington, DE 19850		david.e.white@astrazeneca.com
Kevin P. Durning	US CFO, VP Finance	[redacted] Wilmington, DE 19850		kevin.durning@astrazeneca.com

aZeneca Group

ct of legal entity structure as of 31 December 2022



Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ASTRAZENECA PHARMACEUTICALS LP" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SECOND DAY OF JANUARY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.





2810992 8300

SR# 20240003564

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202502443

Date: 01-02-24

AstraZeneca Pharmaceuticals LP
Home State No Oversight Letter

Per correspondence below with the Delaware Board of Pharmacy, they have no regulatory oversight of virtual manufacturers.

From: noreply@delaware.gov <customerservice.dpr@state.de.us>
Sent: Tuesday, April 11, 2023 1:25 PM
To: Grimes, Shannon <shannon.grimes1@astrazeneca.com>
Subject: Regarding Your Recent Inquiry: Virtual Manufacture License [ref:_00DC016khO._5008y7F1WG:ref]

Good afternoon,

This email is in response to your correspondence and request whether your Company is required to obtain a license to distribute when it is not distributing itself, never touches the drug and uses a third party provide to distribute. 24 **Del. C.** §2540 of the Pharmacy Act states that persons who distribute medicine, drugs, toilet preparations, dentifrices or cosmetics must be registered with the Board of Pharmacy. Section (B) of this law further states that "person may not operate a pharmaceutical establishment to manufacture, pack, package, or distribute on a wholesale basis to persons other than the ultimate consumer any drugs, toilet preparations, dentifrices, or cosmetics without first obtaining from the Board a permit to operate a pharmaceutical establishment." Any third party distributor who distributes drugs into, through or from the state of Delaware would have to be licensed accordingly.

The Board of Pharmacy currently has no regulatory oversight of virtual manufacturers.

Regards,

Delaware Board of Pharmacy
Division of Professional Regulation
Cannon Building
861 Silver Lake Blvd. Suite 203
Dover, Delaware 19904

Phone: (302) 744-4500
Fax: (302) 739-2711

To visit our website, go to http://dpr.delaware.gov

"Delivering Innovative and Responsive Services Through Individual & Team Initiative, Creativity and Leadership."

STATE OF DELAWARE

Department of Finance
Division of Revenue

ACTIVE BUSINESS LICENSE

2000106011

EFFECTIVE	01/01/2022 - 12/31/2024
ISSUED TO	ASTRAZENECA PHARMACEUTICALS LP ATTN TAX DEPT PO BOX 15437 WILMINGTON DE 19850-5437
LOCATION	ASTRAZENECA PHARMACEUTICALS LP 1800 CONCORD PIKE WILMINGTON, DE 19850-
TRADE, BUSINESS OR PROFESSIONAL ACTIVITY	MANUFACTURER

GREAT SEAL OF THE STATE OF DELAWARE · 1704 · 1776 · 1787 ·

2024

ISSUED: 01/23/2022
FEE PAID: $225.00

Is hereby licensed to practice, conduct, or engage in the occupation or business activity indicated above in accordance with the license application duly filed pursuant to Title 30, Delaware Code.

POST CONSPICUOUSLY - NOT TRANSFERABLE

AstraZeneca Pharmaceuticals LP
External Supply and Manufacturing Employees

Name

Derek Seaborn
Miriat Naiga
Lorna Smith
Joanna Kirby
Mia Lilja
Phil Roberts
Tim Sherwell
Richard Curtis
Susannah Oliver
Suzie Stone
Katie Bjerkan
Jessica Taylor
Miriat Naiga
Gina Rutter
Marianna Lorinczova
Bindu Dinakaran
Bin Gao （高彬）
Emma Jackson
Emma Shaw
Jessica Ruiz
Jonathan Ogden
Kieran Lennon
Lindon Francis
Michelle Vincent
Noel Hassett
Sahila Bouchta
Connie Wainwright
Heidi Keeling
Janette Hidalgo
Jenny Sadler
Laura Martin (On Leave)
Lee Balmforth
Matt Clark
Matthew Wright
Mohammad Ali
Peter Rohberg
Rachael Robbins (On Leave)
Wesley Fitzmaurice
Thomas Evans
Ebru Kareem
Evelina Orebrandt
Ian Thompson
Joe Schluck
Kalyani Pemmaraju
Ken Semcken
Lee Wiley
Matt Milks
Pernilla Holmlund
Richard Barker
Gavin Loveday
Govind Pushkar
Jun Honda （本田 淳 - ﾎﾝﾀﾞ ｼﾞｭﾝ）
Peter Davies
Magnus Sjögren
Cecilia Just Davies
Erik Lyall
Nadia Zegrour
Alison Rhodes
Arwyn John
Cydonia Morley (On Leave)
Maria Izar Bellan
Michael Bender
Suzanne Jenkins
Annika Andersson
Bella Zhang （张琼）
Damian Page
Kirsten Froehlich
Max Dolgopyat
Sandra McGechan
Suba Rao
Sussanne Bohman
Susannah Oliver
Arielle Williams
Claire Champion
Ian Jinks
Thomas Wheatley (On Leave)
Yvonne Chondo （ﾁｮﾝﾄﾞ ｲｳﾞｫﾝﾇ）
Ella Wardle
Alistair Stamm
Zach Rahl
David Cooper
Elaine Wilson
Emmanuelle Lundegård
Jeffrey O'Brien
Chris Nelson
Banishree Kaashyap
Bharath Kumar S.B
Elango Selvaraj
Ganesh Krishnamoorthy
Jorge Freyermuth Tamayo
Kowsalya Varathan
Melissa Bernal
Preethy Unnikrishnan
Saran Subramanian
Vineesha Kalamati
David Harper
Emma Adkins
Fathi Hassan
Jagadeesh Putta
Ramkumar R
Samuel Holt
Anne De Ruijter
Danny Warner
Dimitri Princen
Hannah Peuker
izak lamprecht
Jonathan Dekeukelaere
Lila Howard
Marcela Vavrekova
Nathalie Ooms
Raju Derangula
Sara Riehl
Sinnee Teoh
Stefanie Possemiers
Vaclav Bozdech
Vanita Bhat
Wesley Boers
Amit Kumar Javali
Aya Kudo （工藤 亜矢 - ｸﾄﾞｳ ｱﾔ）
Cathy Zhu （祝晓雯）
Marie Chen （陈曼珺）
Shin Woo Kim （김신우 - 金信宇）
Vicky Chen （陈宏宏）
Alejandra Alanis
Alexander Herbert
Anthony Allen
Faisal Ba Rashed
Joanna Gorgis
Karthikeyan Moorthy
Manjuraj H
Prabhu G
Praveen Umamaheswaran
Vijay Joshi
Vijetha Kumari R
Bastien Hermes
Katarina Djak-Bozic
Martin Andersson
Charlotta Karelmo

AstraZeneca Pharmaceuticals LP
External Supply and Manufacturing Employees

Name

Natasha Vass
Donna Sales-Smith
Ebba Frånlund
Elizabeth Sapey
Eric Teneberg
Gary Tughan
Jon Hashemi Tafreshi
Julie Lin （林珏）
Lindsay Purdie
Louise Bell
Michael Sidenqvist
Phil Denham
Wentao Peng （彭雯韬）
Alison Benn
Cliff Veighey
Desmond Northey
Eva Jörgensen
Fiona Laraman
Jeroen Koningen
Jimmy Andersson
John Crawley
Leo Qiu （邱俊平）
Linda Hortlund
Patricia Galvan
Rasia Ahmadi
Sofia Ahl
Christopher James
Brendan O'Neill
Caroline Hill
Chris Bocchetti
David Gray
Malin Wagner
Matt Welham
Michael Tait
Nina Ullah
Raj Adhya
Ryan Shofnos
Sarah Andrews (On Leave)
Hannah Assinder
Jordan Attward
Michael Westerberg
Michelle Herman
Natalia Laskina
Seth Davies
Sophie Perry
Angila Torége
Sharon O'Neal
Becky Burge
Gunilla Onsberger
Maheshkumar (MAC) Ekambaram
Olivia Ward-Stevens
Renee Fierro
Sneha Arun Jagtap
Sruthi Tangirala
Tania Negrete
Tarun Mahankali
Faye Connor
Nay Smith
Robyn Billingham
Tiina Härkönen
Alan Gramlich
Anandan Muthu
Brandon Michael
Chiara Rech
Cristina Valdez
Esthefany Olivas
Govind Gopakumar
Harish Raman
Jayasurya V
Kes McNicholas
LAKSHMANAN. G
Louise Gutteridge
Maikel Hernandez
Megan Harding
Minerva Vega
Mitchell de Groot
Mollie Gallagher
Patric Hellberg
Rachel Obbard
Ruban M
Vaishnavi Vadhri
Areba Mahmood
Åsa Däckfors
Ash de Max
Daniel Stoddart
Jason Capper
Lilian Suliman
Lucy Bryan
Marwa Merghani
Natasha Baxter
Sophie Hill
Brian Jenkins
Gary Wilson
Hassan Dachan
Jenny Borg
Melahat Yan
Nishka Rani Jayagopal
Sam Hunter
Sarah Heapy
Sarika Dengle
Allan Worrall
Andrew Justice
Ben Christman
Brin Marcinek
Charlotte Winell
Cyril Kattah
Dana Hill
Julie Beardmore
Lauren Sherborne
Mai Vu
Megan Evans
Megan Patterson
Neil Greening
Ryan Moorhouse
Shantal Braunskill
AHMED FAROUK
Bayan Alshayeb
Clement Alison
Corinne lang
emanuele trombetta
FAHAD AL WAHAIBY
FERNANDO DIAZ
Hamed Daoud
Ilaria Cei
James Prasad
Janie Tsai
Johanna Argyris
Lara Velati
Melissa Spallieri
MOHAMMED BARHOUMI
riccardo vendetti
Roberta Conforti
Sara Bucci
Sean Abel
Syed Mohammad Akhlaq
Valeria Calvi
Vergel Manalo
Waleed Al-ghulaiga

AstraZeneca Pharmaceuticals LP
External Supply and Manufacturing Employees

Name
Yalcin Yilmaz
Ze Hong Chew
Angel Alex
Anja Dangschat
Bharati Pohare
Brenda Romero
Bryan Jones
Eleonora Bruzzano
Erica Greco
Fabiola Farina
Flavia Romano
Kimball Eng
Lesley Seyer
Maria Chiara Altobello
Maria Letizia Persichetti
Mario Alberto García
Sara Cojeen
Tatiana Belleudi
Timothy Capizzi

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 20-F

(Mark One)

☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☐ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report

For the transition period from _____ to _____

Commission file number: 001-11960

ASTRAZENECA PLC

(Exact name of Registrant as specified in its charter)

England and Wales

(Jurisdiction of incorporation or organization)

1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge CB2 0AA
England

(Address of principal executive offices)

Adrian Kemp
AstraZeneca PLC
1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge CB2 0AA
England
Telephone: +44 20 3749 5000
Facsimile number: +44 1223 352 858

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act

Title of each class	Trading symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing one half of an Ordinary Share of 25¢ each	AZN	The Nasdaq Stock Market LLC
Ordinary Shares of 25¢ each		The Nasdaq Stock Market LLC *
0.700% Notes due 2024	AZN 24	The Nasdaq Stock Market LLC
3.375% Notes due 2025	AZN 25	The Nasdaq Stock Market LLC
0.700% Notes due 2026	AZN 26	The Nasdaq Stock Market LLC
1.200% Notes due 2026	AZN 26A	The Nasdaq Stock Market LLC
3.125% Notes due 2027	AZN 27A	The Nasdaq Stock Market LLC
1.750% Notes due 2028	AZN 28	The Nasdaq Stock Market LLC
4.875% Notes due 2028	AZN 28A	The Nasdaq Stock Market LLC
4.000% Notes due 2029	AZN 29	The Nasdaq Stock Market LLC
1.375% Notes due 2030	AZN 30	The Nasdaq Stock Market LLC
4.900% Notes due 2030	AZN 30A	The Nasdaq Stock Market LLC
2.250% Notes due 2031	AZN 31	The Nasdaq Stock Market LLC
4.875% Notes due 2033	AZN 33	The Nasdaq Stock Market LLC
6.450% Notes due 2037	AZN 37	The Nasdaq Stock Market LLC
4.000% Notes due 2042	AZN 42	The Nasdaq Stock Market LLC
4.375% Notes due 2045	AZN 45	The Nasdaq Stock Market LLC
4.375% Notes due 2048	AZN 48	The Nasdaq Stock Market LLC
2.125% Notes due 2050	AZN 50	The Nasdaq Stock Market LLC
3.000% Notes due 2051	AZN 51	The Nasdaq Stock Market LLC

* Not for trading, but only in connection with the registration of American Depositary Shares representing such Ordinary Shares pursuant to the requirements of the Securities and Exchange Commission

Securities registered or to be registered pursuant to Section 12(g) of the Act

None

(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None
(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

The number of outstanding shares of each class of stock of AstraZeneca PLC as of December 31, 2023 was:

Title of Class	Number of Shares Outstanding
Ordinary Shares of 25¢ each	1,550,162,626
Redeemable Preference Shares of £1 each	50,000

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☒ No ☐

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes ☐ No ☒

Note — Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of "accelerated filer," "large accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer ☒ Accelerated Filer ☐ Non-accelerated Filer ☐
Emerging growth company ☐

If an emerging growth company that prepares its financial statements in accordance with US GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

US GAAP ☐ International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

☐ Item 17 ☐ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

(APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court.

Yes ☐ No ☐

Pursuant to Rule 12b-23(a) of the Securities Exchange Act of 1934, as amended, the information for the 2023 Form 20-F of AstraZeneca PLC (the "Company") set out below is being incorporated by reference from AstraZeneca's "Annual Report and Form 20-F Information 2023" included as exhibit 15.1 to this Form 20-F dated and submitted on February 20, 2024.

References below to major headings include all information under such major headings, including subheadings, unless such reference is a reference to a subheading, in which case such reference includes only the information contained under such subheading. Unless the context otherwise requires, "AstraZeneca" or "Group" refers to the Company and its consolidated entities. Other information contained within AstraZeneca's "Annual Report and Form 20-F Information 2023" included as exhibit 15.1 to this Form 20-F, including graphs and tabular data, is not included in this Form 20-F unless specifically identified below. Photographs are also not included.

In addition to the information set out below, the information (including tabular data) set forth under the headings "Use of terms" on the inside front cover, "Strategic Report—Financial Review—Measuring performance" on page 60, and the tables on pages 61 to 63, "Additional Information —Trade Marks" on page 231, "—Glossary" on pages 232 to 235 and "—Important information for readers of this Annual Report—Cautionary statement regarding forward-looking statements", "—Inclusion of Reported performance, Core financial measures and constant exchange rate growth rates", "—Statements of competitive position, growth rates and sales", "— AstraZeneca websites", "—External/third-party websites" and "—Figures" on page 236, in each case of AstraZeneca's "Annual Report and Form 20-F Information 2023" included as exhibit 15.1 to this Form 20-F dated February 20, 2024 is incorporated by reference. References herein to AstraZeneca websites, including where a link is provided, are textual references only and information on or accessible through such websites does not form part of and is not incorporated into this Form 20-F dated February 20, 2024. Reference to "audited" information (including graphs and tabular data) set forth under the heading "Corporate Governance—Directors' Remuneration Report" refers to procedures performed by the Company's external auditor in accordance with International Standards on Auditing (UK) ('ISAs (UK)') and applicable law and does not form part of the "Report of Independent Registered Public Accounting Firm" in Item 18 herein. For the avoidance of doubt, the "Independent auditors' report to the members of AstraZeneca PLC" on pages 141 to 147 of AstraZeneca's "Annual Report and Form 20-F Information 2023" included as exhibit 15.1 to this Form 20-F dated February 20, 2024 does not form part of, and is not incorporated into, this Form 20-F dated February 20, 2024.

PART 1

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. Reserved

B. Capitalization and Indebtedness

Not applicable.

C. Reason for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Operating in the pharmaceutical sector carries various inherent risks and uncertainties that may affect our business. In this section, we describe the risks and uncertainties that we consider material to our business, in that they may have a significant effect on our financial condition, results of operations and/or reputation.

These risks have been categorised consistently with the "Risk Overview—Principal Risks" detailed on pages 56 and 57 of AstraZeneca's "Annual Report and Form 20-F Information 2023" included as exhibit 15.1 to this Form 20-F dated February 20, 2024, each of which are included below (in addition to other risks that we face). We believe that the forward-looking statements about AstraZeneca in this Form 20-F dated February 20, 2024, identified by words such as 'anticipates', 'believes', 'expects' and 'intends', are based on reasonable assumptions. However, forward-looking statements involve inherent risks and uncertainties such as those summarised below. They relate to events that may occur in the future, that may be influenced by factors beyond our control and that may have actual outcomes materially different from our expectations. Therefore, other risks, unknown or not currently considered material, could have a material adverse effect on our financial condition or results of operations.

Product pipeline risks	Impact
Failure or delay in the delivery of our pipeline or launch of new medicines	
Our continued success depends on the development and successful launch of innovative new drugs. The development of pharmaceutical product candidates is a complex, risky and lengthy process involving significant resources. A project may fail at any stage of the process due to various factors, including: failure to obtain the required regulatory or marketing approvals; unfavourable clinical efficacy data; safety concerns; failure to demonstrate adequate cost-effective benefits to regulatory authorities and/or payers; and the emergence of competing products. Details of projects that have suffered setbacks or failures during 2023 can be found in the "Strategic Report—Therapy Area Review" on pages 16 to 31 of AstraZeneca's 'Annual Report and Form 20-F Information 2023' included as exhibit 15.1 to this Form 20-F dated February 20, 2024. Launch activities may be delayed by a number of factors, including: adverse findings in preclinical or clinical studies; regulatory demands; price negotiation; large-scale natural disasters or global pandemics; competitor activity; and technology transfer. In addition to developing products in-house, we continue to expand our portfolio through licensing arrangements and strategic collaborations which may not ultimately be successful.	Failure or delay in development of new product candidates could damage the reputation of our R&D capabilities and materially adversely affect our future business and results of operations. Delays to launches can lead to excess expenses in the manufacture of pre-launch inventories, marketing materials and sales force training. For the launch of products that are seasonal in nature, delays in regulatory approvals or manufacturing may delay launch to the next season which, in turn, may significantly reduce the return on costs incurred in preparing for the launch for that season. Furthermore, in immuno-oncology in particular, speed to market is critical given the large number of clinical trials being conducted by competitors. Delay of launch can also erode the term of patent exclusivity. Competition from other pharmaceutical companies means that we may have to pay a significant premium over book or market values for our acquisitions. Failure to complete collaborative projects in a timely, cost-effective manner may limit our ability to access a greater portfolio of products, intellectual property (IP), technology and shared expertise. In many cases we make milestone payments in advance of the commercialisation of the products, with no assurance of recouping costs.
Failure to meet regulatory or ethical requirements for medicine development or approval	
We are subject to laws and regulations that control our ability to market our pharmaceutical products. Our development programmes must meet many standards to prove our products are safe, effective and of high quality. Health authorities, such as the FDA in the US and the European Medicines Agency in the EU, can refuse to approve our products or require us to conduct additional clinical trials or scientific testing before they will approve them for marketing. Many factors influence health authority decisions to approve or reject a marketing application for a pharmaceutical product. These include advances in science and technology; new laws, regulations and policies; and different standards for evaluating safety and effectiveness.	Delays in regulatory approvals could delay our ability to market our products and may adversely affect our revenue. Also, post-approval requirements, including additional clinical trials, could cause increased costs. We seek to manage these risks, but policymaking by governments and health authorities can be unpredictable and unforeseen circumstances, such as public health emergencies, may strain health authority resources and delay the approval of our products. Following approval, a health authority may require us to conduct additional clinical trials or scientific testing to address concerns raised after patients have used our products in the marketplace. New data may impact a product's approval status or lead to labelling changes that limit the use of a product.

D. Risk Factors *continued*

Commercialisation risks	Impact
Failures or delays in the quality or execution of the Group's commercial strategies	
Maximising the commercial potential of our new products underpins the success of our strategy and the delivery of our short- and medium-term targets. We may ultimately be unable to achieve commercial success for various reasons, including > difficulties in manufacturing sufficient quantities of the product > any price control measures imposed by governments and healthcare authorities > patient access to healthcare > diagnosis rates > erosion of IP rights > failure to show a differentiated product profile > changes in prescribing habits. The ability to successfully carry out business in emerging markets can be more challenging than in established markets. Such challenges may include > volatility in economic or political climates > inadequate protection against crime (including counterfeiting, corruption and fraud) > inadvertent breaches of local and international law.	Failure to execute our commercial strategies or achieve the level of sales anticipated for a medicine could materially adversely impact our business or results of operations. Failure to leverage potential opportunities or appropriately manage risks in emerging markets may materially adversely affect our reputation, business or results of operations.
Pricing affordability, access and competitive pressures	
Appropriate pricing, reimbursement and policy frameworks enable us to contribute significantly to patients, public health and health practice transformation. The global economic, political and social pressures are creating an ever more challenging environment in which we operate. As a result of global financial pressures there is increased evidence of cost containment measures including > drug pricing system reforms such as the Inflation Reduction Act (IRA) in the US > changes to reference pricing rules impacting prices in some markets > expedited approval of generic drugs and introduction of new laws regulations and policies.	Deterioration of, or lack of improvement in, socio-economic conditions could adversely affect supply and/or distribution in affected countries and the ability or willingness of customers to purchase our medicines, putting pressure on price and/or volumes. This could adversely affect our business or results of operations, for example, those health systems most severely impacted by downturn may seek alternative ways to settle their debts at a discount. Other customers may cease to trade, which may result in losses from writing off debts or a reduction in demand for products. Across the industry, a new government-run drug price-setting programme in the US could reduce the value of certain products sooner than planned and impact the R&D pipeline as companies seek to avoid investing in lower yield products.

D. Risk Factors *continued*

Supply chain and business execution risks	Impact
Failure to maintain supply of compliant, quality medicines	
We may experience challenges, delays or interruptions in the manufacturing and supply of our products for various reasons, including: > Supply shortages or delays in construction of facilities to support future demand of our products caused by significant unforecasted demand growth or supply chain disruptions (e.g. natural disasters, climate impacts, COVID-19, conflict or political unrest). > The inability to supply products due to a product quality failure or regulatory compliance action such as licence withdrawal, product recall or change of regulatory standards (e.g. nitrosamines, where regulators have been introducing new limits/expectations for regulatory filings). It is necessary for us to meet all regulations, including compliance with Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) and comparable regulatory dossier conditions of approval in all countries in which our products are licensed, manufactured or sold. We rely significantly on third parties for the timely supply of goods (e.g. active ingredients and packaging components), many of which are difficult to substitute in a timely manner or at all.	Supply chain difficulties may result in product shortages, which could lead to lost Product Sales and materially affect our reputation and results of operations. Failure to comply with all manufacturing regulations can result in negative regulatory inspection findings that could lead to the halt of manufacturing, and/or product seizure, debarment or recalls which could have an adverse effect on our business, financial condition and results of operations. In the event of insolvency of third-party suppliers, it would be difficult to substitute in a timely manner or at all.

D. Risk Factors *continued*

Illegal trade in the Group's medicines

The illegal trade of pharmaceutical products, including counterfeiting, tampering, theft and illegal diversion (where products are found in a market where we did not send them and where they are not approved to be sold) may lead to a loss of public confidence in the integrity of medicines.

The incidence of illegal trade could materially adversely affect our reputation, financial performance and pose a direct risk to patient safety. In addition, concern about this issue may cause some patients to stop taking their medicines, with consequential risks to their health.

If we are found liable for breaches in our supply chains, authorities may take action, financial or otherwise, that could restrict the distribution of our products.

Reliance on third-party goods and services

A significant proportion of AstraZeneca's annual costs relates to spend with third-party suppliers. The level of spend supports the length of our value chain from discovery to manufacture and commercialisation of our medicines.

Many of our business-critical operations are outsourced to third-party providers. We are, therefore, heavily reliant on these third parties to get medicines to patients, comply with applicable laws and regulations, while also ensuring prudent use of AstraZeneca financial resources.

Failure to successfully secure, onboard and manage outsourced services, particularly with inflationary pressures increasing, or the failure of outsourced providers to deliver timely services, and to the required level of quality, could materially adversely affect our reputation, our financial condition and operating results as well as our ability to deliver medicines to patients.

Failure to effectively manage third-party suppliers when external factors, including geopolitical tensions, or raw materials and components shortages, place increased pressure on AstraZeneca's ability to purchase goods and services may lead to major business disruption.

Any breach of security, whether physical, cyber or data related, or failure of these third parties to operate in a way that is consistent with laws or regulations, may lead to regulatory penalties, materially affect the results of operations and adversely impact our reputation.

Failure in information technology or cybersecurity

IT systems enable critical business functions. Critical business processes and functions are increasingly dependent on partner and vendor IT stability and data integrity. IT systems provide our workforce with continuous access to collaboration environments, global communications channels, applications and data. High availability IT systems remain a business imperative. In addition to availability and reliability, IT systems must comply with provisions specified in data security, privacy and individual protection laws.

Data is a commodity that we prioritise continued access to and protection of. Data is often characterised as strictly confidential information. Examples of strictly confidential data include clinical trial records, personal information, IP, R&D data, and compliance information. AstraZeneca's IT systems and data are potentially vulnerable to service interruptions and security breaches via attacks by malicious third parties or intentional or inadvertent actions by our employees or vendors. Attempts to exploit AstraZeneca are increasingly sophisticated. Threat actors include organised criminal groups, 'hacktivists', nation states, employees and others.

The internet is our primary critical business transaction channel. Internet availability is increasingly at risk due to geopolitical tensions and conflict.

Privacy legislation includes obligations to report data protection breaches to regulators and affected individuals within expedited timeframes.

Disruption to these IT systems and/or the internet (including breaches of data security or cybersecurity, failure to integrate new and existing IT systems) or failure to comply with additional requirements under applicable laws, could harm our reputation and materially adversely affect our financial condition or results of operations. While we invest heavily in the protection of our data and IT, we may be unable to prevent hardware or software failures or breaches which could result in disclosure of confidential information, damage to our reputation, regulatory penalties or sanctions, or financial loss. The inability to back-up and restore data effectively could lead to permanent loss of data that could, in turn, result in non-compliance with applicable laws and regulations and otherwise harm our business.

Data loss could lead to public disclosure of confidential information which may damage our reputation, materially affect our business or results of operations, and expose us to legal risks and/or additional legal obligations. Public disclosure of sensitive information could materially adversely affect our reputation and business or operations results.

Cybersecurity insurance coverage limits may not protect against any future claim or claim proceeds may be delayed.

Failure to comply with regulatory disclosure requirements could cause reputational damage and a loss of public trust.

D. Risk Factors *continued*

Failure of critical processes

Unexpected events and/or events beyond our control could result in the failure of critical processes within the Group or at third parties on whom we are reliant.

The business faces threats to business continuity from many directions. Examples of material threats include:

> Disruption to our business or the global markets if there is instability in a particular geographic region, including as a result of war, terrorism, pandemics, armed conflicts, riots, unstable governments, civil insurrection or social unrest.

> Natural disasters in areas of the world prone to extreme weather events which may increase in frequency or severity as a result of climate change.

> Cyber threats similar to those detailed in the 'Failure in information technology or cybersecurity' section above.

Crystallisation of such material threats may heighten certain other risks, such as those relating to the delivery of the pipeline, launch of new medicines, or the manufacture and supply of medicines, and may lead to loss of revenue and have a materially adverse impact on our financial results.

Failure to collect and manage data in line with legal and regulatory requirements and strategic objectives

Data is increasingly recognised as being AstraZeneca's most valuable commodity. There is an increasing range of legislative and regulatory requirements to manage data across all countries where we conduct business; these may impact certain types of data such as personal data, the way that we conduct business such as restricting the movement of data between countries or jurisdictional regions or how we make use of new technological capabilities such as artificial intelligence (AI). In addition, geopolitical changes may require changes to how AstraZeneca manages data.

Beyond legal and regulatory requirements, achieving strategic objectives will require good management of data across the enterprise. As our organisation increasingly relies on data, including sensitive data relating to health and genomics, a failure to properly understand personal and collective accountabilities for managing data to maximise its value, or failure to address data risks will reduce our ability to execute at pace and deliver strategic objectives.

AI technologies present significant opportunities and risks to our business. Harnessing AI's transformative potential may enable AstraZeneca to speed up the discovery and development of new drugs, optimise our manufacturing processes, drive efficiencies and productivity, and accelerate our growth. Failure to exploit these opportunities may put AstraZeneca at a competitive disadvantage.

AstraZeneca is investing significant resources into AI experimentation, development, and deployment across many parts of our business. As we scale our use of AI, it is possible not all investments will succeed.

AI technologies may exacerbate existing risks, like those risks associated with data privacy, cybersecurity and IP. AI also introduces new risks due to the autonomous nature of the technology, the ease at which AI-enabled decision making can be scaled up, and the commercial pressures to adopt AI. AI systems can amplify biased and discriminatory decision making, perform unreliably and malfunction, generate insights which are difficult to interpret and explain, and cause direct harm to individuals or groups. These risks may become more significant as we increasingly utilise AI to inform, augment and automate decision making and processes in sensitive areas (e.g. clinical trials, medical decision making).

The adoption and exploitation of AI is occurring under the backdrop of intense global media scrutiny, heightened political attention and low levels of public trust and understanding. There is also a range of new AI regulations being adopted and implemented worldwide, including in the EU, China and the US.

Despite taking measures designed to ensure compliance with applicable privacy- and AI-related laws and regulations by our personnel and our third parties, non-compliance has occurred and may occur again in the future. If future instances of non-compliance are deemed significant, these may attract material regulatory sanctions or fines and corresponding reputational damage, orders to stop certain processing of personal data, or legal action on behalf of impacted individuals. Further, failure to protect personal data could lead to a competitive disadvantage, loss of trust from our stakeholders, including patients, and prevent us from delivering our strategic objectives.

If the scope of data-related laws is expanded or if the interpretation or enforcement of existing laws change or new privacy laws are implemented, AstraZeneca and its third-party vendors may be required to change their business practices or data processing practices and policies. This may lead to substantial compliance-related costs or materially adversely impact our business and financial condition.

Our failure to use AI technologies in a way that maintains trust, quality and control in our business activities would pose reputational, legal, regulatory and financial risks to AstraZeneca. Investments in AI may not realise the benefits that were anticipated.

D. Risk Factors *continued*

Failure to attract, develop, engage and retain a diverse, talented and capable workforce

We rely heavily on recruiting and retaining talented employees with a diverse range of skills and capabilities to meet our strategic objectives. Externally there is intense competition for well-qualified individuals, as the supply of people with certain skills or in specific geographic regions may be limited.

Ensuring our employees are continually developed and engaged with strategic objectives embeds commitment across the workforce.

The inability to attract and retain highly skilled personnel may weaken our succession plans for critical positions, impact the implementation of our strategic objectives and ultimately result in the failure of our business operations.

Failure to develop and engage our workforce could result in business disruption, a loss of productivity and higher turnover rates, all of which could materially adversely affect our business.

Focus in 2024 will be to look at our global footprint to ensure we are best positioned to support science and the business towards the 2030 Bold Ambition.

Legal, regulatory and compliance risks	Impact

Failure to meet regulatory or ethical expectations on environmental impact, including climate change

Environmental issues will become more material as healthcare systems embrace net-zero climate targets.

Our environmental targets and performance will have increased scrutiny by investors, governments and non-governmental organisations.

Environmental considerations are becoming embedded in the public procurement of goods and services, including medicinal products and devices.

Specific materials used to manufacture medicines, or used as excipients or propellants, are coming under increased regulation and may be subject to time-limited exemptions or potential phase-out.

The physical impacts of climate change could impact the resilience of our business operations and supply chain.

Investors are increasingly focusing on environmental issues. We continue to see an increased requirement to quantify the impact of specific environmental issues and to disclose our strategy, targets and performance.

Failure to maximise our environmental sustainability credentials could expose us to increased regulatory risk and put us at a commercial disadvantage relative to our peers. This could adversely impact our financial results and lead to reputational damage.

Failure to proactively manage the physical risks associated with climate change could impact the resilience of our operations and supply chain. This could result in supply interruptions, loss of stock and adversely impact our financial results.

Safety and efficacy of marketed medicines is questioned

Our ability to accurately assess, prior to launch, the eventual safety or efficacy of a new product once in broader clinical use can only be based on data available at that time, which is inherently limited due to relatively short periods of product testing and relatively small clinical study patient samples.

Any unforeseen safety concerns or adverse events relating to our products, or failure to comply with laws, rules and regulations relating to provision of appropriate warnings concerning the dangers and risks of our products that result in injuries, could expose us to large product liability claims, settlements and awards, particularly in the US. Adverse publicity relating to the safety of a product, or of other competing products, may increase the risk of product liability claims. Details of material product liability litigation matters can be found in "Financial Statements—Notes to the Group Financial Statements—Note 30—Commitments, contingent liabilities and contingent assets" on pages 204 to 210 of AstraZeneca's "Annual Report and Form 20-F Information 2023" included as exhibit 15.1 to this Form 20-F dated February 20, 2024.

Serious safety concerns or adverse events relating to our products could lead to product recalls, seizures, loss of product approvals, declining sales and interruption of supply, and could materially adversely impact patient access, our reputation and financial revenues. Significant product liability claims could also arise which could be costly, divert management attention, or damage our reputation and demand for our products.

Unfavourable resolution of such current and similar future product liability claims could subject us to enhanced damages, consumer fraud and/or other claims, including civil and criminal governmental actions. This could require us to make significant provisions in our accounts relating to legal proceedings and could materially adversely affect our financial condition or results of operations, particularly where such circumstances are not covered by insurance.

Adverse outcome of litigation and/or governmental investigations

Our business is subject to a wide range of laws and regulations around the world. We have been, and may continue to be, subject to various legal proceedings and governmental investigations.

Actual or perceived failure to comply with laws or regulations may result in AstraZeneca and/or its employees being investigated by government agencies and authorities and/ or in civil legal proceedings. Relevant authorities have wide-ranging administrative powers to deal with any failure to comply with laws, regulations or continuing regulatory oversight, and this could affect us whether such failure is our own or that of our contractors or external partners. In particular, the manufacturing, marketing, exportation, promotional, clinical pharmacovigilance and pricing practices of pharmaceutical manufacturers, as well as manufacturer interaction with regulatory agencies, purchasers, prescribers and patients, are subject to extensive regulation, litigation and governmental investigation. Moreover, such laws, rules and regulations are subject to change. Details of material litigations and governmental investigations can be found in 'Financial Statements—Notes to the Group Financial Statements—Note 30—Commitments, contingent liabilities and contingent assets' on pages 204 to 210 of AstraZeneca's 'Annual Report and Form 20-F Information 2023' included as exhibit 15.1 to this Form 20-F dated February 20, 2024.

Many companies, including AstraZeneca, have been subject to legal claims asserted by federal and state governmental authorities and private payers and consumers, which have resulted in substantial expense and other significant consequences. Governmental investigations or proceedings could result in civil or criminal sanctions and/or the payment of fines or damages. Civil litigation, particularly in the US, is inherently unpredictable, and unexpectedly high awards for damages can result from an adverse result. In many cases, litigation adversaries may claim enhanced damages in extremely high amounts. Government investigations, litigations, and other legal proceedings, regardless of the outcome, could be costly, divert management attention, or damage our reputation and demand for our products.

Unfavourable resolutions to current and similar future proceedings against us that could subject us to criminal liability, fines, penalties or other monetary or non-monetary remedies, including enhanced damages, require us to make significant provisions in our accounts relating to legal proceedings and could materially adversely affect our business or results of operations.

IP risks related to our products

IP protection provides the foundation for continued investment in developing innovative medicines to improve patient health. However, the pharmaceutical industry is experiencing pressure from governments and other healthcare payers to impose limits on IP protections in an effort to manage healthcare costs. Additionally, policymakers are progressively leveraging regulations to expedite the approval of generic drugs and encourage generic drug utilisation. These policies may drive accelerated utilisation of generic alternatives to our products following expiry or loss of our IP rights. We also recognise increasing use of compulsory licensing in some countries in which we operate.

We are subject to numerous patent challenges relating to various products or processes and assertions of non-infringement of our patents. A loss in any of these challenges could result in loss of patent protection on the covered product and a risk to the revenue generated by the product. We also face the risk that our products may be found to infringe patents owned or licensed by third parties and we may be subject to monetary damages or compelled to cease sales of the infringing product, resulting in a potential risk to revenue. These challenges threaten the value of our investment in pharmaceutical development. Details of material patent litigation matters can be found in 'Financial Statements—Notes to the Group Financial Statements—Note 30—Commitments, contingent liabilities and contingent assets' on pages 204 to 210 of AstraZeneca's 'Annual Report and Form 20-F Information 2023' included as exhibit 15.1 to this Form 20-F dated February 20, 2024.

If we are unable to obtain, defend and enforce our IP, we may experience accelerated and intensified competition. Also, if our products are found to infringe a third-party patent, we may be subject to monetary damages or compelled to cease sales of the infringing product. These negative outcomes could have an adverse material impact on our financial results.

D. Risk Factors *continued*

Economic and financial risks	Impact
Failure to achieve strategic plans or meet targets or expectations	
When we communicate our business strategy, targets or performance expectations, all such statements are forward-looking and based on assumptions and judgements, all of which are subject to significant inherent risks and uncertainties.	To achieve our strategic objectives, we must continue to develop commercially viable new products and successfully integrate new organisations we have acquired. There can be no guarantee that our strategy or expectations will materialise. Any failure to successfully implement our business strategy may frustrate the achievement of our financial targets, which may therefore materially damage our brand, business, financial position or results of operations.
Geopolitical and/or macroeconomic volatility disrupts the operation of our global business	
Operating in more than 100 countries, we are subject to political, socio-economic and financial factors around the world. A sustained global economic downturn may adversely impact financial markets and/or exacerbate pressure from governments and other healthcare payers on medicine prices and other cost control measures in order to limit healthcare spending. Geopolitical tensions may lead to the imposition or escalation of trade controls, tariffs, taxes or other restrictions to market access which may increase our costs or reduce revenues.	A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for medicines and our ability to raise additional capital when needed or on favourable terms, if at all. A weak or declining economy could strain our suppliers, possibly resulting in supply disruption, or cause delays in payments for our services by third-party payers. Measures taken to limit healthcare spending may lead to lower than anticipated rates of growth in some markets and an adverse impact on revenues and profitability. Any escalation in barriers to the global free flow of medicines is likely to increase costs to serve affected markets which may lead to downward pressure on margins. While the introduction of severe sanctions is unlikely in relation to medicines, it could occur if matters escalate significantly and could impact processes for the commercialisation of medicines and levels of sales in affected markets. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.
Failure in financial control or the occurrence of fraud	
Effective internal controls assist in the provision of reliable Financial Statements and the detection and prevention of fraud. Testing of internal controls provides only limited assurance over the accuracy of Financial Statements and may not prevent or detect misstatements or fraud.	Significant resources may be required to remediate any deficiency in internal controls. Any such deficiency may trigger related investigations and may result in fines being levied against individual directors or officers. Serious fraud may lead to prosecution of senior management. Any of the foregoing could adversely affect our financial results and lead to reputational damage.

D. Risk Factors *continued*

Unexpected deterioration in the Group's financial position

Movements in exchange rates against the US dollar, our reporting currency, impact our reported results. The key currencies of Product Sales and costs are: US dollar, Chinese renminbi, euro, Japanese yen, Swedish krona and pound sterling.

Most of our cash is invested in AAA credit-rated institutional money market funds, fixed income securities issued by government, financial and non-financial entities and collateralised and non-collateralised bank deposits. Our credit exposure is a mix of US, EU and rest of world default risk across these institutions.

We invest in many projects in an effort to develop a successful portfolio of approved products. Our Consolidated Statement of Financial Position therefore contains significant investments in intangible assets, including goodwill. Our ability to realise value on these investments depends on regulatory approvals, market acceptance, competition, and legal developments.

Our defined benefit post-retirement obligations (primarily in the UK and Sweden) can materially change in value but are largely backed by assets invested in growth and liability hedging portfolios, which hedge some of the risks inherent in liability valuations.

Although we maintain relevant insurance coverage for risks arising within the Group, we may not be able to maintain our insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

Tax law is complex, leading to the risk of different interpretations. Revenue authorities can make conflicting claims to the profits taxed in individual countries leading to double taxation and the potential for fines and penalties. Tax laws can change following action by international bodies such as the Organisation for Economic Co-operation and Development (OECD) or individual governments.

Foreign exchange rate movements may materially adversely affect our financial condition or results of operations.

In a sustained economic downturn, such institutions may cease to trade and there can be no guarantee that we will be able to access the full value of our investments.

We expect that some of our intangible assets will become impaired in the future. Impairment losses may materially adversely affect our financial condition or results of operations.

Solvency levels could fall, leading to higher contributions if there are: falls in assets; increases in liability valuations (from falls in bond yields, increases in inflation or lower mortality); or changes in regulations. As liability valuation risks are hedged to a material level, significant collateral may need to be posted, which in extreme circumstances could lead to a short-term liquidity risk in some pension schemes and a request to the Group to provide temporary liquidity.

Uninsured losses, or those where an insurer denies coverage, could materially adversely affect our financial condition.

The resolution of tax disputes can result in incremental tax costs, a reallocation of profits or losses between jurisdictions, or even double taxation, fines and penalties. They are costly, divert management attention and may adversely affect our reputation.

If tax treaties are withdrawn or amended, or Competent Authorities are unable to reach an agreement that eliminates double taxation, this could materially adversely affect our financial position. For details of our financial risk management policies, see "Strategic Report—Financial Review—Financial risk management" on page 71 and for details of current tax disputes, see "Financial Statements—Notes to the Group Financial Statements—Note 30—Commitments, contingent liabilities and contingent assets" on pages 204 to 210 of AstraZeneca's "Annual Report and Form 20-F Information 2023" included as exhibit 15.1 to this Form 20-F dated February 20, 2024.

Changes in tax regimes could result in a material impact on the Group's cash tax liabilities and tax charge, resulting in either an increase or a reduction in financial results.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

AstraZeneca PLC was incorporated in England and Wales on June 17, 1992 under the Companies Act 1985. It is a public limited company domiciled in the UK. The Company's registered number is 2723534 and its registered office is at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, UK (Tel: +44 (0)20 3749 5000). From February 1993 until April 1999, the Company was called Zeneca Group PLC. On April 6, 1999, the Company changed its name to AstraZeneca PLC.

The Company was formed when the pharmaceutical, agrochemical and specialty chemical businesses of Imperial Chemical Industries PLC were demerged in 1993. In 1999, the Company sold the specialty chemical business. Also in 1999, the Company merged with Astra of Sweden. In 2000, it demerged the agrochemical business and merged it with the similar business of Novartis to form a new company called Syngenta AG. In 2007, the Group acquired MedImmune, a biologics and vaccines business based in the US. In 2021, the Group acquired Alexion, a rare disease business based in the US.

In 1999, in connection with the merger between Astra and Zeneca, the Company's share capital was redenominated in US dollars. On 6 April 1999, Zeneca shares were cancelled and US dollar shares issued, credited as fully paid on the basis of one dollar share for each Zeneca share then held.

This was achieved by a reduction of capital under section 135 of the Companies Act 1985. Upon the reduction of capital becoming effective, all issued and unissued Zeneca shares were cancelled and the sum arising as a result of the share cancellation credited to a special reserve, which was converted into US dollars at the rate of exchange prevailing on the record date. This US dollar reserve was then applied in paying up, at par, newly created US dollar shares.

At the same time as the US dollar shares were issued, the Company issued 50,000 Redeemable Preference Shares for cash, at par. The Redeemable Preference Shares carry limited class voting rights, no dividend rights and are capable of redemption, at par, at the option of the Company on the giving of seven days' written notice to the registered holder of the Redeemable Preference Shares.

A total of 826 million Ordinary Shares were issued to Astra shareholders who accepted the merger offer before the final closing date, 21 May 1999. The Company received acceptances from Astra shareholders representing 99.6% of Astra's shares and the remaining 0.4% was acquired in 2000, for cash.

In 2021, in connection with the acquisition of Alexion, a total of 236 million Ordinary Shares (the majority of which were represented by new AstraZeneca ADRs) were issued to Alexion shareholders in part consideration for the acquisition.

The information (including tabular data) set forth under the headings "Strategic Report—Financial Review—Collaboration Revenue" on pages 65 to 66, "Strategic Report—Financial Review—Restructuring" on page 67, "Strategic Report—Financial Review—Acquisitions treated as Business combinations" and "—Acquisitions treated as asset acquisitions" on page 69, "Strategic Report—Financial Review—Investments, divestments and capital expenditure" on page 70, "Corporate Governance—Corporate Governance Report—Compliance with the UK Corporate Governance Code—Board Leadership and Company Purpose" on page 81 and "Additional Information—Important information for readers of this Annual Report—AstraZeneca websites" on page 236, in each case of AstraZeneca's "Annual Report and Form 20-F Information 2023" included as exhibit 15.1 to this Form 20-F dated February 20, 2024 is incorporated by reference. Additionally, the information set forth under the heading "Strategic Report—Financial Review" on pages 60 to 76 of AstraZeneca's "Annual Report and Form 20-F Information 2022" included as exhibit 15.1 to the Form 20-F dated February 21, 2023 is incorporated herein by reference.

The United States Securities and Exchange Commission (the "SEC") maintains a website at www.sec.gov which contains in electronic form each of the reports and other information that we have filed electronically with the SEC.

B. Business Overview

The information (including graphs and tabular data) set forth under the headings "Strategic Report—AstraZeneca at a Glance" on page 5, "Strategic Report—Chair's Statement" on page 2, "Strategic Report—Chief Executive Officer's Review" on pages 3 to 4, "Strategic Report—Science can..." on page 6, "Strategic Report—Healthcare in a Changing World" on pages 7 to 9, "Strategic Report—Our Purpose, Values and Business Model" on pages 10 to 11, "Strategic Report—Our strategy and Key Performance Indicators" on pages 12 to 15, "Strategic Report—Therapy Area Review" on pages 16 to 31, "Strategic Report—Business Review" on pages 32 to 49, "Strategic Report—Task Force on Climate-related Financial Disclosures Summary Statement" on pages 51 to 53, "Strategic Report—Risk Overview—Managing risk", "—Risk Overview—Emerging risks", "—Risk Overview—Climate risk", "—Risk Overview—Cybersecurity Risk" on page 54, "Corporate Governance—Corporate Governance Report—Compliance with the UK Corporate Governance Code—Global Compliance and Group Internal Audit (GIA)" on page 83, "Corporate Governance—Corporate Governance Report—Principal Decisions—Acquisitions and collaborations to strengthen pipeline" on page 87, "Financial Statements—Notes to the Group Financial Statements—Note 1—Revenue" on pages 160 to 161, "Financial Statements—Notes to the Group Financial Statements—Note 6—Segment information" on page 167 to 169, "Additional Information—Sustainability: supplementary information" on page 230, and "Additional Information—Important information for readers of this Annual Report—Statements of competitive position, growth rates and sales" on page 236, in each case of AstraZeneca's "Annual Report and Form 20-F Information 2023" included as exhibit 15.1 to this Form 20-F dated February 20, 2024 is incorporated by reference.

Development Pipeline as of February 8, 2024

This section sets out AstraZeneca-sponsored or -directed trial New Molecular Entities (NMEs) and significant indications.

First major market regulatory submission date and submission status is provided for assets in Phase III or beyond. As disclosure of compound information is balanced by the business need to maintain confidentiality, information in relation to some compounds listed here has not been disclosed at this time.

Key:
PP = Partnered product

Phase I

Compound	Mechanism	Additional Information	Area Under Investigation
Oncology			
AZD0305	GPRC5D ADC		relapsed/refractory multiple myeloma
AZD0486	CD19-CD3 TCE		R/R B-cell non-Hodgkin lymphoma
AZD0486	CD19-CD3 TCE		B-cell acute lymphoblastic leukaemia
AZD1390	ATM inhibitor		glioblastoma
AZD3470	PRMT5 inhibitor		classic Hodgkin lymphoma, solid tumours
AZD5335	anti-folate receptor alpha topoisomerase 1 inhibitor ADC		ovarian cancer, lung adenocarcinoma
AZD5851	GPC3 CAR-T		hepatocellular carcinoma
AZD5863	CLDN18.2 x CD3 bi-specific antibody (HBM7022)		solid tumours
AZD6422	CLDN18.2 CAR-T		solid tumours
AZD8421	CDK2 inhibitor		solid tumours
AZD9592	EGFR/cMET		solid tumours
AZD9829	CD123 TOP1i ADC		acute myeloid leukemia, myelodysplastic syndromes
NT-125	autologous, fully-individualised, multi-specific TCR-T targeting neoantigens		solid tumours
NT-175	TGFBR2 KO armoured TCR-T targeting TP53 R175H/HLA-A*02:01		solid tumours
volrustomig + lenvatinib	PD-1/CTLA-4 bispecific mAb + VEGF		advanced renal cell carcinoma
CVRM			
AZD2373	podocyte health		nephropathy
AZD2389	anti-fibrotic mechanism		metabolic dysfunction-associated steatohepatitis
AZD4144	inflammation modulator		cardiorenal disease
AZD5462	RXFP1 agonist	(PP)	heart failure
AZD6234	peptide		obesity with related comorbidities
AZD7503	ASO		non-alcoholic steatohepatitis
AZD9550	GLP-1R glucagon dual agonist		non-alcoholic steatohepatitis
Respiratory & Immunology			
AZD1163	bispecific antibody		rheumatoid arthritis
AZD5055	porcupine inhibitor		idiopathic pulmonary fibrosis
AZD6793	IRAK4 inhibitor		inflammatory diseases
AZD6912	siRNA		rheumatoid arthritis
AZD7798	humanised monoclonal antibody targets T cells subset		Crohn's disease
AZD8630	inhaled TSLP FAb	(PP)	asthma
Other Medicines			
AZD4041	orexin 1 receptor antagonist	(PP)	opioid use disorder
MEDI0618	PAR2 antagonist mAb	Phase I/IIa	migraine
MEDI1814	amyloid beta mAb	(PP)	Alzheimer's disease
Rare Disease			
ALXN1910	next generation TNSALP ERT		bone metabolism
ALXN1920	kidney-targeted factor H fusion protein		nephrology
ALXN2030	siRNA targeting complement C3		nephrology
ALXN2080	oral factor D inhibitor		healthy volunteers
Vaccine and Immune therapies			
COVID mRNA VLP vaccine	Vaccine		COVID-19

4G

PTC Therapeutics US, Inc.
500 Warren Corporate Center Drive
Suite A
Warren, NJ 07059

September 20, 2024

Mark Sedar
COO
Nevada State Board of Pharmacy
NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

Dear Mr. Sedar:

PTC Therapeutics US, Inc. ("PTC US") hereby requests the issuance of a temporary permit pursuant to NAC 639.200.

- PTC Therapeutics, Inc. ("PTC Inc.") has been licensed in Nevada since January 23, 2019 (WH02530) when it began the sale of Emflaza. PTC Inc. recently formed a wholly-owned subsidiary, PTC US, which will take over sales and marketing activities and related personnel for PTC Therapeutics across the United States. This transition will occur on or about Oct 15, 2024.

- PTC Inc. is the corporate parent and the 100% owner of PTC US. PTC US is located at 500 Warren Corporate Center Drive, Suite A, Warren, NJ 07059.

- PTC Inc. is transferring its sales and marketing activities, assets and personnel to PTC US, to optimize its overall corporate structure for purposes of efficient operation of its business. However, the business, capabilities and make-up of the PTC companies overall will not change as a result of this transfer.

- PTC US will be using a title model to distribute PTC Inc.'s proprietary product Emflaza, selling all product to its third party logistics provider (3PL), Integrated Commercialization Solutions ("ICS"), which is located in Reno, Nevada. ICS, in term, will sell Emflaza nationwide under its wholesale distributor license (WH02036). PTC Therapeutics is the sole supplier of Emflaza in the United States.

- PTC US has submitted an application for a Nevada Wholesale Distributor permit which was received by the Board on September 11, 2024. We are seeking this interim permit, until the Nevada State Board of Pharmacy can review and act upon our regular license application at its next scheduled meeting. As the sole distribution point is in Nevada, the failure to have a permit at the time of the switch will impact patients nationwide. The interim license will ensure that the supply of Emflaza to our patient population for Duchenne's Muscular Dystrophy (boys and men 2 years of age and older) will not be interrupted or delayed. This is critical for the welfare of these patients throughout the country.

Very truly yours,

DocuSigned by:
Donald Mankoff
C860B97A88B54E3...

Name: Donald Mankoff
Title: VP, Associate General Counsel

DocuSign

Certificate Of Completion

Envelope Id: 6A923E17C8D74EABB1844E68F724890E
Subject: Complete with Docusign: PTC US -- Ltr to Nevada State Bd -- Mr Sedar.docx
Source Envelope:
Document Pages: 1
Certificate Pages: 4
AutoNav: Disabled
EnvelopeId Stamping: Disabled
Time Zone: (UTC-05:00) Eastern Time (US & Canada)

Signatures: 1
Initials: 0

Status: Completed

Envelope Originator:
Donald Mankoff
500 Corporate Center Drive
Warren, NJ 07059
dmankoff@ptcbio.com
IP Address: [redacted]

Record Tracking

Status: Original
9/20/2024 5:01:50 PM

Holder: Donald Mankoff
dmankoff@ptcbio.com

Location: DocuSign

Signer Events	Signature	Timestamp
Donald Mankoff dmankoff@ptcbio.com VP, Associate General Counsel PTC Therapeutics, Inc. Security Level: Email, Account Authentication (None)	DocuSigned by: Donald Mankoff D880B97A88B54E3...	Sent: 9/20/2024 5:02:11 PM Viewed: 9/20/2024 5:02:19 PM Signed: 9/20/2024 5:02:53 PM Freeform Signing
	Signature Adoption: Pre-selected Style Using IP Address: [redacted]	

Electronic Record and Signature Disclosure:
Accepted: 3/10/2017 10:16:24 AM
ID: 96c7459b-430c-4cfb-91aa-59990ed9956b

In Person Signer Events	Signature	Timestamp
Editor Delivery Events	**Status**	**Timestamp**
Agent Delivery Events	**Status**	**Timestamp**
Intermediary Delivery Events	**Status**	**Timestamp**
Certified Delivery Events	**Status**	**Timestamp**
Carbon Copy Events	**Status**	**Timestamp**
Witness Events	**Signature**	**Timestamp**
Notary Events	**Signature**	**Timestamp**

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	9/20/2024 5:02:11 PM
Certified Delivered	Security Checked	9/20/2024 5:02:19 PM
Signing Complete	Security Checked	9/20/2024 5:02:53 PM
Completed	Security Checked	9/20/2024 5:02:53 PM

Payment Events	Status	Timestamps

Electronic Record and Signature Disclosure

ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

From time to time, PTC Therapeutics, Inc. (we, us or Company) may be required by law to provide to you certain written notices or disclosures. Described below are the terms and conditions for providing to you such notices and disclosures electronically through your DocuSign, Inc. (DocuSign) Express user account. Please read the information below carefully and thoroughly, and if you can access this information electronically to your satisfaction and agree to these terms and conditions, please confirm your agreement by clicking the 'I agree' button at the bottom of this document.

Getting paper copies

At any time, you may request from us a paper copy of any record provided or made available electronically to you by us. For such copies, as long as you are an authorized user of the DocuSign system you will have the ability to download and print any documents we send to you through your DocuSign user account for a limited period of time (usually 30 days) after such documents are first sent to you. After such time, if you wish for us to send you paper copies of any such documents from our office to you, you will be charged a $0.00 per-page fee. You may request delivery of such paper copies from us by following the procedure described below.

Withdrawing your consent

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

Consequences of changing your mind

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. To indicate to us that you are changing your mind, you must withdraw your consent using the DocuSign 'Withdraw Consent' form on the signing page of your DocuSign account. This will indicate to us that you have withdrawn your consent to receive required notices and disclosures electronically from us and you will no longer be able to use your DocuSign Express user account to receive required notices and consents electronically from us or to sign electronically documents from us.

All notices and disclosures will be sent to you electronically

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through your DocuSign user account all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

How to contact PTC Therapeutics, Inc.:
You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:

To advise PTC Therapeutics, Inc. of your new e-mail address
To let us know of a change in your e-mail address where we should send notices and disclosures electronically to you, you must send an email message to us at IT@PTCbio.com and in the body of such request you must state: your previous e-mail address, your new e-mail address. We do not require any other information from you to change your email address..
In addition, you must notify DocuSign, Inc to arrange for your new email address to be reflected in your DocuSign account by following the process for changing e-mail in DocuSign.
To request paper copies from PTC Therapeutics, Inc.
To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an e-mail to IT@PTCbio.com and in the body of such request you must state your e-mail address, full name, US Postal address, and telephone number. We will bill you for any fees at that time, if any.
To withdraw your consent with PTC Therapeutics, Inc.
To inform us that you no longer want to receive future notices and disclosures in electronic format you may:

i. decline to sign a document from within your DocuSign account, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;
ii. send us an e-mail to IT@PTCbio.com and in the body of such request you must state your e-mail, full name, IS Postal Address, telephone number, and account number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

Required hardware and software

Operating Systems:	Windows2000? or WindowsXP?
Browsers (for SENDERS):	Internet Explorer 6.0? or above
Browsers (for SIGNERS):	Internet Explorer 6.0?, Mozilla FireFox 1.0, NetScape 7.2 (or above)
Email:	Access to a valid email account
Screen Resolution:	800 x 600 minimum
Enabled Security Settings:	•Allow per session cookies •Users accessing the internet behind a Proxy Server must enable HTTP 1.1 settings via proxy connection

** These minimum requirements are subject to change. If these requirements change, we will provide you with an email message at the email address we have on file for you at that time providing you with the revised hardware and software requirements, at which time you will have the right to withdraw your consent.

Acknowledging your access and consent to receive materials electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please verify that you were able to read this electronic disclosure and that you also were able to print on paper or electronically save this page for your future reference and access or that you were able to e-mail this disclosure and consent to an address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format on the terms and conditions described above, please let us know by clicking the 'I agree' button below.
By checking the 'I Agree' box, I confirm that:

- I can access and read this Electronic CONSENT TO ELECTRONIC RECEIPT OF ELECTRONIC RECORD AND SIGNATURE DISCLOSURES document; and

- I can print on paper the disclosure or save or send the disclosure to a place where I can print it, for future reference and access; and

- Until or unless I notify PTC Therapeutics, Inc. as described above, I consent to receive from exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to me by PTC Therapeutics, Inc. during the course of my relationship with you.

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH N/A	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: PTC Therapeutics US, Inc.

Physical Address: 500 Warren Corporate Center Drive, Suite A

City: Warren State: NJ Zip: 07059

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

City: State: Zip:

Telephone: 908-222-7000 Website: www.ptcbio.com

Name of Designated Representative (DR): Jeffrey R. LoPrete

Licensing Company Email: info@ptcbio.com DR Email: jloprete@ptcbio.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☑ Pharmacies	☑ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☑ Others: Distributors		☑ Others: Virtual Wholesaler

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

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

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware Parent Company (if any): _____

CorporationName: PTC Therapeutics, Inc.

Mailing Address: 500 Warren Corporate Center Drive

City: Warren State: NJ Zip: 07059

Telephone: 908-222-7000 Email: djones@ptcbio.com

Contact Person Name: Diane Jones

Date of SEC Registration: 6/20/2013	SEC Registration Number: 0001070081	Stock Exchange Symbol: PTCT

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. N/A - Parent company is publicly traded.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		X
N/A 1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment A	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment A		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment B	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - publicly traded parent		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment C	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment D	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
N/A - parent company is publicly traded • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

N/A - parent company is publicly traded.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

PTC Therapeutics US, Inc.

Facility Name

Jeffrey R. LoPrete

Print Name of Authorized Person Submitting Application

Jeffrey R. LoPrete

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

10 Sept 2024

Date

Board Use Only	Date Received: 9/11/24	Amount: $1000-CC

Attachment A

Corporate Officer Information

PTC Therapeutics US, Inc.

PTC Therapeutics US Inc. is wholly-owned by its publicly-traded parent company, PTC Therapeutics, Inc.

Abraham S. Adler
Corporate Secretary

Frank J. Ricca, Jr.
Corporate Treasurer

Jennifer Roan
President

Directors:

Abraham Adler
Frank Ricca

Attachment B

Delaware Certificate of Good Standing

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "PTC THERAPEUTICS US, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTIETH DAY OF FEBRUARY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "PTC THERAPEUTICS US, INC." WAS INCORPORATED ON THE TWELFTH DAY OF DECEMBER, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL FRANCHISE TAXES HAVE BEEN ASSESSED TO DATE.

Jeffrey W. Bullock, Secretary of State

2752930 8300

SR# 20240587399

Authentication: 202845211

Date: 02-20-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 10/3/2024

Registration Number: 5005212 **Registered as:** Manufacturer and Wholesale
Name: PTC THERAPEUTICS, INC.
DBA:
Address: 500 WARREN CORPORATE CENTER DR, WARREN, NJ 07059
Original Issue Date: 05/11/2017 **Expiration Date:** 01/31/2025
Current Issue Date: 01/09/2024
Disciplines: No

Attachment E

Nature of Business

PTC Therapeutics US, Inc. (PTC US) is a virtual wholesale distributor of prescription drugs. PTC US is wholly owned by PTC Therapeutics, Inc. (PTC Inc.) and will purchase goods from PTC Inc. The information for the facilities utilized by PTC US to manufacture and distribute products is the following:

Third Party Logistics Provider:

Integrated Commercialization Solutions, LLC (ICS)
1195 Trademark Drive
Suite 102B
Reno, NV 89521

Contract Manufacturer:

Alcami Carolinas Corporation
2320 Scientific Park Dr.
Wilmington, NC 28405
Lindsey Jones
910-254-7302
FDA Registration #: 1049418

Full Name	Business Title
Kyle Raventos	Regional Account Manager
Jennifer Roan	VP, GM - US
Mark Lingle	Executive - Regional Business Director
Lynne Michele Messner	Market Development Manager
Teresa Doroba	Assoc Dir, Field and Marketing Operations
Brian Koziara	Executive, Regional Business Dir
Margaret A McCloskey	Regional Account Manager
Michael McIver	Regional Account Manager
Bryan Passink	Regional Account Manager
Andrew Sternfield	Regional Account Manager
James Taylor	Regional Account Manager
Brian Varca	Regional Account Manager
Christie Castaneda	Regional Account Manager
Riaz R Rahimtoola	Senior - National Accounts Director
Tena Aardal	Regional Account Manager
Todd Joseph Jankowski	Regional Account Manager
Rupert Evans Jr.	Regional Account Manager
Robin Desmarais	Regional Account Manager
John Pat Clougherty	Regional Account Manager
Alexis Jeanae Krolick	Sr Dir, Medical Affairs - North America
Anne Bruns	Patient Engagement Liaison
David J. Bastyr	Regional Account Manager
Ann Gillotti	Regional Account Manager
Mark Sveda	Director, Distribution & Trade
Jennifer Coyle	Market Development Manager
Greg Iovine	Sr Dir, Patient Services
Frank Quintieri	VP, Patient Engagement
Shawen Bradshaw	Regional Account Manager
John Howard Gans	Regional Account Manager
Malisa Rust	Patient Engagement Liaison
Rachel Coleman	Sr Case Manager, Patient Services
Rick Rodriguez	Sr Case Manager, Patient Services
Peter Apito	Case Manager, Patient Services
Norma I Rios	Case Manager, Patient Services
Courtney Cruz	Case Manager, Patient Services
Celeste Calafiore	Mgr, Patient Services
Aurora Flores	Patient Engagement Liaison
Leah Svoboda	Dir, US Marketing
Shaleema Graham	Case Manager, Patient Services
Bertrand Smith	Sr Case Manager, Patient Services
Christina Rosol	Mgr, Patient Services
Mathangi Esakkimuthu	Sr Mgr, Commercial Effectiveness
Teja Jayanthi	Senior Director, U.S Marketing
Eddie Ward	Regional Account Manager
Ann Janeski	Regional Business Director - Gene Therapy
Nick Chaplin	Regional Account Manager
Lissette Rodriguez	Case Manager
Amanda Higgins	Sr Case Manager, Patient Services
Ryan Miller	Dir, Field Medical Development & Strategy
Aurealicia Mercedes	Case Manager
Rosanna Casillo	Case Manager
Austin Joseph Gautier	Director, National Accounts
Cristian David Ramirez-Loaiza	Sr. Associate - Product Manager
Karina Lambertini	Patient Engagement Liaison

Sarah Sanchez	Case Manager, Patient Services
Kenneth Phung	Case Manager
Jacqueline Guarraci	Case Manager
Moheez Dean	Case Manager
Jonathan Blaize	Sr Medical Science Liaison
Elaine Dong	Medical Science Liaison
Sravya Narne	Specialist II, Clinical Operations
Emily Hintze	Patient Engagement Liaison
Lauren Warn	Associate Director, Treatment Lead - US Gene Therapy
Jeffrey LoPrete	Designated Representative

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☑ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended: December 31, 2023

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 001-35969

PTC THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**04-3416587**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
100 Corporate Court **South Plainfield, NJ**	**07080**
(Address of principal executive offices)	(Zip Code)

(908) 222-7000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol (s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	PTCT	Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☑

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

The aggregate market value of the Common Stock held by non-affiliates of the registrant, based upon the last sale price of the Common Stock reported on the Nasdaq Global Select Market on June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, was $2,330,616,515. For purposes of this calculation, shares of Common Stock held by directors and officers have been treated as shares held by affiliates.

As of February 27, 2024, the registrant had 76,608,030 shares of Common Stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report incorporates by reference information from the definitive Proxy Statement for the registrant's 2024 Annual Meeting of Shareholders which is expected to be filed with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2023.

TABLE OF CONTENTS
PTC Therapeutics, Inc.

	Page No.
PART I	
Item 1. Business	6
Item 1A. Risk Factors	61
Item 1B. Unresolved Staff Comments	111
Item 1C. Cybersecurity	111
Item 2. Properties	112
Item 3. Legal Proceedings	113
Item 4. Mine Safety Disclosures	113
PART II	
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuers Purchases of Equity Securities	114
Item 6. [Reserved]	114
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	114
Item 7A. Quantitative and Qualitative Disclosures about Market Risk	136
Item 8. Financial Statements and Supplementary Data	138
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	197
Item 9A. Controls and Procedures	197
Item 9B. Other Information	200
Item 9C. Disclosures Regarding Foreign Jurisdictions that Prevent Inspections	200
PART III	
Item 10. Directors, Executive Officers and Corporate Governance	202
Item 11. Executive Compensation	202
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	202
Item 13. Certain Relationships and Related Transactions, and Director Independence	202
Item 14. Principal Accountant Fees and Services	202
PART IV	
Item 15. Exhibits and Financial Statement Schedules	203
Item 16. Form 10-K Summary	209
SIGNATURES	210

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Annual Report on Form 10-K include, among other things, statements about:

- our ability to negotiate, secure and maintain adequate pricing, coverage and reimbursement terms and processes on a timely basis, or at all, with third-party payors for our products or product candidates that we commercialize or may commercialize in the future;
- our expectations with respect to the European Commission's potential adoption of the Committee for Medicinal Products for Human Use's negative opinion for the renewal of the conditional marketing authorization for Translarna™ (ataluren) for the treatment of nonsense mutation Duchenne muscular dystrophy, or nmDMD, in the European Economic Area, or EEA, following a re-examination procedure and our ability to maintain such conditional marketing authorization or identify other potential mechanisms in which we may provide Translarna to nmDMD patients in the EEA;
- our ability to maintain our marketing authorizations in other jurisdictions in which Translarna has been approved;
- our ability to utilize results from Study 041 and from our international drug registry study to support a marketing approval for Translarna for the treatment of nmDMD in the United States;
- expectations with respect to our ability to commercialize Upstaza™ (eladocagene exuparvovec) for the treatment of Aromatic L-Amino Acid Decarboxylase, or AADC deficiency, in the EEA, any potential regulatory submissions and potential approvals for our product candidates, our manufacturing capabilities and the potential financial impact and benefits of our leased biologics manufacturing facility and the potential achievement of development, regulatory and sales milestones and contingent payments that we may be obligated to make;
- our expectations with respect to the commercial status of Evrysdi® (risdiplam) and our program directed against spinal muscular atrophy in collaboration with F. Hoffmann La Roche Ltd and Hoffmann La Roche Inc. and the Spinal Muscular Atrophy Foundation and our estimates regarding future revenues from sales-based royalty payments or the achievement of milestones in that program;
- our expectations and the potential financial impact and benefits related to our Collaboration and License Agreement with a subsidiary of Ionis Pharmaceuticals, Inc. including with respect to the timing of regulatory approval of Tegsedi® (inotersen) and Waylivra™ (volanesorsen) in countries in which we are licensed to commercialize them, the commercialization of Tegsedi and Waylivra, and our expectations with respect to royalty payments by us based on our potential achievement of certain net sales thresholds;
- the timing and scope of our commercialization of our products and product candidates;
- our estimates regarding the potential market opportunity for our products or product candidates, including the size of eligible patient populations and our ability to identify such patients;
- our ability to obtain additional and maintain existing reimbursed named patient and cohort early access programs for our products on adequate terms, or at all;

- our estimates regarding expenses, future revenues, third-party discounts and rebates, capital requirements and needs for additional financing, including our ability to maintain the level of our expenses consistent with our internal budgets and forecasts and to secure additional funds on favorable terms or at all;
- the timing and conduct of our ongoing, planned and potential future clinical trials and studies for sepiapterin and our splicing and ferroptosis and inflammation programs as well as studies in our products for maintaining authorizations, label extensions and additional indications, including the timing of initiation, enrollment and completion of the trials and the period during which the results of the trials will become available;
- our ability to realize the anticipated benefits of our acquisitions or other strategic transactions, including the possibility that the expected impact of benefits from the acquisitions or strategic transactions will not be realized or will not be realized within the expected time period, significant transaction costs, the integration of operations and employees into our business, our ability to obtain marketing approval of our product candidates we acquired from the acquisitions or other strategic transactions and unknown liabilities;
- the rate and degree of market acceptance and clinical utility of any of our products or product candidates;
- the ability and willingness of patients and healthcare professionals to access our products and product candidates through alternative means if pricing and reimbursement negotiations in the applicable territory do not have a positive outcome;
- the timing of, and our ability to obtain additional marketing authorizations for our products and product candidates;
- the ability of our products and our product candidates to meet existing or future regulatory standards;
- the potential receipt of revenues from future sales of our products or product candidates;
- the expected impact of our loss of market exclusivity for Emflaza® (deflazacort) for the treatment of Duchenne muscular dystrophy in the United States under the Orphan Drug Act of 1983;
- our sales, marketing and distribution capabilities and strategy, including the ability of our third-party manufacturers to manufacture and deliver our products and product candidates in clinically and commercially sufficient quantities and the ability of distributors to process orders in a timely manner and satisfy their other obligations to us;
- our ability to establish and maintain arrangements for the manufacture of our products and product candidates that are sufficient to meet clinical trial and commercial launch requirements;
- the extent, timing and financial aspects of our strategic pipeline prioritization and reductions in workforce;
- our ability to complete any post-marketing requirements imposed by regulatory agencies with respect to our products;
- our expectations with respect to the potential financial impact and benefits of our leased biologics manufacturing facility and our ability to satisfy our obligations under the terms of the lease agreement for such facility;
- our ability to satisfy our obligations under the indenture governing our 1.50% convertible senior notes due September 15, 2026;
- our regulatory submissions, including with respect to timing and outcome of regulatory review;
- our plans to advance our earlier stage programs and pursue research and development of other product candidates, including our splicing and ferroptosis and inflammation programs;

- whether we may pursue business development opportunities, including potential collaborations, alliances, and acquisition or licensing of assets and our ability to successfully develop or commercialize any assets to which we may gain rights pursuant to such business development opportunities;
- the potential advantages of our products and any product candidate;
- our intellectual property position;
- the impact of government laws and regulations;
- the impact of litigation that has been or may be brought against us or of litigation that we are pursuing against others; and
- our competitive position.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly under the heading "Summary of Risk Factors" and the risk factors detailed further in Part I, Item 1A. Risk Factors that we believe could cause actual results or events to differ materially from the forward-looking statements that we make.

Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Annual Report on Form 10-K and the documents that we have filed as exhibits to this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by applicable law.

In this Annual Report on Form 10-K, unless otherwise stated or the context otherwise requires, references to "PTC," "PTC Therapeutics," "we," "us," "our," "the Company," and similar references refer to PTC Therapeutics, Inc. and, where appropriate, its subsidiaries. The trademarks, trade names and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners.

All website addresses given in this Annual Report on Form 10-K are for information only and are not intended to be an active link or to incorporate any website information into this document.

SUMMARY OF RISK FACTORS

Below is a summary of the principal risk factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks and uncertainties that we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found in Item 1A. Risk Factors, of this Annual Report on Form 10-K, and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the Securities Exchange Commission, before making an investment decision regarding our common stock. The forward-looking statements discussed above are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Summary of Risk Factors

- We may be unable to continue to commercialize Translarna for nmDMD in the EEA if the EC adopts the negative opinion issued by the CHMP for the renewal of the existing conditional authorization for Translarna.
- We may be unable to continue to execute our commercial strategy for our products, fail to obtain renewal of, or satisfy the conditions of our marketing authorization for our products;
- Delays or failures in obtaining regulatory approval would materially impair our commercialization capabilities;
- We may not qualify for certain specialized pathways to develop our product candidates or to seek approval;
- We or our collaborators may experience any of a number of possible unforeseen events in connection with clinical trials related to our products and product candidates;
- Subgroup, retrospective, post-hoc, and certain statistical analyses may not be reliable and typically will not form the basis for regulatory approval;
- We may experience delays or difficulties in the enrollment of patients in our clinical trials;
- We may identify serious adverse side effects during the development or further development of any product or product candidate;
- Our products and product candidates may be difficult to manufacture;
- Our products and product candidates may fail to achieve market acceptance in the medical community;
- We may be unable to establish or maintain sales, marketing and distribution capabilities or enter into agreements with third parties to market, sell and distribute our products or product candidates;
- A substantial portion of our commercial sales currently occurs in territories outside of the United States which subjects us to additional business risks and laws and regulations, including those governing export restrictions and economic sanctions;
- We face substantial competition;
- Our products or product candidates may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives;
- We have incurred significant losses since our inception and expect to continue to incur significant operating expenses for the foreseeable future. We may need additional funding and we may never generate profits from operations or maintain profitability;
- We may engage in strategic transactions to acquire assets, businesses, or rights to products, product candidates or technologies or from collaborations or make investments in other companies or technologies that could harm our business and dilute our stockholders' ownership;
- Raising additional capital may dilute our stockholders' ownership, restrict our operation or require us to relinquish rights to our technologies or product candidates;
- We may not be able to comply with applicable laws and regulations for our products or product candidates;
- We may not be able to obtain orphan drug exclusivity for our products or product candidates in either the United States or the EU;
- All pharmaceutical products for which marketing authorization has been granted are subject to extensive and rigorous regulation;
- Failure to obtain and maintain acceptable pricing and reimbursement terms for our products would delay our commercialization efforts;

- Legislative and regulatory changes affecting the pharmaceutical industry or the healthcare system more broadly may negatively affect our business;
- We may fail to properly allocate our resources;
- We contract with third parties for the manufacture and distribution of our products and certain of our product candidates and these third parties may encounter issues that affect our business;
- We rely on third parties to conduct our preclinical and clinical trials and other essential services;
- We currently depend, and expect to continue to depend, on collaborations with third parties for the development and commercialization of some of our products and product candidates;
- Our business and operations would suffer in the event of computer system failures, cyber-attacks or a deficiency in our, or our collaborators' or third-party vendors', cyber-security;
- We may be subject to product liability and other civil lawsuits;
- We may be unable to retain our key executives;
- We may be unable to obtain or maintain patent protection for our technology and products;
- We may become involved in lawsuits to protect or enforce our intellectual property or in connection with allegations that we are infringing on third party intellectual property rights;
- Without patent protection, our marketed products may face generic competition;
- We may not obtain or maintain adequate trademark protection for our brand names;
- Our rights to develop and commercialize Upstaza are subject, in part, to the terms and conditions of licenses granted to us by others;
- We may not have sufficient cash flow from our business to make payments on our debt; and
- The price of our common stock may be volatile and fluctuate substantially.

PART I

Item 1. Business

Overview

We are a global biopharmaceutical company focused on the discovery, development and commercialization of clinically differentiated medicines that provide benefits to patients with rare disorders. Our ability to innovate to identify new therapies and to globally commercialize products is the foundation that drives investment in a robust and diversified pipeline of transformative medicines. Our mission is to provide access to best-in-class treatments for patients who have little to no treatment options. Our strategy is to leverage our strong scientific and clinical expertise and global commercial infrastructure to bring therapies to patients. We believe that this allows us to maximize value for all of our stakeholders.

Our Pipeline

We have a diversified therapeutic portfolio that includes several commercial products and product candidates in various stages of development, including discovery, research and clinical stages, focused on the development of new treatments for multiple therapeutic areas for rare diseases relating to neurology and metabolism. The chart and the disclosure directly below summarizes the status of our significant clinical-stage programs and commercial products as of the date of this report, including those with our strategic partners:



- *Global Commercial Footprint*
  - *Global DMD Franchise* – We have two products, Translarna™ (ataluren) and Emflaza® (deflazacort), for the treatment of Duchenne muscular dystrophy, or DMD, a rare, life threatening disorder. Translarna currently has conditional marketing authorization in the European Economic Area, or EEA, for the treatment of nonsense mutation Duchenne muscular dystrophy, or nmDMD, in ambulatory patients aged two years and older. On January 25, 2024, the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, issued a negative opinion for the conditional marketing authorization following a re-examination procedure. In accordance with EMA regulations, the European Commission, or EC, has 67 days to adopt the opinion from the date of its issuance. If the EC adopts the negative opinion, Translarna would no longer have marketing authorization in the EEA. Translarna also has marketing authorization in Russia for the treatment of nmDMD in patients aged two years and older, and in Brazil for the treatment of nmDMD in ambulatory patients two years and older and for continued treatment of patients that become non-ambulatory, as well as in various other countries as described below. Emflaza is approved in the United States for the treatment of DMD in patients two years and older.

- ***Upstaza™ (eladocagene exuparvovec)*** – Upstaza, a gene therapy for the treatment of Aromatic L-Amino Decarboxylase, or AADC, deficiency, a rare central nervous system, or CNS, disorder is approved for the treatment of AADC deficiency for patients 18 months and older within the EEA and the United Kingdom. We expect to submit a biologics license application, or BLA, for Upstaza for the treatment of AADC deficiency in the United States to the United States Food and Drug Administration, or FDA, in March 2024.
- ***Tegsedi® (inotersen) and Waylivra® (volanesorsen)*** – We hold the rights for the commercialization of Tegsedi and Waylivra for the treatment of rare diseases in countries in Latin America and the Caribbean pursuant to our Collaboration and License Agreement with a subsidiary of Ionis Pharmaceuticals, Inc., or Ionis. Tegsedi has received marketing authorization in the United States, European Union, or EU, and Brazil for the treatment of stage 1 or stage 2 polyneuropathy in adult patients with hereditary transthyretin amyloidosis, or hATTR amyloidosis. Waylivra is approved in Brazil for the treatment of familial chylomicronemia syndrome, or FCS, and familial partial lipodystrophy, or FPL.
- ***Evrysdi® (risdiplam)*** – Evrysdi, a treatment for spinal muscular atrophy, or SMA, was approved by the FDA for the treatment of SMA in adults and children of all ages and by the EC for the treatment of 5q SMA in patients of all ages with a clinical diagnosis of SMA Type 1, Type 2 or Type 3 or with one to four SMN2 copies. Evrysdi has also received marketing authorization for the treatment of SMA in over 100 countries. Evrysdi is a product of our SMA program and our collaboration with F. Hoffman-La Roche Ltd. and Hoffman-La Roche Inc., which we refer to collectively as Roche, and the Spinal Muscular Atrophy Foundation, or SMA Foundation.

- ***Diversified Development Pipeline***
  - ***Sepiapterin*** – We expect to submit a marketing authorization application, or MAA, to the EMA for sepiapterin for the treatment of phenylketonuria, or PKU, in the EEA in March 2024. We also expect to submit a New Drug Application, or NDA, to the FDA for sepiapterin for the treatment of PKU no later than the third quarter of 2024.
  - ***Splicing Platform*** – In addition to our SMA program, our splicing platform also includes PTC518, which is being developed for the treatment of Huntington's disease, or HD. We initiated a Phase 2 study of PTC518 for the treatment of HD in the first quarter of 2022, which consists of an initial 12-week placebo-controlled phase focused on safety, pharmacology and pharmacodynamic effects followed by a nine-month placebo-controlled phase focused on PTC518 biomarker effect. In June 2023, we announced interim data from the 12-week placebo-controlled phase. We expect to provide 12-month interim data from the Phase 2 study of PTC518 for the treatment of HD in the second quarter of 2024.
  - ***Ferroptosis and Inflammation Platform*** – The two most advanced molecules in our ferroptosis and inflammation platform are vatiquinone and utreloxastat. We announced topline results from a registration-directed Phase 3 trial of vatiquinone in children and young adults with Friedreich ataxia, called MOVE-FA, in May 2023. While the trial did not meet its primary endpoint, vatiquinone treatment did demonstrate significant benefit on key disease subscales, including the upright stability subscale, as well as on other disease relevant endpoints. In the first quarter of 2024, we met with the FDA, who expressed willingness to review an NDA for vatiquinone for the treatment of Friedreich ataxia based on the MOVE-FA trial as well as data from the ongoing open label extension study following the MOVE-FA trial, potentially allowing for the submission of an NDA in late 2024. In the first quarter of 2024, we also received scientific advice from the EMA on the MOVE-FA trial results, in which the EMA stated that the MOVE-FA data would likely not be sufficient for conditional authorization. We initiated a Phase 2 registration directed trial of utreloxastat for amyotrophic lateral sclerosis, or ALS, in the first quarter of 2022. We expect topline results from this trial in the fourth quarter of 2024.

- ***Pre-clinical Pipeline***
  - We continue to invest in our pre-clinical product pipeline by committing significant resources to research and development programs to provide access to best-in-class treatments for patients who have an unmet medical need. Our pre-clinical efforts are focused on two scientific platforms: splicing and ferroptosis, two areas of science where PTC has significant expertise.

Global Commercial Footprint

Global DMD Franchise

Duchenne muscular dystrophy (DMD)

Muscular dystrophies are genetic disorders involving progressive muscle wasting and weakness. DMD is the most common and one of the most severe types of muscular dystrophy. DMD occurs when a mutation in the dystrophin gene prevents the cell from making a functional dystrophin protein. Dystrophin is a muscle membrane associated protein and is critical to the structural and membrane stability of muscle fibers in skeletal, diaphragm and heart muscle. The absence of normally functioning dystrophin results in muscle fragility, such that muscle injury occurs when muscles contract or stretch during normal use. As muscle damage progresses, connective tissue and fat replace muscle fibers, resulting in inexorable muscle weakness.

Because the dystrophin gene is located on the X chromosome, DMD occurs primarily in young boys, although approximately 10% of female carriers show some disease symptoms. DMD is rare, and estimates of occurrence include approximately 1 in every 3,500 live male births, according to the National Organization for Rare Diseases and approximately 1 in every 5,000 live male births according to Ryder (2017) in the European Journal of Human Genetics. We estimate that there are between approximately 10,000 to 15,000 DMD patients in the United States. Several different types of mutation in the dystrophin gene can result in DMD, including deletion, duplication and nonsense mutations. A test known as multiplex ligation-dependent probe amplification (MLPA) can detect large deletions and duplications, which account for approximately 75% of all mutations. However, gene sequencing is required to identify small mutations such as nonsense mutations. We estimate that nonsense mutations account for approximately 13% of cases of DMD. Without treatment, patients with DMD typically lose walking ability by their early teens, require ventilation support in their late teens, and eventually experience premature death due to heart and lung failure. Even with medical care, most people with DMD die from cardiac or respiratory failure before or during their 30s.

Marketing authorization matters

Translarna for the treatment of nonsense mutation Duchenne muscular dystrophy

European Economic Area

We received marketing authorization from the EC in August 2014 for Translarna for the treatment of nmDMD in ambulatory patients aged five years and older in the member states of the EEA, subject to annual renewal and other conditions. In July 2018, the EC approved a label-extension request to our marketing authorization for Translarna in the EEA to include patients from two to up to five years of age. In July 2020, the EC approved the removal of the statement "efficacy has not been demonstrated in non-ambulatory patients" from the indication statement for Translarna.

The marketing authorization is subject to annual review and renewal by the EC following reassessment by the EMA of the benefit-risk balance of continued authorization, which we refer to as the annual EMA reassessment. In September 2022, we submitted a Type II variation to the EMA to support conversion of the conditional marketing authorization for Translarna to a standard marketing authorization, which included a report on the placebo-controlled trial of Study 041 and data from the open-label extension as further described below. In February 2023, we also submitted an annual marketing authorization renewal request to the EMA. In September 2023, the CHMP gave a negative opinion on the conversion of the conditional marketing authorization to full marketing authorization of Translarna for the treatment of nmDMD and a negative opinion on the renewal of the existing conditional marketing authorization of Translarna for the treatment of nmDMD. On January 25, 2024, the CHMP issued a negative opinion for the renewal of the conditional marketing authorization following a re-examination procedure. In accordance with EMA regulations, the EC has 67 days to adopt the opinion. If the EC adopts the negative opinion, Translarna would no longer have marketing authorization in the member states of the EEA. We are exploring other potential mechanisms in which we may provide Translarna to nmDMD patients in the EEA if the negative opinion is adopted by the EC.

Marketing authorization is required in order for us to engage in any commercialization of Translarna in the EEA, which allows us to participate in pricing and reimbursement negotiations, on a country-by-country basis with each country in the EEA. Individual countries in the EEA have the ability to make Translarna available under early access programs, or EAP programs, or through similar styled programs. There is substantial risk that if the EC adopts the CHMP's negative opinion or we are otherwise unable to renew our EEA marketing authorization during any annual renewal cycle or we are unable to identify other potential mechanisms in which we may provide Translarna to nmDMD patients in the EEA should the CHMP's negative opinion be adopted by the EC or our product label is materially restricted, we would lose all, or a significant portion of, our ability to generate revenue from sales of Translarna in the EEA and other territories. For more information regarding the risks associated with the a potential EC adoption of the CHMP's negative opinion on Translarna's marketing authorization, see Item 1A. Risk Factors, "*We may be unable to continue to commercialize Translarna for nonsense mutation Duchenne muscular dystrophy in the European Economic Area if the European Commission adopts the negative opinion issued by the Committee for Medicinal Products for Human Use of the European Medicines Agency for the renewal of the existing conditional authorization for Translarna.*"

See "Item 1. Business-Commercial Matters-Market Access Considerations" and "Item 1A. Risk Factors-Risks Related to the Development and Commercialization of our Product and our Product Candidates" and "-Risks Related to Regulatory Approval of our Product and our Product Candidates" for further information regarding the marketing authorization in the EEA, the market access process and related risks.

As the marketing authorization holder, we are obligated to monitor the use of Translarna for nmDMD to detect, assess and take required action with respect to information that could impact the safety profile of Translarna and to report this information, through pharmacovigilance submissions, to the EMA. Following its assessment of these submissions, the EMA can recommend to the EC actions ranging from the continued maintenance of the marketing authorization to its withdrawal.

United States

Translarna is an investigational new drug in the United States. During the first quarter of 2017, we filed an NDA for Translarna for the treatment of nmDMD over protest with the FDA. In October 2017, the Office of Drug Evaluation I of the FDA issued a Complete Response Letter, or CRL, for the NDA, stating that it was unable to approve the application in its current form. In response, we filed a formal dispute resolution request with the Office of New Drugs of the FDA. In February 2018, the Office of New Drugs of the FDA denied our appeal of the CRL. In its response, the Office of New Drugs recommended a possible path forward for our ataluren NDA submission based on the accelerated approval pathway. This would involve a re-submission of an NDA containing the current data on effectiveness and safety of ataluren with new data to be generated on dystrophin production in nmDMD patients' muscles. We followed the FDA's recommendation and collected, using newer technologies via procedures and methods that we designed, such dystrophin data in a new study, Study 045, and announced the results of Study 045 in February 2021. Study 045 did not meet its pre-specified primary endpoint. In June 2022, we announced top-line results from the placebo-controlled trial of Study 041, which was our 18-month, placebo-controlled trial, followed by an 18-month open-label extension, of Translarna in the treatment of ambulatory patients with nmDMD aged five years or older. Following this announcement, we submitted a meeting request to the FDA to gain clarity on the regulatory pathway for a potential re-submission of an NDA for Translarna. The FDA provided initial written feedback that Study 041 does not provide substantial evidence of effectiveness to support NDA re-submission. We held a Type C meeting with the FDA in the fourth quarter of 2023 to discuss the totality of Translarna data. Based on this discussion, the FDA suggested we request a pre-submission Type C meeting to discuss the specific contents of an NDA resubmission based on results from Study 041 and from our international drug registry study for nmDMD patients receiving Translarna. This meeting is scheduled for March 2024.

See "Item 1. Business-Government Regulation-The new drug and biologic approval process" below for further discussion with respect to the NDA process. See "Item 1. Business-Translarna (ataluren)" and "Item 1A. Risk Factors-Risks Related to the Development and Commercialization of our Product and our Product Candidates" and "-Risks Related to Regulatory Approval of our Product and our Product Candidates" for further detail regarding the results of our completed trials and studies of Translarna for the treatment of nmDMD, our regulatory strategy in the United States, our history with submissions to the FDA and the related risks to our business.

Other Territories

Translarna received marketing authorization for the treatment of nmDMD in Israel and South Korea in 2015, Chile in 2018, Brazil in 2019 and Russia in 2020, in addition to approvals from other countries, and these licenses are currently active. Many territories outside of the EEA, including Israel, South Korea and Chile, reference and depend on the determinations by the EMA when considering the grant of a marketing authorization. It is possible that we would not be able to maintain our marketing authorizations in these regions in the event the EMA decides not to renew or otherwise modifies or withdraws our marketing authorization in the EEA. In addition, Translarna is authorized in the United Kingdom and will undergo a national assessment. The marketing authorization for Translarna in Brazil and Russia are subject to renewal every five years. We have been pursuing and expect to continue to pursue marketing authorizations for Translarna for the treatment of nmDMD in other regions.

Emflaza for the treatment of Duchenne muscular dystrophy in the United States

Emflaza, both in tablet and suspension form, received approval from the FDA in February 2017 as a treatment for DMD in patients five years of age and older in the United States. In June 2019, the FDA approved our label expansion request for Emflaza for patients two to five years of age. We estimate that there are between approximately 10,000 and 15,000 DMD patients in the United States.

Emflaza received a seven-year marketing exclusivity period in the United States for its approved indications, commencing on the date of FDA approval, under the provisions of the Orphan Drug Act of 1983, or the Orphan Drug Act. We have previously relied on this exclusivity period to commercialize Emflaza in the United States. Emflaza's seven-year period of orphan drug exclusivity related to the treatment of DMD in patients five years and older expired in February 2024. We expect the expiration of this orphan drug exclusivity to have a significant negative impact on Emflaza net product revenue. Emflaza's orphan drug exclusivity related to the treatment of DMD in patients two years of age to less than five expires in June 2026. See "Item 1. Business-Government Regulation" for further discussion with respect to marketing protection we rely on.

Upstaza

Upstaza is a gene therapy for the treatment of AADC deficiency, a rare CNS disorder arising from reductions in the enzyme AADC that results from mutations in the dopa decarboxylase gene. In July 2022, the EC approved Upstaza for the treatment of AADC deficiency for patients 18 months and older within the EEA. In November 2022, the Medicines and Healthcare products Regulatory Agency approved Upstaza for the treatment of AADC deficiency for patients 18 months and older within the United Kingdom. We are also preparing a BLA for Upstaza for the treatment of AADC deficiency in the United States. In October 2022, we held a Type C meeting with the FDA to discuss the details of a potential submission package for Upstaza. At that meeting, the FDA asked for additional bioanalytical data in support of comparability between the drug product used in the clinical studies and the commercial drug product. We completed these analyses and provided the results to the FDA for review. The FDA stated that the data that we provided were still not sufficient. However, the FDA also said that the available data from the ongoing clinical study in the United States assessing the safety of the drug delivery cannula for Upstaza could be used to support a BLA for accelerated approval based on biomarker data demonstrating a treatment-related increase in de novo dopamine production. At the FDA's suggestion, we held a pre-BLA meeting in December 2023. We expect to submit a BLA to the FDA for Upstaza for the treatment of AADC deficiency in March 2024.

AADC is the enzyme responsible for the conversion of L-dopa to dopamine. Dopamine is a key neurotransmitter that acts within the striatum (caudate and putamen), a component of the brain's deep grey matter, to modulate output of neurons that project to the motor and premotor cortices of the brain that plan and execute normal motor function. Dopamine is required in the brain for humans to develop and maintain proper motor function.

AADC deficiency is a monogenic disorder of neurotransmitter synthesis that manifests in young children and most commonly results in profound developmental delay, often seen as complete arrest of motor development. AADC deficiency generally causes the inability to develop motor control, resulting in breathing, feeding, and swallowing problems, frequent hospitalizations, and the need for life-long care. On average, patients with AADC deficiency die in the

first decade of life due to profound motor dysfunction and secondary complications such as choking, hypoxia, and pneumonia. Currently, no treatment options are available for the underlying cause of the disorder, and care is limited to palliative options with significant burden on caregivers.

The prevalence of AADC deficiency has been estimated to be approximately 5,000 patients worldwide, with a live-birth incidence of up to 1 in 40,000 worldwide. While several diagnostic tests for AADC deficiency are available, we believe the condition remains largely undiagnosed or misdiagnosed and may be confused with cerebral palsy.

Upstaza is an adeno-associated virus, or AAV, gene therapy, which has been assessed in three completed clinical trials, AADC-1601, AADC-010 and AADC-011. The three completed trials included a total of 30 children with AADC deficiency who were treated with Upstaza during a single procedure in which the gene therapy was administered directly to the region of the brain, called the putamen, where dopamine is made and released. The targeted micro-dosing approach administering small amounts of gene therapy directly to focal regions of affected cells in the putamen has the benefit of keeping the supply requirements for materials low, improving access of the therapeutic gene to key cells, potentially limiting immune and complement-mediated responses and reducing the risk of off-target uptake and excretion of the gene therapy by the liver and kidneys. Results from these trials suggest that patients may have a gain of motor functions and improvement in cognitive scales following gene therapy administration and have shown significant increases in motor function, which contrasts with the published natural history.

AADC-1601, AADC-010 and AADC-011, were each single-arm, open-label, interventional trials. The primary and secondary objectives of these trials were to assess the safety and efficacy of Upstaza administered via bilateral putaminal-infusions in patients with severe AADC deficiency. Study enrollment required a diagnosis of AADC deficiency, defined as decreased homovanilic acid, or HVA, and 5-hydroxyindoleacetic acid, or 5-HIAA, and elevated levels of L-DOPA in the cerebrospinal fluid, or CSF, the presence of more than one DDC gene mutation, and the presence of clinical symptoms of AADC deficiency (including developmental delay, hypotonia, dystonia, and oculogyric crisis), and a patient age of older than 2 years.

Patients were evaluated monthly for safety assessments and every three months for efficacy assessments that included tests of motor developmental testing (Peabody Developmental Motor Scale, Second Edition, or PDMS-2, and Alberta Infant Motor Scale, or AIMS) through the first year after treatment with Upstaza and at periodic intervals thereafter through five years following treatment. The PDMS-2 and AIMS are validated scales used to assess motor skills in young children. Pharmacodynamic testing of CNS AADC activity over time included analyses of CSF neurotransmitter metabolites and F-DOPA PET imaging intervals, also through five years.

At baseline, patients had no functional movement and failed to achieve any motor milestones, including head control, sitting or standing capabilities, consistent with the published natural history of severe AADC deficiency. Compared to baseline, at one-year and at five-years after Upstaza administration, patients had objective evidence of de novo dopamine production as visualized by F-DOPA PET imaging of the brain, consistent with successful and stable gene expression and enzyme activity over time. Additionally, HVA levels, which is the major metabolite of dopamine metabolism, were measured at month 12 to determine if new dopamine was synthesized. HVA levels increased significantly from baseline at month 12, consistent with de novo dopamine synthesis.

Following administration of Upstaza, the combined group of patients showed significant improvements from baseline capabilities at one-year post-treatment in functional motor skills assessed with the PDMS-2 total score, as well as on the locomotion, grasping, visual-motor integration and stationary subscales. Significant improvements from baseline at one-year post-treatment were also observed for the combined group of patients on the AIMS total score and on the prone, supine, sit and stand subscales.

Compared to published natural history data, patients in these trials showed statistically significant improvements at both two- and five-year post-treatment in achievement of motor milestones of full head control (at 2 and 5 years), sitting unassisted (at 2 and 5 years), standing with support (at 5 years) and walking with assistance (at 5 years), reinforcing the clinical benefit and sustainability of functional motor improvements.

Surgical injection of Upstaza in the completed trials was well tolerated. Adverse events were generally associated with the disease state. The most frequent adverse event associated with Upstaza was dyskinesia and these events completely resolved over time. No serious adverse events have been attributed to Upstaza.

Patients from our completed trials have been offered to continue to follow up in Study 1602, which is intended to assess long-term safety and efficacy of Upstaza. Additionally, Study AADC-002, a multicenter, open-label trial to assess and efficacy of Upstaza, is ongoing. We have enrolled 13 patients in this study.

Upstaza for the treatment of AADC deficiency has orphan drug designation in the United States and EU, and rare pediatric disease designation in the United States, and upon BLA approval the FDA may grant us a priority review voucher, depending on the timing of the approval.

Due to its orphan medicinal product designation by the EMA, we rely on a ten-year exclusive marketing period for Upstaza in the EEA, which may potentially be extended for two additional years if we receive approval for a pediatric exclusivity incentive. If Upstaza for the treatment of AADC deficiency receives FDA approval, we expect that Upstaza would have a twelve-year exclusive marketing period in the United States for the approved indication, commencing on the date of FDA approval, under the provisions of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as well as a concurrent seven-year exclusive marketing period, which would commence on the date of FDA approval, under the provisions of the Orphan Drug Act. We expect to rely on the twelve-year BPCIA regulatory exclusivity and concurrent seven-year Orphan Drug Act exclusivity to commercialize Upstaza in the United States, if it is approved.

See "Item 1. Business-Government Regulation-The new drug and biologic approval process" below for further discussion with respect to the BLA process.

Tegsedi and Waylivra

In August 2018 we entered into a Collaboration and License Agreement with Akcea Therapeutics, Inc., or Akcea, a subsidiary of Ionis for the commercialization by us of Tegsedi, Waylivra and products containing those compounds in countries in Latin America and the Caribbean, or the PTC Territory. See "Item 1. Business-Our Collaborations, License Agreements and Funding Arrangements-Tegsedi and Waylivra" below for further discussion with respect to this collaboration and license agreement.

Tegsedi

Tegsedi, a product of Ionis' proprietary antisense technology, is an antisense oligonucleotide, or ASO, inhibitor of human transthyretin, or TTR, production. Tegsedi is the world's first RNA-targeted therapeutic to treat patients with hereditary transthyretin amyloidosis, or hATTR amyloidosis. In October 2019, it received marketing authorization from ANVISA, the Brazilian health regulatory authority, for the treatment of stage 1 or stage 2 polyneuropathy in adult patients with hATTR amyloidosis in Brazil. Our marketing authorization for Tegsedi in Brazil is subject to renewal every five years. It has also received marketing authorization in the United States and EU for the same indication.

hATTR amyloidosis is a progressive, systemic and fatal inherited disease caused by the abnormal formation of the TTR protein and aggregation of TTR amyloid deposits in various tissues and organs throughout the body, including in peripheral nerves, heart, intestinal tract, eyes, kidneys, central nervous system, thyroid and bone marrow. The progressive accumulation of TTR amyloid deposits in these tissues and organs leads to sensory, motor and autonomic dysfunction often having debilitating effects on multiple aspects of a patient's life. Patients with hATTR amyloidosis often present with a mixed phenotype and experience overlapping symptoms of polyneuropathy and cardiomyopathy.

Ultimately, hATTR amyloidosis generally results in death within three to fifteen years of symptom onset. Therapeutic options for the treatment of patients with hATTR amyloidosis are limited and there are currently no disease-modifying drugs approved for the disease. There are an estimated 50,000 patients with hATTR amyloidosis worldwide, including approximately 6,000 patients with polyneuropathic hATTR amyloidosis in Latin America.

Waylivra

Waylivra is an ASO that has received marketing authorization in the EU for the treatment of FCS, subject to certain conditions. The United States and EU regulatory agencies have granted orphan drug designation to Waylivra for the treatment of FCS. In connection with the marketing approval for Waylivra in the EU, the EC is requiring Akcea to provide results of a study based on a registry of patients to investigate how blood checks and adjustments to frequency of injections are carried out in practice and how well they work to prevent thrombocytopenia and bleeding in FCS patients taking Waylivra. In August 2021, ANVISA approved Waylivra as the first treatment for FCS in Brazil. Our marketing authorization for Waylivra in Brazil is subject to renewal every five years.

FCS is an ultra-rare disease caused by impaired function of the enzyme lipoprotein lipase, or LPL, and characterized by severe hypertriglyceridemia (>880mg/dL) and a risk of unpredictable and potentially fatal acute pancreatitis. Because of limited LPL function, people with FCS cannot break down chylomicrons, lipoprotein particles that are 90% triglycerides. In addition to pancreatitis, FCS patients are at risk of chronic complications due to permanent organ damage. They can experience daily symptoms including abdominal pain, generalized fatigue and impaired cognitions that affect their ability to work. People with FCS also report major emotional and psychosocial effects including anxiety, social withdrawal, depression and brain fog. There is no effective therapy for FCS currently available.

Additionally, we received approval of Waylivra for the treatment of FPL in Brazil in December 2022. FPL is a rare genetic metabolic disease characterized by selective, progressive loss of body fat (adipose tissue) from various areas of the body leading to ectopic fat deposition in liver and muscle and development of insulin resistance, diabetes, dyslipidemia and fatty liver disease. Individuals with FPL often have reduced subcutaneous fat in the arms and legs and the head and trunk regions may or may not have loss of fat. Conversely, affected individuals may also have excess subcutaneous fat accumulation in other areas of the body, especially the neck, face and intra-abdominal regions.

Evrysdi

Evrysdi was approved by the FDA in August 2020 for the treatment of SMA in adults and children two months and older and by the EC in March 2021 for the treatment of 5q SMA in patients two months and older with a clinical diagnosis of SMA Type 1, Type 2 or Type 3 or with one to four SMN2 copies. Evrysdi has also received marketing authorization for the treatment of SMA in over 100 countries. In May 2022, the FDA approved a label expansion for Evrysdi to include infants under two months old with SMA. In August 2023, the EC approved an extension of the Evrysdi marketing authorization to include infants under two months old in the EU. Evrysdi is a product of our SMA program and our collaboration with Roche and the SMA Foundation. For additional information, see "Item 1. Business – Our Collaborations, License Agreements and Funding Arrangements – Roche and the SMA Foundation."

SMA is a genetic neuromuscular disease characterized by muscle wasting and weakness. The disease generally manifests early in life. SMA is caused by mutation or deletion of the Survival of Motor Neuron 1, or SMN1, gene that encodes the survival of motor neuron, or SMN, protein. The SMN protein is critical to the health and survival of the nerve cells in the spinal cord responsible for muscle contraction. A second gene, Survival of Motor Neuron 2, or SMN2, is very similar to SMN1, contains a T nucleotide at position 6 in exon 7 and produces low, insufficient levels of functional SMN protein due to alternative splicing of exon 7. According to the SMA Foundation, SMA is the leading genetic cause of death in infants and toddlers. Approximately 1 in 10,000 children is born with the disease. We estimate that there are between 20,000 to 30,000 children and adults living with SMA in the United States, Europe and Japan.

Diversified Development Pipeline

Our pipeline includes a number of programs at various stages of development including sepiapterin, PTC518 and other programs from our splicing and ferroptosis and inflammation platforms. Additionally, we have ongoing clinical studies of our current commercial product for maintaining authorizations and enabling additional authorizations.

Sepiapterin

Sepiapterin is a precursor to intracellular tetrahydrobiopterin, which is a critical enzymatic cofactor involved in metabolism and synthesis of numerous metabolic products. Sepiapterin has been pursued as a possible treatment for orphan metabolic diseases associated with defects in the tetrahydrobiopterin biochemical pathways, including PKU. PKU is an inborn error of metabolism caused predominantly by mutations in the phenylalanine hydroxylase gene resulting in toxic buildup of the amino acid phenylalanine, or Phe, in the brain, and, if left untreated, severe and irreversible disabilities such as permanent intellectual disability, seizures, delayed development, behavioral problems and possibly psychiatric disorders can occur. We believe that there are approximately 58,000 PKU patients globally. In May 2023, we announced that the primary endpoint was achieved in our registration-directed Phase 3 trial for sepiapterin for PKU. The primary endpoint of the study was the achievement of statistically-significant reduction in blood Phe level. The primary analysis population included those patients who have a greater than 30% reduction in blood Phe levels during the Part 1 run-in phase of the trial. Sepiapterin demonstrated Phe level reduction of approximately 63% in the overall primary analysis population and Phe level reduction of approximately 69% in the subset for classical PKU patients. Additionally, sepiapterin was well tolerated with no serious adverse events. Following the placebo-controlled study, patients were eligible to enroll in a long-term open-label study, which is still ongoing and will evaluate long-term safety, durability and Phe tolerance. We expect to submit an MAA to the EMA for sepiapterin for the treatment of PKU in the EEA in March 2024. Additionally, we participated in a pre-NDA meeting with the FDA in the third quarter of 2023. At that meeting, the FDA stated that the sepiapterin clinical safety and efficacy data supported NDA submission for the treatment of pediatric and adult PKU patients. However, the FDA has requested that we complete a 26-week nonclinical mouse study to assess sepiapterin carcinogenicity potential prior to NDA submission. This nonclinical study was not initially required when we acquired sepiapterin, as the NDA submission was planned under the Section 505(b)(2) pathway. Given that sepiapterin is a novel therapy with distinct pharmacology, biodistribution, mechanism of action and differentiated efficacy, we subsequently decided to make the NDA submission under the Section 505(b)(1) pathway, which requires the 26-week study, which is considered a required NDA component needed to inform labeling and is typically completed prior to submission. Based on the timing to complete this study, we expect to submit an NDA to the FDA for sepiapterin for the treatment of PKU no later than the third quarter of 2024 and we intend to discuss with the FDA the potential for an earlier submission if we are permitted to submit the 26-week mouse study report during the NDA review process.

Splicing Platform

Our splicing platform focuses on the development of innovative therapies for diseases, such as SMA, that involve regulation of mRNA splicing in the cell.

In addition to Evrysdi and our SMA program, our splicing platform also includes PTC518, which is being developed for the treatment of HD. HD is a neurodegenerative and progressive brain disorder caused by a toxic gain-of-function triplet repeat expansion in the Huntingtin gene resulting in uncontrolled movements and cognitive loss. There are currently no disease-modifying therapies approved to delay the onset or slow the progression of HD. We believe that there are approximately 135,000 HD patients globally. PTC518 is an orally bioavailable molecule with broad central nervous system and systemic distribution that has been designed to target Huntingtin protein expression with high selectivity and specificity. We announced the results from our Phase 1 study of PTC518 in healthy volunteers in September 2021 demonstrating dose-dependent lowering of huntingtin messenger ribonucleic acid and protein levels, that PTC518 efficiently crosses blood brain barrier at significant levels and that PTC518 was well tolerated. We initiated a Phase 2 study of PTC518 for the treatment of HD in the first quarter of 2022, which consists of an initial 12-week placebo-controlled phase focused on safety, pharmacology and pharmacodynamic effects followed by a nine-month placebo-controlled phase focused on PTC518 biomarker effect. In June 2023, we announced interim data from the 12-week placebo-controlled phase. The study demonstrated dose-dependent lowering of Huntingtin, or HTT, protein levels in peripheral blood cells, reaching an approximate mean 30% reduction in mutant HTT levels at the 10mg dose level. In

addition, PTC518 exposure in the cerebrospinal fluid was consistent with or higher than plasma unbound drug levels. Furthermore, PTC518 was well tolerated with no treatment-related serious adverse events. The Phase 2 study is actively ongoing outside the United States, while it has been paused within the United States as the FDA requested additional data to allow the Phase 2 study to proceed. We expect to provide 12-month interim data from the Phase 2 study of PTC518 for the treatment of HD in the second quarter of 2024. We expect to submit a safety data update to the FDA in the second quarter of 2024 to support lifting of the partial clinical hold on the program.

Ferroptosis and Inflammation Platform

Our ferroptosis and inflammation platform consists of small molecule compounds that target oxidoreductase enzymes that regulate oxidative stress and inflammatory pathways central to the pathology of a number of CNS diseases. Oxidation-reduction, or redox, reactions are an essential component of the generation and regulation of energy in living systems. These reactions are regulated through a set of enzymes known as oxidoreductase enzymes that uniquely require the transfer of an electron, or a redox chemical reaction, to affect their biological activity.

One of the advanced molecules in our ferroptosis and inflammation platform is vatiquinone. Vatiquinone is a small molecule orally bioavailable compound that has been in development for inherited mitochondrial diseases and related genetic disorders of oxidative stress. Vatiquinone targets 15-lipoxygenase, or 15-LO, a key regulator of oxidative stress, lipid-based neuro-inflammation, alpha-synuclein oxidation and aggregation and cell death. We are developing vatiquinone for the treatment of Friedreich ataxia. Friedreich ataxia is a rare and life-shortening neurodegenerative disease caused by a single defect in the FXN gene which causes reduced production of the frataxin protein. We believe that there are approximately 25,000 Friedreich ataxia patients globally. Vatiquinone has previously been studied in Friedreich ataxia patients in a Phase 2 trial that included a six-month placebo-controlled phase followed by an 18-month open label extension. In this trial, long-term vatiquinone treatment (18-24 months) was associated with an improvement in overall disease severity and neurological function relative to natural history. Vatiquinone has been generally well-tolerated in the clinic.

We announced topline results from our MOVE-FA trial, a registration-directed Phase 3 trial of vatiquinone in children and young adults with Friedreich ataxia, in May 2023. While the trial did not meet its primary endpoint of statistically significant change in modified Friedreich Ataxia Rating Scale, or mFARS, score at 72 weeks in the primary analysis population, vatiquinone treatment did demonstrate significant benefit on key disease subscales and secondary endpoints. In addition, in the population of subjects that completed the study protocol, significance was reached in the mFARS endpoint and several secondary endpoints, including the upright stability subscale. Furthermore, vatiquinone was well tolerated. In the first quarter of 2024, we met with the FDA, who expressed willingness to review an NDA for vatiquinone for the treatment of Friedreich ataxia based on the MOVE-FA trial as well as data from the ongoing open label extension study following the MOVE-FA trial, potentially allowing for the submission of an NDA in late 2024. In the first quarter of 2024, we also received scientific advice from the EMA on the MOVE-FA trial results, in which the EMA stated that the MOVE-FA data would likely not be sufficient for conditional authorization.

The other advanced molecule in our ferroptosis and inflammation platform is utreloxastat, a small molecule orally bioavailable compound that targets 15-LO and is in development for the potential treatment of adult CNS patients, including ALS. ALS is a rapidly progressing neurodegenerative disease caused by oxidative damage which leads to neuronal cell death and muscular atrophy. We believe that there are approximately 150,000 ALS patients globally. In the third quarter of 2021, we completed a Phase 1 trial in healthy volunteers to evaluate the safety and pharmacology of utreloxastat. Utreloxastat was found to be well-tolerated with no reported serious adverse events while demonstrating predictable pharmacology. We initiated a Phase 2 registration directed trial of utreloxastat for ALS in the first quarter of 2022. We expect topline results from this trial in the fourth quarter of 2024.

Translarna (ataluren)

Mechanism of action

We discovered Translarna by applying our technologies to identify molecules that promote or enhance the suppression of nonsense mutations. Nonsense mutations are implicated in a variety of genetic disorders. Nonsense mutations create a

4H

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: McKesson Medical-Surgical Inc.

Physical Address: 1005 Satellite Blvd

City: Suwanee State: GA Zip: 30024

Mailing Address (if different from physical address): Attn: Facility Manager/Licensing 1005 Satellite Blvd

City: Suwanee State: GA Zip: 30024

Telephone: 678.957.8170 Website: www.mckesson.com

Name of Designated Representative (DR): Joseph Ferry

Licensing Company Email: McKessonLicensing@McKesson.com DR Email: Joe.Ferry@McKesson.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Seattlecred

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

7/18/24
Date

Please note that the disciplinary actions described below do NOT pertain to operations at the location set forth in this application.

McKesson Corporation and its wholly owned subsidiaries (hereinafter "McKesson") delivers pharmaceutical and medical products and business services to retail pharmacies and institutional providers like hospitals and health systems throughout North America and globally. Over the past 185 years, McKesson has developed multiple businesses that operate pharmacies, medical supply distribution centers, wholesale drug distribution centers, 3PL facilities, repackaging facilities, and other entities subject to federal and state regulation. Currently, McKesson owns and operates over 100 facilities in the United States that are licensed, permitted, or registered with the respective state agency with jurisdiction over its business type. Due to the breadth of its operations, it is practical that we limit this summary to disciplinary actions taken against these facilities during the last five years or the time frame specified in the question. ***The information in this statement is provided to the best of our knowledge and belief and includes all public disciplinary actions. This statement does not include any fines that are deemed non-disciplinary by the issuing state (for example, it does not include non-disciplinary Citations and Fines issued by California). Please let us know if your state requires information regarding non-disciplinary fines.***

On January 7, 2020, **McKesson Corporation** entered into a Consent Agreement and Final Order with the Iowa Board of Pharmacy regarding pseudoephedrine products that had not been included in the McKesson's Clear Lake, IA facility's annual controlled substance inventory and butalbital products that continued to be treated as legend drugs after such products became schedule III products in the state on June 26, 2019 (the "2020 Clear Lake Consent").

On January 14, 2020, **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Arizona State Board of Pharmacy, regarding its Tempe, AZ distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $1,000 was imposed and paid on January 14, 2020.

On February 20, 2020, in response to the DEA Settlement, **McKesson Corporation** entered into a final agreement with the Indiana Board of Pharmacy. The agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Indiana has been placed on indefinite probation until the facility's DEA Registration is fully re-instated on or about February 16, 2021. The suspension period imposed by Indiana aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On May 29, 2020, the Colorado Department of Regulatory Agencies cited **McKesson Medical-Surgical Inc.** concerning its Roseville, CA distribution center for failure to submit in a timely manner, an application to the Board detailing a change of designated representative. A fine of $1,150 was imposed and paid on July 1, 2020.

On April 20, 2021, **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Ohio Board of Pharmacy, regarding its Leetsdale, PA distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $1,125 was imposed and paid on April 20, 2021.

On May 05, 2021, **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Maine Board of Pharmacy, regarding its Roseville, CA distribution center, in relation to the late reporting of a disciplinary action that was imposed by the Colorado Board of Pharmacy, for failure to report a change of designated representative within the required timeframe. A $500 civil penalty/fine was paid on 5/7/2021.

On May 27, 2021, **McKesson Corporation** entered into a consent agreement with the Maine Board of Pharmacy regarding its Aurora, IL distribution center failing to report the Colorado disciplinary action to the Maine Board of Pharmacy within 10 days as required. The Colorado disciplinary action is now reported to the Maine Board of Pharmacy. The terms of the consent agreement included a fine in the amount of $500.00.

On June 6, 2021, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Leetsdale, PA distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $500 was imposed and paid on June 8, 2021.

On June 15, 2021, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Urbancrest, OH distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $3000.00 was imposed and paid on June 15, 2021.

On June 23, 2021, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Urbancrest, OH distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $125 was imposed and paid on June 23, 2021.

On October 1, 2021, **McKesson Corporation** ("McKesson") entered into a non-disciplinary agreement with the Connecticut Department of Consumer Protection, regarding its Memphis, TN distribution center. The agreement resolves allegations that, from January 2015 – January 2021, McKesson sold controlled substances to a practitioner that did not have an active Connecticut Controlled Substances Certificate of Registration. McKesson made no admission of liability and there were no findings of any violation of law. A monetary penalty of $4,500 was imposed.

On October 14, 2021, in response to the DEA Settlement, **McKesson Corporation** entered into a Settlement Agreement with the Ohio Board of Pharmacy (the "WCH Ohio Settlement"). The WCH Ohio Settlement applies to the McKesson distribution center located in Washington Court House, Ohio. The Ohio Settlement also resolved allegations of suspicious order reporting violations related to sales occurring between 2011 and 2017. Under the terms of terms of the WCH Ohio Settlement, there were no findings of any violation of law and McKesson made no admissions to the same. McKesson was subject to a reprimand and a fine of twenty-thousand dollars ($20,000).

On December 20, 2021, **McKesson Corporation** entered into a Consent Order with the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation (the "IDFPR") based on reciprocal state action from the 2020 Clear Lake Consent. The Illinois Consent applied to McKesson's Clear Lake, IA distribution center. Under the terms of the Illinois Consent Order, the facility was subject to a public reprimand by the IDFPR.

On January 18, 2022, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Urbancrest, OH distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $500 was imposed and paid on January 18, 2022.

On March 24, 2022, **McKesson Corporation** and the California Board of Pharmacy (the "Board") entered into a settlement agreement which resolved allegations against McKesson relating to the sale of controlled substances in 2017 and 2018 to an outpatient hospital pharmacy that the pharmacy discovered were being stolen by a pharmacy employee. Pursuant to the settlement agreement, the Board publicly reproved McKesson's Santa Fe Springs distribution center permit, and McKesson agreed to pay the board's costs related to the investigation and enforcement of the matter. As set forth in the settlement agreement, McKesson denies any allegation that it violated California laws regarding the distribution of controlled substances and there are no findings of any violation of state or federal laws.

On May 20, 2022, **McKesson Medical Surgical, Inc.**'s Urbancrest, Ohio facility entered into a consent order with the MI Dept of Licensing in connection with an Administrative Compliant from January 2022. The Administrative Complaint is a result of two settlement agreements with the Ohio BOP. Michigan states that these settlement agreements violated MCL 333.17768(2)(d). A $500.00 fine was imposed and paid.

On July 19, 2022, **McKesson Medical Surgical, Inc.**'s Urbancrest, Ohio facility entered into a settlement agreement with the Alabama Board of Pharmacy. The Alabama discipline was in response to discipline the facility received from the Ohio Board of Pharmacy in 2021 McKesson paid a $3,000 fine under the Alabama settlement.

On September 16, 2022, **McKesson Medical-Surgical Inc.'s** Leetsdale, PA facility entered into a consent order with the MI Dept of Licensing in connection with an Administrative Compliant from January 2022. The Administrative Complaint is a result of two settlement agreements with the Ohio BOP. Michigan states that these settlement agreements violated MCL 333.17768(2)(d). A $500.00 fine was imposed and paid.

On July 10, **McKesson Medical-Surgical Inc.**'s Bethlehem, PA facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with an alleged discipline for failure to notify the Board of Designated Representative changes that occurred at the facility in violation of Rule 680-X-2.23(2)(h)(1)(ii). Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023 upon compliance with the Deferral Agreement and payment of $5,000.00 costs to the Board.

On July 22, 2023, **McKesson Corporation**'s Santa Fe Springs, CA distribution center entered into a Consent Order with the Alabama Board of Pharmacy. The Consent Order constitutes reciprocal disciplinary action that was based entirely on a February 22, 2022, Decision and Order from the California Board of Pharmacy. There were no new facts giving rise to the Alabama Consent. Your office was notified of the California Order on or about 03/25/2022. Pursuant to the terms of the Alabama Consent, McKesson agreed to pay a fine of $25,000.

On August 29, 2023, **McKesson Medical-Surgical Inc.**'s Hanover Park, IL's facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with

failing to provide notice of a change of ownership on a permit that the Board itself has deemed unnecessary. Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023, upon compliance with the Deferral Agreement and payment of $4,000 costs to the Board.

On April 12, 2024, **McKesson Corporation**'s Duluth, GA distribution center entered into a Public Consent Agreement with the Georgia State Board of Pharmacy. McKesson Corporation was disciplined for failure to maintain prescription drugs securely and assessed a fine of $10,000.

On May 29, 2024, **McKesson Medical-Surgical Inc**.'s Jacksonville, FL facility entered into a Consent Agreement with the Georgia State Board of Pharmacy due to the facility changing ownership and updating their licensure prior to receiving board approval. Under O.C.G.A § 26-4-40, the Georgia State Board of Pharmacy is authorized to deny Applicants application for licensure due to changing ownership without Board Approval. Based on the Consent Agreement, McKesson Medical-Surgical Inc shall submit a payment of One-Thousand Seven-Hundred Dollars ($1,700) for the violation. The Board agrees to grant the ownership change and licensure update once the terms and conditions of the agreement are met.

On August 29, 2024, the Ohio Board of Pharmacy issued a Final Order to **McKesson Corporation** for activities that occurred at McKesson's former distribution center previously located in Washington Courthouse, OH for purchases of dangerous drugs from an unlicensed entity from July 2019 to April 2021. The Board imposed a monetary fine in the amount of $2,750.00.

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: see attached

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Virginia

Parent Company (if any): McKesson Medical Surgical Holdings Inc. - ultimate owner McKesson Corporation publicly traded

Corporation Name: McKesson Medical-Surgical Inc.

Mailing Address: 9954 Mayland Drive, Suite 4000

City: Richmond State: VA Zip: 23233

Telephone: 804.264.7500 Email: McKesssonLicensing@McKesson.com

Contact Person Name: Vicki McKee

Date of SEC Registration: 7.7.1994 | SEC Registration Number: 2417015 | Stock Exchange Symbol: MCK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

McKesson Medical-Surgical Inc.

Facility Name

Vicki McKee

Print Name of Authorized Person Submitting Application

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

9/18/24

Date

Board Use Only	Date Received: 10/7/24	Amount: $1000-cc

NABP ACCREDITED
DRUG DISTRIBUTOR

McKesson Medical-Surgical Inc.

located at

1005 Satellite Blvd, Suwanee, GA 30024

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

06/03/2022 - 06/02/2025
Period of Accreditation

Title	Name	Address	Phone
President; Director	Stanton J. McComb	[redacted] Richmond, VA 23233	[redacted]
VP & Treasurer; Director	Willard Station	[redacted] Richmond, VA 23233	
Secretary	Saralisa Charlotte Brau	[redacted] Irving, TX, 75039	
Vice President	Vicki McKee	[redacted] Irving, TX, 75039	
Vice President	Steven Tarantino III	[redacted] Jacksonville, FL 32256	

Ownership
McKesson Corporation Federal ID 94-3207296 6535 N. State Highway 161 Irving, TX 75039

McKesson Medical-Surgical Top Holdings Inc. Federal ID 59-2280364 6651 Gate Parkway Jacksonville, FL 32216

McKesson Medical-Surgical Holdings Inc. Federal ID 13-3734754 9954 Mayland Drive Suite 4000 Richmond, VA 23233

McKesson Medical-Surgical Inc. Federal ID 94-2640465 9954 Mayland Drive, Suite 4000 Richmond, VA 23233

McKesson Medical-Surgical Inc. Federal ID 94-2640465 1005 Satellite Blvd. Suwanee, GA 30024

Top RA Suppliers

All	ADDRESS_1	ADDRESS_2	CITY	STATE	ZIP
PFIZER	BANK OF AMERICA	P.O. BOX 100539	ATLANTA	GA	30384
ABBOTT RAPID DX N AMERICA LLC	30 S KELLER ROAD	SUITE 100	ORLANDO	FL	32810
NESTLE HEALTHCARE NUTRITION IN	ATTN REBATE ANALYST 9THFLOOR	800 N.BRAND BLVD	GLENDALE	CA	91203

Commonwealth of Virginia

State Corporation Commission

CERTIFICATE OF GOOD STANDING

I Certify the Following from the Records of the Commission:

That McKesson Medical-Surgical Inc. is duly incorporated under the law of the Commonwealth of Virginia;

That the corporation was incorporated on February 27, 1980;

That the corporation's period of duration is perpetual; and

That the corporation is in existence and in good standing in the Commonwealth of Virginia as of the date set forth below.

Nothing more is hereby certified.

Signed and Sealed at Richmond on this Date:

September 23, 2024

Bernard J. Logan, Clerk of the Commission

CERTIFICATE NUMBER : 2024092320807522

STATE OF GEORGIA
Georgia Board of Pharmacy
Wholesaler Pharmacy
LICENSE NO. PHWH001594 Status: Active

McKesson Medical-Surgical Inc
1005 Satellite Blvd
Suwanee GA 30024

Expires: 06/30/2025
Issued: 11/16/2001

Real-time license verification is available at gadch.mylicense.com/verification

Above is your wall certificate license to practice as a **Wholesaler Pharmacy** in the State of Georgia. A pocket-sized license card is below.

Please make note of the expiration date on your license. It is your responsibility to renew your license before it expires.
Please notify the Board if you have a change of address.

STATE OF GEORGIA
Georgia Board of Pharmacy
Wholesaler Pharmacy
LICENSE NO. PHWH001594 Status: Active
McKesson Medical-Surgical Inc
1005 Satellite Boulevard
Suwanee GA 30024

Expires: 06/30/2025
Issued: 11/16/2001
Real-time license verification is available at gadch.mylicense.com/verification

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY)
06/21/2024

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

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

PRODUCER	CONTACT NAME:	
Aon Risk Insurance Services West, Inc. San Francisco CA Office 425 Market Street Suite 2800 San Francisco CA 94105 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
McKesson Corporation and all its subsidiaries 6555 North State Highway 161 Irving TX 75039 USA	INSURER A: Old Republic Insurance Company	24147
	INSURER B:	
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570106560155 **REVISION NUMBER:**

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

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY317743	07/01/2024	07/01/2025	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000
	X Contractual Liability						MED EXP (Any one person)	$10,000
							PERSONAL & ADV INJURY	$1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$2,000,000
	OTHER:							
A	AUTOMOBILE LIABILITY			MWTB 317742 Self Insured for Phys Dam	07/01/2024	07/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / HIRED AUTOS ONLY / SCHEDULED AUTOS / NON-OWNED AUTOS ONLY						BODILY INJURY (Per accident)	
							PROPERTY DAMAGE (Per accident)	
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: N / N/A If yes, describe under DESCRIPTION OF OPERATIONS below			MWC31382624	07/01/2024	07/01/2025	X PER STATUTE OTH-ER	
							E.L. EACH ACCIDENT	$1,000,000
							E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000

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

EVIDENCE OF INSURANCE

CERTIFICATE HOLDER

MCKESSON CORPORATION
6555 State Hwy 161
Irving TX 75039 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Insurance Services West, Inc.

Holder Identifier :

Certificate No : 570106560155

©1988-2015 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG McKesson Medical-Surgical Inc. MDEG License # (if applicable) _____

Physical Address 1005 Satellite Boulevard

City Suwanee State GA Zip 30024

Mailing Address (if different from physical address) same as above

City _____ State _____ Zip _____

Telephone 678.957.8170 Website www.mckesson.com

Licensing Company Email Elaine.Stutman@McKesson.com or McKessonLicensing@McKesson.com

Section 2: Personal Information

First Joseph Middle Adam Last Ferry

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

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

Mailing Address 1005 Satellite Boulevard

City Suwanee State GA Zip 30024

Telephone [redacted] Email Joe.Ferry@McKesson.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
California State Universiry			
Address	City	State	Zip
	Sacramento	CA	
Diploma/Degree obtained, if any			
Bachelors of Science, Strategic Management			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
6/2020 - Present	[redacted]	Suwanee	GA	30024
From - To (MM/YY – MM/YY)		City	State	Zip
09/2002 - 6/2020		Roseville	CA	95747
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
McKesson Medical-Surgical Inc.			6/2020- Present	
Business Address		City	State	Zip
1005 Satellite Blvd		Suwanee	GA	30024
Phone	Title		Number of Employed Hours	
770-990-1306	Director, Operations		4+ years	
Description of Duties				
see attached				

Business Name			From - To (MM/YY – MM/YY)	
McKesson Medical-Surgical Inc.				
Business Address		City	State	Zip
7701 Foothills Blvd		Roseville	CA	95747
Phone	Title		Number of Employed Hours	
	Sr Operations Manager		2+ years	
Description of Duties				
see attached				

Business Name			From - To (MM/YY – MM/YY)	
Walgreens Distribution			1/1996-5/2018	
Business Address		City	State	Zip
2370 E. Main Street		Woodland	CA	95776
Phone	Title		Number of Employed Hours	
	Sr Operations Manager		22 years	
Description of Duties				
see attached				

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

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

Continue on next page if additional space is needed.

JOE FERRY

DIRECTOR OF OPERATIONS

[redacted]

SUMMARY

Over 20 years' experience leading distribution and supply-chain operations, logistics, projects, and implementing LEAN principles for Fortune 500 companies. Dedicated to innovative process improvement in the face of rapidly changing logistical needs.

EXPERIENCE

5/2018- PRESENT, McKesson Medical Surgical
Director of Operations: Suwanee, GA

- Leader of 330,000 square foot distribution center (DC) with 300+ employees and 100 private fleet drivers.
- Responsible for 7 cross-dock facilities in TN, AL, GA.
- P&L responsible.
- Moved struggling Atlanta-based DC from number 14 to top three large DC's in the US.
- Increased employee engagement scores year over year.
- Created leadership development program for manager, supervisors, and leads.

Senior Operations Manager: Roseville, CA

- Managed 4 supervisors, 8 leads, and more than 100 team members.
- Resolved complex problems at all levels of the organization.
- Facilitated staff planning sessions, reviewed commitments, and provided status reports/updates.
- Motivated, mentored, set deadlines, and provided growth opportunities for subordinates.
- Hired new team members and reviewed cases for termination.
- Pharmaceutical Designated Representative covering over 30 states.
- Experienced with OPEX Perfect Pick ASRS system.
- *2019 recipient of McKesson companywide "ILEAD" award, recognizing contribution to leadership in the building and throughout the company.*

1/1996-5/2018, Walgreens/Boots Alliance
Senior Operations Manager (Inbound and Outbound)

- Overall responsibility for multiple departments, including managers (exempt employees), supervisors, and team members.
- Facilitated staff planning, budgeting, and strategy sessions with corporate management.
- Selected to the *2018 COE (Center of Excellence) Audit Team.*

Manager of various inbound and outbound departments within the building, including Schedule II pharmaceuticals.

REFERENCES

Available upon request.

EDUCATION

Bachelor of Science
Strategic Management, 2001
California State University, Sacramento

Speakeasy, May 2022
Communicate to Drive Results

KEY STRENGTHS

- LEADERSHIP DEVELOPMENT
- LEADING ORGANIZATIONAL CHANGE
- RECRUITMENT AND MOTIVATION
- MEDIATION AND CONFLICT RESOLUTION
- PROCESS AND EFFICIENCY IMPROVEMENT
- INVENTORY MANAGEMENT
- BUDGETING
- BUILDING ORGANIZATIONAL CULTURE
- DATA ANALYSIS
- STRATEGIC PLANNING/VISIONING/GOAL SETTING
- EXECUTION

CERTIFICATIONS

- LEAN SIX SIGMA BLACK BELT, ACUITY INSTITUTE, 2022
- LEAN SIX SIGMA GREEN BELT, PURDUE UNIVERSITY, 2020

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Joseph F

Original Signature (electronic, copies or stamps not accepted)

9-17-2024

Date

I, Joseph Ferry, **certify that as the MDEG Administrator for**

McKesson Medical-Surgical Inc.,

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

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

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

Joseph Ferry
Print Name (First, Last)

Joseph F
Original Signature (electronic, copies or stamps not accepted)

9-30-2024
Date

Board Use Only	Date Received: 10/7/24

Employee list

First Name	Last Name	Location
Bosede	Ajayi	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Peter	Odumang	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Yaw	Owusu-Ansah	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Rodolfo	Villagomez	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Franklin	Oduro	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Mireya	Fland	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Stephanie	Young	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Darrell	Williams	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Wilbert	Yarbrough	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Douglas	Forbes	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Melvin	Ford	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Jeffrey	Allen	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Olevia	Paymon	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Mel	Parker	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
David	Sims	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Jason	Roberts	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Franklin	Johnston	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Thuy Linh	Le	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Myhien	Nguyen	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Duyentrang	Le	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)

Jenerick	Hill	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Thuy	Pham	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Anita	Maisuria	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Daouda	Hann	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Amadou	Sy Savane	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Cutid	Kelly	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Alen	Pasic	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Exal	Fernandez	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Tom	Jozwiak	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Kokibe	Sanami	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Lorraine	Broussard	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Glenn	Walker	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Phillip	Gilstrap	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Lewis	Kemp	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Kenyona	Dunbar	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Michael	Chukwu	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
John	Taylor	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Lakessia	Harris	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Ronald	Lomax	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Truc	Phan	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)

Alhassane	Diaoune	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Felicite	Brownlee	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Pamela	Jackson	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Michael	Huey	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Luel	Babu	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Helene	Camara	Suwanee, GA, USA - 1005 Satellite Blvd (A004)
Charise	Vaughn	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Wallace	Brown	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Veronica	Graham	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Eddie	Toliver	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Monica	Banks	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Brad	Turnipseed	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
James	Gleaton	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Chantell	Ryans	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Elizabeth	Quartey	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Alexander	Bannerman	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Kenneth	Williams	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Pierre	Robinson	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Earl	Johnson	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Edwin	Kozar	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)

Phil	Seiders	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Tuan	Vu	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Marvin	Gardner	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Samuell	Hutchins	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Michael	Lyons	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Mary	Tavenner	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Marcus	Henry	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Donald	Smith	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Janet	Mattox	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Pete	Hedrick	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Sheryl	Pyle	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Glenn	Moore	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Jesse	Douglas	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Beth	Connell	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Carey	Wiggins	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Phuong	Nguyen	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
André	Dumont	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Donovan	McLean	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Ufuoma	Slocum	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Joe	Ferry	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)

Kim-Eva	Hutchins	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Hien	Tran	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Miriam	Duran	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Ath	Im	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Larry	Poe	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Dereck	Huiel	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Dylan	Johnson	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Scott	Corbin	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Ngoc	Le	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Moy	Phouanesouvanh	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Bryon K	Johnson	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Steyania	Johnson	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Edward	Miller	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Myhang	Ngo	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Twanna	Carruthers	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Richard	Mensah	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Dawn	McPherson	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Pamela	Enenmuo	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Nour	Bokoum	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Barbara	Richardson	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)

Andrew	Mor	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Clyde	Tarber	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Daniel	Wilson	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Raven	Wells	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Michael	Osho	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Kristen	Sumpter	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Antonio	Hodges	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Lorenzo	Mata	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Bernice	Appoh	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Eric	Agyemang	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Kadidiatou	Diakhaby	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Doeun	Rin	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Leon	Wedderburn	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Phidelia	Hatsu	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Donna	Smith	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Florinel	Marica	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Robert	Felder	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Carolyn	Reid	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Lloyd	Johnson	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Macky	Diallo	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)

Eric	Merriman	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Juan mariano	Mojica aybar	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Chee Wai	Lai	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Jamar	Colston	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Thang	Lian	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Hlawn	Mawi	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Man	Lun	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Cher	Zing	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Helen	Thluai	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Run	Zahau	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Siang	Sung	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Tha	Kim	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Sui	Lan	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Noela	Men	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Martin	Grant	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Toan	Van	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Abdul	Sulemana	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Jacob	Lewis	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Jimmie	Mcclendon	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Hawa	Camara	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)

Garry	Kaushal	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Van Huu	Vu	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Malique	Henderson	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Juan	Garcia	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Susamma	Sam	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Kevin	van der Veen	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Phun	Sang	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Maria	Galicia Martinez	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Chundra	Jones	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Zam	Mawi	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Romario	Ramjhattan	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Amanda	Gomez Morales	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Norma	Aleman	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Eleni	Degefu	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Britani	Jennings	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Manuel	Ramirez	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Crisleudy	Perez De Nunez	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Hady	Santoso	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Elcey	Joseph	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Sang	Puia	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)

Yadisha	Roman	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Singsavath	Hongkham	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Yoselin	Ruiz	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Syed	Iqbal	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Mickey	McNair	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Jimmy	Tran	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Mia	Islam	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
William	Walters	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Nicola	Jackson	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Adrain	Burton	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Justin	Brown	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Edwardo	Conde	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Trong	Nguyen	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Gerard	Atkins	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Tha	Lian	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Edward	Cherry	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Matthew	Mcdade	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Efetite	Ogbevire	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Miguel A	Barrientos	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Claudiu	Aciu	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)

Mia	Guzman	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Daniel	Tyson	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Georlette	Yepez	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Lesi	Yepez	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Ignatius	Thang	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Neethu	Jacob	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Najma	Wajid	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Sulma	Zapata Moncada	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Gabriel	Hidalgo Estrada	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Javier Andres	Ibanez Meneses	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Than	Zuala	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Chhoeuth	Seang	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Raquel	Lopez	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Yatcer A	Valecillos Zuleta	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Hai	Nguyen	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Raisa	Ortiz	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Leighton	Hill	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Jorge	Vasquez	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Tina	Holley	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Chi Lam	Ung	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)

Ernelis	Aquino	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Jimmy	Brown	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Grewill	Marquez	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Biak	Muana	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Bila	Nuimi	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Ledys M	Del Rosario	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
James	Brantley	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Lal	Pui	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Brianna	Riddick	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Jember	Balga	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Maria	Romero	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Jamarco	Hughes	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Marisol	Perez Bello	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Darren	Scantlebury	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Eldrich	Granger	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Lian	Lual	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Valrie	Rose	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Jennifer	Christian	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Walter	Banks	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Chandler	Roberts	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)

Gregory	Beriguete Angomas	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Walsham	Vernon	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Michael	Simons	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Thi	Nguyen	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Mai	Par	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Rozalia	Si	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Mamadou	Balde	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Ronnie	Heard	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Carlos Jonathan	Samame Davila	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Adelaida	Angomas	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Raul	Hidalgo	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Joshua	Brown	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Erin	Rudley	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Mario	Bigby	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Precy	Tep	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Thawng	Zahau	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
John	Mcelroy	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Stanford	Smith	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Vay	Luu	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Angel	Acosta	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)

Michael	Anderson	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Eldin	Sisic	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Delali	Aklamati	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Wanda	Persaud	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Jean Luis	Gomez Eduardo	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Loan	Nguyen	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Gabriel	Castilleja	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Delshiner	Arkilley	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
NaTasha	Judkins	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Abdulkader	Ahmed	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Rosangelica	Ojeda	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Kimberly	Campbell	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Kelvin	Patrick	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
John-Erik	Morgan	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Dwight	Survis	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Ricky	Perez	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Yolonda	England	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Curtis	Ezell	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Scott	Dallesasse	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Rozenia	Osby	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)

Jamal	Mcfarlande	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
William	Tillmon	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Norma	De La Cruz	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Ayrton	Paredes	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
John	Jefferson	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Rashad	Higginbotham	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Adebusola	Adu	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Frank	Baxter	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Erika	Johnson	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Christopher	Ortiz	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Georgia	Brown	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Jerimey	Best	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Joyce	Dempsey	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Hammad	Hussain	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Kevon	Rolle	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Warren	Craddieth	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Ngoc Loan	To	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Vinessa	Gandy	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Martin	Rodriguez	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Regina	Johnston	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)

Angela	Jordan	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Tatiya	Tantimawanich	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Peter Abisai	Rodriguez Ortiz	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Scott	Sabellona	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Ingrid	Terrero	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Phonethip	Phonsoumphon	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Matthew	Doctor	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Tarus	Cantrell	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Migel	Beganovic	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Alberto	Arthur	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Lesaundra	Latham	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Isaiah	Wiggins	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
James	Horton	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Naquan	France	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Tyler	Polacky	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Marilyn	Fland	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Reynold	Walker	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)
Nguyet	Pham	Suwanee, GA, USA - 1005 Satellite Blvd. (A004)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): September 5, 2024

McKESSON

McKesson Corporation

(Exact name of registrant as specified in its charter)

Delaware	1-13252	94-3207296
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

6555 State Hwy 161, Irving, TX	75039
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (972) 446-4800

Not Applicable

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.01 par value	MCK	New York Stock Exchange
1.500% Notes due 2025	MCK25	New York Stock Exchange
1.625% Notes due 2026	MCK26	New York Stock Exchange
3.125% Notes due 2029	MCK29	New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

The information set forth in Item 8.01 regarding the Notes (as defined below) is incorporated herein by reference.

Item 8.01 Other Events.

Closing of Notes Offering

On September 5, 2024, McKesson Corporation (the "Company") entered into an Underwriting Agreement (the "Underwriting Agreement") with the several underwriters named therein (the "Underwriters"), pursuant to which the Company agreed to issue and sell $500,000,000 aggregate principal amount of its 4.250% Notes due 2029 (the "Notes"). On September 10, 2024, the Notes were issued pursuant to the Indenture, dated February 15, 2023 (the "Indenture"), between the Company and U.S. Bank Trust Company, National Association, as trustee (the "Trustee"), as amended and supplemented by an Officer's Certificate, dated September 10, 2024, setting forth certain terms of the Notes (the "Officer's Certificate").

The Notes will bear interest at the rate of 4.250% per year. Interest on the Notes is payable on September 15 and March 15 of each year, beginning on March 15, 2025.

Upon at least 10 days' and not more than 60 days' notice to holders of the Notes, the Company may redeem the Notes for cash in whole, at any time, or in part, from time to time, (x) prior to August 15, 2029, at a redemption price that includes accrued and unpaid interest and a make-whole premium that is calculated based on the Treasury Rate (as defined in the Officer's Certificate) plus 15 basis points and (y) on or after August 15, 2029, at par plus accrued and unpaid interest, in each case, as specified in the Indenture and the Officer's Certificate. The Indenture and the Officer's Certificate include certain covenants, including limitations on the Company's ability to create certain liens on its assets or enter into sale and leaseback transactions with respect to its properties, or consolidate, merge or sell all or substantially all of its assets, subject to a number of important exceptions as specified in the Indenture. The Notes are unsecured and unsubordinated obligations of the Company and rank equally with all of the Company's existing and future unsecured and unsubordinated indebtedness outstanding from time to time. The Indenture contains customary event of default provisions. In the event of the occurrence of both (1) a change of control of the Company and (2) a downgrade of the Notes below an investment grade rating by each of the Rating Agencies (as defined in the Officer's Certificate) within a specified period, unless the Company has previously exercised its optional redemption right with respect to the Notes in whole, the Company will be required to offer to repurchase the Notes from the holders at a price in cash equal to 101% of the then outstanding principal amount of the Notes, plus accrued and unpaid interest to, but not including, the date of repurchase.

The public offering price of the Notes was 99.946%% of the principal amount. The Company received approximately $498.0 million in net proceeds from the offering of the Notes, after deducting the underwriting discount but before deducting estimated offering expenses. The Company intends to use the net proceeds from the offering of the Notes, together with cash on hand, to fund the 2026 Notes Redemption (as defined below).

The Notes were offered and sold pursuant to the Company's automatic shelf registration statement on Form S-3 (Registration No. 333-269523) under the Securities Act of 1933, as amended. The Company has filed with the Securities and Exchange Commission (the "SEC") a prospectus supplement, dated September 5, 2024, together with the accompanying prospectus, dated February 2, 2023.

For a complete description of the terms and conditions of the Officer's Certificate, the Notes and the Underwriting Agreement, please refer to the Officer's Certificate, the form of Note and the Underwriting Agreement, which are incorporated herein by reference and attached to this Current Report on Form 8-K as Exhibits 4.1, 4.2, and 99.1, respectively.

In reviewing the agreements included as exhibits to this Current Report on Form 8-K, note that they are included to provide you with information regarding their terms and are not intended to provide any other factual or disclosure information about the Company or the other parties to the agreements. The agreements may contain representations

and warranties by each of the parties to the applicable agreement. Those representations and warranties have been made solely for the benefit of the other parties to the applicable agreement and:

- should not in all instances be treated as categorical statements of fact, but rather as a way of allocating the risk to one of the parties if those statements prove to be inaccurate;
- may have been qualified by disclosures that were made to the other party in connection with the negotiation of the applicable agreement, which disclosures would not necessarily be reflected in the agreement;
- may apply standards of materiality in a way that is different from what may be viewed as material to you or other investors; and
- were made only as of the date of the applicable agreement or such other date or dates as may be specified in the agreement and are subject to more recent developments.

Accordingly, those representations and warranties may not describe the actual state of affairs as of the date they were made or at any other time. Additional information about the Company may be found in our other public filings, which are available without charge through the SEC's website at http://www.sec.gov.

From time to time in the ordinary course of their respective businesses, certain of the Underwriters, the Trustee and their respective affiliates have engaged in and may in the future engage in commercial banking, derivatives and/or financial advisory, investment banking and other commercial transactions and services with the Company and its affiliates for which they have received or will receive customary fees and commissions.

Redemption of 2026 Notes

Concurrently with the launch of the offering of the Notes, on September 5, 2024, the Company issued a notice of redemption of all of its outstanding 5.250% notes due February 15, 2026 (the "2026 Notes"). The redemption of the 2026 Notes (the "2026 Notes Redemption") will be made in accordance with the terms of the Indenture, as amended and supplemented by the Officer's Certificate, dated February 15, 2023, setting forth certain terms of the 2026 Notes (collectively, the "2026 Notes Indenture"), which provides for a redemption price on or after February 15, 2024 equal to 100% of the principal amount of the 2026 Notes being redeemed plus accrued and unpaid interest thereon to, but not including, the redemption date. The foregoing description of the 2026 Notes Redemption is provided for informational purposes only, and this Current Report on Form 8-K does not constitute a notice of redemption of the 2026 Notes. The 2026 Notes Redemption will only be made in accordance with the provisions of the 2026 Notes Indenture.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibits
4.1	Officer's Certificate, dated as of September 10, 2024, with respect to the Notes.
4.2	Form of Note (included in Exhibit 4.1 above).
5.1	Opinion of Morrison & Foerster LLP regarding the validity of the Notes.
23.1	Consent of Morrison & Foerster LLP (included in Exhibit 5.1 above).
99.1	Underwriting Agreement, dated as of September 5, 2024, by and among McKesson Corporation and the several underwriters named therein.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: September 10, 2024

McKesson Corporation

By: /s/ Britt J. Vitalone

Britt J. Vitalone

Executive Vice President and Chief Financial Officer

OFFICER'S CERTIFICATE

The undersigned, McKesson Corporation, a Delaware corporation (the "Company"), hereby certifies through Akinjide Falaki, its Senior Vice President and Treasurer, pursuant to Sections 2.1, 2.3 and 11.5 of the Indenture, dated February 15, 2023 (the "Indenture"), by and between the Company, as Issuer, and U.S. Bank Trust Company, National Association, as Trustee, as follows:

1. The form and terms of the 4.250% Notes due 2029 (the "Notes"), as set forth on Annex A attached hereto, have been established pursuant to Sections 2.1 and 2.3 of the Indenture and comply with the Indenture.

2. The undersigned has read the Indenture.

3. The statements made in this Officer's Certificate are based upon an examination of the Notes under the Indenture, upon an examination of and familiarity with the Indenture, upon the general knowledge of and familiarity with the operations of the Company of the undersigned and upon the performance of his duties as an Officer of the Company.

4. In the opinion of the undersigned, he has made such examination or investigation as is necessary to enable him to express an informed opinion as to whether or not the covenants and conditions provided for in the Indenture relating to the issuance and authentication of the Notes have been complied with.

5. In the opinion of the undersigned, with respect to the foregoing, the covenants and conditions provided for in the Indenture relating to the issuance and authentication of the Notes have been complied with.

Capitalized terms used herein without definition have the meanings assigned to them in the Indenture.

Signatures transmitted by facsimile or other electronic transmission (including any electronic signature permitted and complying with the federal Electronic Signatures in Global and National Commerce Act, statement enactments of the Uniform Electronic Transactions Act, the U.S. Federal ESIGN Act of 2000, e.g., www.docusign.com) and/or any other relevant electronic signatures law, including any relevant provision of the Uniform Commercial Code/UCC (collectively, "Signature Law"), in each case to the extent applicable, shall be deemed to be an original signature for all purposes, and have the same validity, legal effect, and admissibility in evidence as an original manual signature. The Trustee shall be entitled to conclusively rely upon, and shall have no liability with respect to, any faxed, scanned, or photocopied manual signature, or other electronic signature, of any other party and shall have no duty to investigate, confirm or otherwise verify the validity or authenticity thereof.

[Signature Page Follows]

IN WITNESS WHEREOF, the undersigned has caused this Officer's Certificate to be executed by its duly authorized officer this 10th day of September, 2024.

McKESSON CORPORATION

By: /s/ Akinjide Falaki

Name: Akinjide Falaki

Title: Senior Vice President and Treasurer

ANNEX A

Pursuant to Section 2.3 of the Indenture, dated February 15, 2023 (the "Indenture"), between McKesson Corporation, a Delaware corporation (the "Issuer"), and U.S. Bank Trust Company, National Association, as trustee (the "Trustee"), the terms of a series of securities to be issued pursuant to the Indenture are as follows:

A. Designation. The designation of the securities is "4.250% Notes due 2029" (the "Notes").

B. Initial Aggregate Principal Amount. The Notes shall be limited in initial aggregate principal amount to $500,000,000 (except for Notes authenticated and delivered upon registration of transfer of, or in exchange for, or in lieu of, other Notes pursuant to Section 2.8, 2.9, 2.11, 8.5 or 12.3 of the Indenture).

C. Currency Denomination. The Notes shall be denominated in Dollars.

D. Maturity. The date on which the principal of the Notes is payable is September 15, 2029.

E. Rate of Interest; Interest Payment Date; Regular Record Dates. The Notes shall bear interest from September 10, 2024 at 4.250% per annum until the principal thereof is paid. Such interest shall be payable semi-annually in arrears on March 15 and September 15 of each year, commencing on March 15, 2025, to the persons in whose names the Notes are registered at the close of business on the immediately preceding March 1 and September 1, respectively, whether or not a Business Day. Interest on the Notes shall accrue from the most recent date to which interest has been paid, or if no interest has been paid, from September 10, 2024. Interest on the Notes will be computed on the basis of a 360-day year composed of twelve 30-day months. If any interest payment date would otherwise be a day that is not a Business Day, such interest payment date will be postponed to the next date that is a Business Day and no additional interest shall accrue. If the maturity date of the Notes falls on a day that is not a Business Day, the related payment of principal, premium, if any, and interest will be made on the next Business Day as if it were made on the date such payment was due, and no interest will accrue on the amounts so payable for the period from and after such date to the next Business Day. For the purposes of the Notes, "Business Day" is any day that is not a Saturday, Sunday or other day on which banking institutions in New York City or the place of payment on the Notes are authorized or required by law to close.

F. Place of Payment. Principal of, premium, if any, and interest on the Notes shall be payable, and the transfer of the Notes shall be registrable, at the office or agency of the Issuer to be maintained for such purpose in Philadelphia, Pennsylvania, except that, at the option of the Issuer, interest may be paid by mailing a check to the address of the person entitled thereto as it appears on the Notes register; provided, however, that while any Notes are represented by a Registered Global Security, payment of principal of, premium, if any, or interest on the Notes may be made by wire transfer to the account of the Depositary or its nominee.

G. Optional Redemption.

Prior to August 15, 2029, the Issuer may redeem the Notes at its option, in whole or in part, at any time and from time to time, for cash, at a redemption price (expressed as a percentage of principal amount and rounded to three decimal places) equal to the greater of: (i) (a) the sum of the present values of the remaining scheduled payments of principal and interest thereon discounted to the redemption date on a semi-annual basis (assuming a 360-day year consisting of twelve 30-day months) at the Treasury Rate plus 15 basis points less (b) interest accrued to, but not including, the date of redemption; or (ii) 100% of the principal amount of the Notes being redeemed; plus, in either case, accrued and unpaid interest thereon to, but not including, the redemption date. On or after August 15, 2029, the Issuer may redeem the Notes at its option, in whole or in part, at any time and from time to time, for cash at a redemption price equal to 100% of the principal amount of the Notes being redeemed plus accrued and unpaid interest thereon to, but not including, the redemption date.

"*Treasury Rate*" means, with respect to any redemption date, the yield determined by us in accordance with the following two paragraphs.

The Treasury Rate will be determined by the Issuer after 4:15 p.m., New York City time (or after such time as yields on U.S. government securities are posted daily by the Board of Governors of the Federal Reserve System), on the third Business Day preceding the redemption date based upon the yield or yields for the most recent day that appear after such time on such day in the most recent statistical release published by the Board of Governors of the Federal Reserve System designated as "Selected Interest Rates (Daily)—H.15" (or any successor designation or publication) ("H.15") under the caption "U.S. government securities–Treasury constant maturities–Nominal" (or any successor caption or heading) ("H.15 TCM"). In determining the Treasury Rate, the Issuer will select, as applicable: (1) the yield for the Treasury constant maturity on H.15 exactly equal to the period from the redemption date to the maturity date (the "Remaining Life"); or (2) if there is no such Treasury constant

maturity on H.15 exactly equal to the Remaining Life, the two yields – one yield corresponding to the Treasury constant maturity on H.15 immediately shorter than and one yield corresponding to the Treasury constant maturity on H.15 immediately longer than the Remaining Life – and will interpolate to the maturity date on a straight-line basis (using the actual number of days) using such yields and rounding the result to three decimal places; or (3) if there is no such Treasury constant maturity on H.15 shorter than or longer than the Remaining Life, the yield for the single Treasury constant maturity on H.15 closest to the Remaining Life. For purposes of this paragraph, the applicable Treasury constant maturity or maturities on H.15 shall be deemed to have a maturity date equal to the relevant number of months or years, as applicable, of such Treasury constant maturity from the redemption date.

If on the third Business Day preceding the redemption date H.15 TCM is no longer published, the Issuer will calculate the Treasury Rate based on the rate per annum equal to the semi-annual equivalent yield to maturity at 11:00 a.m., New York City time, on the second Business Day preceding such redemption date of the United States Treasury security maturing on, or with a maturity that is closest to, the maturity date, as applicable. If there is no United States Treasury security maturing on the maturity date but there are two or more United States Treasury securities with a maturity date equally distant from the maturity date, one with a maturity date preceding the maturity date and one with a maturity date following the maturity date, the Issuer will select the United States Treasury security with a maturity date preceding the maturity date. If there are two or more United States Treasury securities maturing on the maturity date or two or more United States Treasury securities meeting the criteria of the preceding sentence, the Issuer will select from among these two or more United States Treasury securities the United States Treasury security that is trading closest to par based upon the average of the bid and asked prices for such United States Treasury securities at 11:00 a.m., New York City time. In determining the Treasury Rate in accordance with the terms of this paragraph, the semi-annual yield to maturity of the applicable United States Treasury security shall be based upon the average of the bid and asked prices (expressed as a percentage of principal amount) at 11:00 a.m., New York City time, of such United States Treasury security, and rounded to three decimal places.

The Issuer's actions and determinations in determining the redemption price shall be conclusive and binding for all purposes, absent manifest error.

Notice of any redemption will be mailed or electronically delivered (or otherwise transmitted in accordance with the Depositary's procedures) at

least 10 days but not more than 60 days before the redemption date to each Holder of the Notes to be redeemed.

Any notice of redemption may be given prior to the completion of any event or transaction, including any securities offering or other corporate transaction, and any redemption or notice of redemption may be subject to the satisfaction of one or more conditions precedent, including the completion of any such securities offering or corporate transaction. If any redemption or notice of redemption is subject to the satisfaction of one or more conditions precedent, the applicable notice of redemption will so state and will state that the redemption date may be delayed until such time as any or all of such conditions precedent have been satisfied, or such redemption may not occur and such notice of redemption may be rescinded in the event that any or all such conditions precedent have not been satisfied by the redemption date, or by the redemption date so delayed.

In the case of a partial redemption, selection of the Notes for redemption will be made pro rata, by lot or by such other method as the Trustee in its sole discretion deems appropriate and fair. No Notes of a principal amount of $2,000 or less will be redeemed in part. If any Note is to be redeemed in part only, the notice of redemption that relates to the Note will state the portion of the principal amount of the Note to be redeemed. A new Note in a principal amount equal to the unredeemed portion of the note will be issued in the name of the Holder of the Note upon surrender for cancellation of the original note. For so long as the Notes are held by DTC, the redemption of the Notes shall be done in accordance with the policies and procedures of the Depositary.

Unless the Issuer defaults in payment of the redemption price, on and after the redemption date interest will cease to accrue on the Notes or portions thereof called for redemption.

H. Change of Control. If a Change of Control Triggering Event (as defined below) occurs, unless the Issuer has previously exercised its right to redeem the Notes in whole as described above, Holders of the Notes will have the right to require the Issuer to repurchase all or any part (in integral multiples of $1,000 original principal amount) of their Notes pursuant to the offer described below (the "Change of Control Offer"); *provided* that the principal amount of any Note remaining outstanding after a repurchase in part shall be $2,000 or a higher integral multiple of $1,000. In the Change of Control Offer, the Issuer will be required to offer payment in cash equal to 101% of the then outstanding aggregate principal amount of Notes repurchased plus accrued and unpaid interest, if any, on the Notes repurchased, to, but not including, the date of repurchase (the "Change of

Control Payment"). Within 30 days following any Change of Control Triggering Event, the Issuer will be required to mail a notice to Holders of the Notes describing the transaction or transactions that constitute the Change of Control Triggering Event and offering to repurchase the Notes on the date specified in the notice, which date will be no earlier than 30 days and no later than 60 days from the date such notice is mailed (the "Change of Control Payment Date"), pursuant to the procedures described herein and in such notice. The Issuer must comply with the requirements of Rule 14e-1 under the Exchange Act and any other securities laws and regulations thereunder to the extent those laws and regulations are applicable in connection with the repurchase of the Notes as a result of a Change of Control Triggering Event. To the extent that the provisions of any securities laws or regulations conflict with the Change of Control provisions herein, the Issuer will be required to comply with the applicable securities laws and regulations and will not be deemed to have breached its obligations under the Change of Control provisions herein by virtue of such conflicts.

On the Change of Control Payment Date, the Issuer will be required, to the extent lawful, to: (i) accept for payment all Notes or portions thereof properly tendered pursuant to the Change of Control Offer; (ii) irrevocably deposit with the Paying Agent, no later than 10:00 a.m., New York City time, an amount equal to the Change of Control Payment in respect of all Notes or portions thereof properly tendered; and (iii) deliver or cause to be delivered to the Trustee the Notes properly accepted together with an Officer's Certificate stating the aggregate principal amount of Notes or portions of Notes being repurchased.

The Paying Agent will promptly mail (or, in the case of Notes held in book-entry form, transmit electronically) to each Holder of the Notes properly tendered the repurchase price for such Notes, and the Trustee will promptly authenticate and mail (or cause to be transferred by book-entry) to each Holder a new Note equal in principal amount to any unrepurchased portion of any Notes surrendered; *provided*, that each new Note will be in a principal amount of $2,000 or an integral multiple of $1,000 thereafter.

The Issuer will not be required to make a Change of Control Offer upon the occurrence of a Change of Control Triggering Event if a third party makes such an offer in the manner, at the times and otherwise in compliance with the requirements for a Change of Control Offer made by the Issuer and the third party repurchases all Notes properly tendered and not withdrawn under its offer. In addition, the Issuer will not repurchase any Notes if there has occurred and is continuing on the Change of Control Payment Date an Event of Default, other than a default in the

payment of the Change of Control Payment upon a Change of Control Triggering Event.

"*Below Investment Grade Rating Event*" means the Notes are rated below an Investment Grade Rating by each of the Rating Agencies (as defined below) on any date from the date of the public notice of an arrangement that could result in a Change of Control until the end of the 60-day period following public notice of the occurrence of the Change of Control (which 60-day period shall be extended so long as the rating of the Notes is under publicly announced consideration for possible downgrade by any of the Rating Agencies).

"*Change of Control*" means the occurrence of any of the following: (1) the direct or indirect sale, transfer, conveyance or other disposition (other than by way of merger or consolidation), in one or a series of related transactions, of all or substantially all of the properties or assets of the Issuer and its Subsidiaries taken as a whole to any Person other than the Issuer or one of its Subsidiaries; (2) the consummation of any transaction (including, without limitation, any merger or consolidation) the result of which is that any Person becomes the beneficial owner, directly or indirectly, of more than 50% of the then outstanding number of shares of the Issuer's voting stock; or (3) the first day on which a majority of the members of the Issuer's Board of Directors are not Continuing Directors. Notwithstanding the foregoing, a transaction will not be deemed to result in a Change of Control if (i) the Issuer becomes a wholly owned subsidiary of a holding company and (ii) the holders of the voting stock of such holding company immediately following that transaction are substantially the same as the holders of the Issuer's voting stock immediately prior to that transaction.

"*Change of Control Triggering Event*" means the occurrence of both a Change of Control and a Below Investment Grade Rating Event.

"*Continuing Directors*" means, as of any date of determination, any member of the Board of Directors of the Issuer who (1) was a member of such Board of Directors on the date of original issue of the Notes; or (2) was nominated for election or elected to such Board of Directors with the approval of a majority of the Continuing Directors who were members of such Board of Directors at the time of such nomination or election (either by a specific vote or by approval of the Issuer's proxy statement in which such member was named as a nominee for election as a director, without objection to such nomination).

"*Fitch*" means Fitch Ratings Inc., a subsidiary of Hearst Corporation and Fimalac, S.A., or its successor.

"*Investment Grade Rating*" means a rating equal to or higher than Baa3 (or the equivalent) by Fitch or Moody's and BBB- (or the equivalent) by S&P.

"*Moody's*" means Moody's Investors Service, Inc., or its successor.

"*Rating Agencies*" means (1) each of Fitch, Moody's and S&P; and (2) if any one or more of Fitch, Moody's or S&P ceases to rate the Notes or fails to make a rating of the Notes publicly available for reasons outside of the Issuer's reasonable control, then, at the Issuer's election, either (x) each of the remaining agencies, as the case may be, or (y) each of the remaining agencies, as the case may be, and any "nationally recognized statistical rating organization" within the meaning of Section 3(a)(62) under the Exchange Act, selected by the Issuer (as certified by a Board Resolution) as a replacement agency for Fitch, Moody's or S&P, or all of them, as the case may be.

"*S&P*" means S&P Global Ratings, a division of S&P Global, Inc., or its successor.

I. Mandatory Redemption. The Notes are not mandatorily redeemable and are not entitled to the benefit of a sinking fund or any analogous provisions.

J. Denominations. The Notes shall be issued initially in minimum denominations of $2,000 and shall be issued in integral multiples of $1,000 in excess thereof.

K. Amount Payable Upon Acceleration. The principal of the Notes shall be payable upon declaration of acceleration pursuant to Section 5.1 of the Indenture.

L. Payment Currency. Principal and interest on the Notes shall be payable in Dollars.

M. Payment Currency - Election. The principal of and interest on the Notes shall not be payable in a currency other than Dollars.

N. Payment Currency - Index. The principal of and interest on the Notes shall not be determined with reference to an index based on a coin or currency.

O. Registered Securities. The Notes shall be issued only as Registered Securities. The Notes shall be issuable as Registered Global Securities.

P. Additional Amounts. The Issuer shall not pay additional amounts on the Notes held by a Person that is not a U.S. Person in respect of taxes or similar charges withheld or deducted.

Q. Registrar; Paying Agent; Depositary. The entity acting as Trustee shall initially serve as the Registrar and Paying Agent. The Depository Trust Company shall initially serve as the Depositary for the Registered Global Security representing the Notes.

R. Events of Default; Covenants. There shall be no deletions from or modifications or additions to the Events of Default set forth in Section 5.1 of the Indenture with respect to the Notes. There shall be the following additions to the covenants of the Issuer set forth in Article III of the Indenture with respect to the Notes:

Limitation on Liens. The Issuer covenants that, so long as any of the Notes remain outstanding, it shall not, nor shall it permit any Consolidated Subsidiary to, create or assume any Indebtedness for money borrowed which is secured by a mortgage, pledge, security interest or lien ("liens") of or upon any assets, whether now owned or hereafter acquired, of the Issuer or any such Consolidated Subsidiary without equally and ratably securing the Notes by a lien ranking equally to and ratably with (or at the option of the Issuer, senior to) such secured Indebtedness, except that the foregoing restriction shall not apply to (a) liens on any assets of any corporation existing at the time such corporation becomes a Consolidated Subsidiary; (b) liens on any assets existing at the time of acquisition of such assets by the Issuer or a Consolidated Subsidiary, or liens to secure the payment of all or any part of the purchase price of such assets upon the acquisition of such assets by the Issuer or a Consolidated Subsidiary or to secure any indebtedness incurred or guaranteed by the Issuer or a Consolidated Subsidiary prior to, at the time of, or within 360 days after such acquisition (or in the case of real property, the completion of construction (including any improvements on an existing asset) or commencement of full operation of such asset, whichever is later), which indebtedness is incurred or guaranteed for the purpose of financing all or any part of the purchase price thereof or, in the case of real property, construction or improvements thereon; (c) liens on any assets securing indebtedness owed by any Consolidated Subsidiary to the Issuer or another wholly owned Subsidiary; (d) liens on any assets of a corporation existing at the time such corporation is merged into or consolidated with the Issuer or a Subsidiary or at the time of a purchase, lease or other acquisition of the assets of a corporation or firm as an entirety or substantially as an entirety by the Issuer or a Subsidiary; (e) liens on any assets of the Issuer or a Consolidated Subsidiary in favor of the United States of America or any state thereof, or any department, agency or instrumentality or political subdivision of the United States of America or any State thereof, or in favor of any other country, or any political subdivision thereof, to secure partial, progress, advance or other payments pursuant to any contract or statute or to secure any indebtedness incurred or guaranteed for the purpose of financing all or any part of the purchase price (or, in the case of real property, the cost of construction) of the assets subject to such liens (including, but not limited to, liens incurred in

connection with pollution control, industrial revenue or similar financing); (f) any extension, renewal or replacement (or successive extensions, renewals or replacements), in whole or in part, of any lien referred to in the foregoing clauses (a) to (e), inclusive; (g) liens imposed by law, such as mechanics', workmen's, repairmen's, materialmen's, carriers', warehousemen's, vendors' or other similar liens arising in the ordinary course of business, or governmental (federal, state or municipal) liens arising out of contracts for the sale of products or services by the Issuer or any Consolidated Subsidiary, or deposits or pledges to obtain the release of any of the foregoing liens; (h) pledges, liens or deposits under workers' compensation laws or similar legislation and liens or judgments thereunder which are not currently dischargeable, or in connection with bids, tenders, contracts (other than for the payment of money) or leases to which the Issuer or any Consolidated Subsidiary is a party, or to secure public or statutory obligations of the Issuer or any Consolidated Subsidiary, or in connection with obtaining or maintaining self-insurance or to obtain the benefits of any law, regulation or arrangement pertaining to unemployment insurance, old age pensions, social security or similar matters, or to secure surety, appeal or customs bonds to which the Issuer or any Consolidated Subsidiary is a party, or in litigation or other proceedings such as, but not limited to, interpleader proceedings, and other similar pledges, liens or deposits made or incurred in the ordinary course of business; (i) liens created by or resulting from any litigation or other proceeding which is being contested in good faith by appropriate proceedings, including liens arising out of judgments or awards against the Issuer or any Consolidated Subsidiary with respect to which the Issuer or such Consolidated Subsidiary is in good faith prosecuting an appeal or proceedings for review or for which the time to make an appeal has not yet expired; or final unappealable judgment liens which are satisfied within 15 days of the date of judgment; or liens incurred by the Issuer or any Consolidated Subsidiary for the purpose of obtaining a stay or discharge in the course of any litigation or other proceeding to which the Issuer or such Consolidated Subsidiary is a party; (j) liens for taxes or assessments or governmental charges or levies not yet due or delinquent, or which can thereafter be paid without penalty, or which are being contested in good faith by appropriate proceedings; landlords' liens on property held under lease; and any other liens or charges incidental to the conduct of the business of the Issuer or any Consolidated Subsidiary or the ownership of the assets of any of them which were not incurred in connection with the borrowing of money or the obtaining of advances or credit and which do not, in the opinion of the Issuer, materially impair the use of such assets in the operation of the business of the Issuer or such Consolidated Subsidiary or the value of such assets for the purposes thereof; (k) liens relating to accounts receivable of the Issuer or any of its Subsidiaries which have been sold, assigned or otherwise transferred to another Person in a transaction classified as a sale of accounts receivable in accordance with accounting principles generally accepted in the United States of America (to the extent the sale by the Issuer or the applicable Subsidiary is deemed to give rise to a lien in favor of the purchaser thereof in such accounts

41

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

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

Section 1: General Information

Facility Name: Arvinas Operations, Inc.

Physical Address: 5 Science Park, 395 Winchester Ave, Suite NE 100

City: New Haven State: CT Zip: 06511

Mailing Address (if different from physical address): 5 Science Park, 395 Winchester Ave, Suite NE 100

City: New Haven State: CT Zip: 06511

Telephone: 1-203-535-1456 Website: https://www.arvinas.com

Name of Designated Representative (DR): Lisa Sinclair

Licensing Company Email: statelicensing@arvinas.com DR Email: lisa.sinclair@arvinas.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Distributors		☒ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: DE

Parent Company (if any): Arvinas, Inc.

Corporation Name: Arvinas Operations, Inc.

Mailing Address: 5 Science Park, 395 Winchester Ave, Suite NE 100

City: New Haven State: CT Zip: 06511

Telephone: 1-203-535-1456 Email: info@arvinas.com

Contact Person Name: John Houston

Date of SEC Registration: 10/10/2018	SEC Registration Number: 0001655759	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

Date of Event/Arrest	Disposition Date	State	City	County

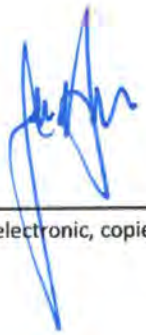
Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted)

9/26/24

Date

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		x
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/boponvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form at:** http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Arvinas Operations, Inc.
Facility Name

John Houston
Print Name of Authorized Person Submitting Application

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

9/26/24
Date

Board Use Only	Date Received: _____	Amount: _____

ARVINAS

Description of Operations

Arvinas Operations, Inc. (Arvinas) is a Virtual Manufacturer. Arvinas' products are manufactured by a Contract Manufacturer and will be distributed to Specialty Distributors by their Third-Party Logistics Providers, ICS, who is licensed to ship pharmaceutical products into your state.

Contract Manufacturer Information:
We are using the following contract manufacturer to produce our product:

Pfizer Manufacturing Deutschland GMBH dba Betriebsstatte Freiburg
MOOSWALDALLEE 1 79090 FRIEBURG
FRIEBURG
Germany
FDA Establishment Number: 88-M-6205

Pfizer manufactures Arvinas' product and packages finished product. Arvinas' products are not Controlled Substances.

Labeler Code: 84043

Third Party Logistic information:
For distribution into the commercial supply channels, ICS acts as Arvinas' Third-Party Logistics (3PL) provider to manage the storage and distribution of Arvinas' product-throughout the United States. ICS's address is listed below:

ICS
420 International Blvd
Brooks, KY 40109

Arvinas has 448 employees working on site during normal business hours.
Arvinas' hours of operation are 8:00 am – 5:30pm Monday through Friday.
Arvinas' records are stored at ICS (3PL).
Arvinas facility square footage is 62 square feet.

From: edrls@fda.hhs.gov <edrls@fda.hhs.gov>
Sent: Wednesday, January 17, 2024 2:34:07 PM
To: Suzette Dowling <suzette.dowling@arvinas.com>
Subject: Labeler Code Request Approved

eDRLS - Electronic Drug Registration & Listing System

Current Date: 17-JAN-2024
Labeler DUNS: 079125842
Labeler Name: Arvinas Operations, Inc.
Labeler Code Assigned: 84043

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. **The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).



Arvinas Operations, Inc.
5 Science Park, 395 Winchester Ave, Suite NE 100
New Haven, CT 06511
1-203-535-1456
www.arvinas.com
statelicensing@arvinas.com
FEIN: 46-3139663

Arvinas Operations, Inc. is a 100% owned subsidiary of Arvinas, Inc., a Publicly Traded company on the NASDAQ stock exchange under the symbol [ARVN].

Parent Company Address: 5 Science Park, 395 Winchester Ave, New Haven, CT 06511
Parent Company Phone: 1-203-535-1456
Parent Company FEIN: 47-2566120

Officers:

John Houston, Chairperson, CEO & President
5 Science Park, 395 Winchester Ave, Suite NE 100, New Haven, CT 06511
Business Phone: 475-234-5685
Email: John.Houston@Arvinas.com

John Northcott, Chief Commercial Officer
5 Science Park, 395 Winchester Ave, Suite NE 100, New Haven, CT 06511
Business Phone: 832-684-7713
Email: john.northcott@arvinas.com

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ARVINAS OPERATIONS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-NINTH DAY OF MARCH, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "ARVINAS OPERATIONS, INC." WAS INCORPORATED ON THE FOURTH DAY OF FEBRUARY, A.D. 2013.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.





5283608 8300

SR# 20241233514

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203146460

Date: 03-29-24

CPL-03 Rev 06/13

STATE OF CONNECTICUT
DEPARTMENT OF CONSUMER PROTECTION

This is your registration certificate for your records. Such registration shall be shown to any properly interested person on request. Do not attempt to make any changes or alter this certificate in any way. This registration is not transferable. Questions can be emailed to the Drug Control Division at dcp.drugmanufacturers@ct.gov.

In an effort to be more efficient and Go Green, the department asks that you keep your email information with our office current to receive correspondence. All renewal notifications and certificates will only be emailed to your last reported email on record. You can update your email, mailing address or print a duplicate certificate by logging into your account with your User ID and Password at www.elicense.ct.gov. Visit our website at www.ct.gov/dcp.

Mailing address:

ARVINAS OPERATIONS INC
5 Science Park, 395 Winchester Ave, Suite NE 100
New Haven, CT 06511

Email on file to be used for receiving all notices from this office:

derek.rossman@twolabs.com

1046157

STATE OF CONNECTICUT ✦ DEPARTMENT OF CONSUMER PROTECTION

Be it known that

ARVINAS OPERATIONS INC
5 Science Park, 395 Winchester Ave, Suite NE 100
New Haven, CT 06511

has satisfied the qualifications required by law and is hereby issued a

MANUFACTURER OF DRUGS, COSMETICS & MEDICAL DEVICES

Controlled Substances: No **Rx Legend Drugs: Yes** **Non Rx Legend Drugs: No** **Medical Devices: No** **Cosmetics: No**

Medical Gases and Oxygen: No **Durable Medical Equipment (DME): No** **Number of Chemists: 0**

Registration #: CSM.0002725
Effective Date: 08/20/2024
Expiration Date: 06/30/2025

verify online at www.elicense.ct.gov

Bryan T. Cafferelli, Commissioner

State of Connecticut

Lookup Detail View

Name and Address

Name	Mailing Address	License Address
ARVINAS OPERATIONS INC	ARVINAS OPERATIONS INC 5 Science Park, 395 Winchester Ave, Suite NE 100 New Haven, CT 06511	5 Science Park, 395 Winchester Ave, Suite NE 100 New Haven, CT 06511

Credential Information

Credential	License Type	Effective Date	Expiration Date	Status
CSM.0002725	MANUFACTURER OF DRUGS, COSMETICS & MEDICAL DEVICES	08/20/2024	06/30/2025	ACTIVE

Generated on: 10/3/2024 2:41:26 PM

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Arvinas Operations, Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 5 Science Park, 395 Winchester Ave, Suite NE 100

City New Haven State CT Zip 06511

Mailing Address (if different from physical address) 5 Science Park, 395 Winchester Ave, Suite NE 100

City New Haven State CT Zip 06511

Telephone 1-203-535-1456 Website https://www.arvinas.com

Licensing Company Email statelicensing@arvinas.com

Section 2: Personal Information

First Lisa Middle Russ Last Sinclair

Alias(es, nicknames, name changes, etc.) Lisa Russ

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

Mailing Address 5 Science Park, 395 Winchester Ave, Suite NE 100

City New Haven State CT Zip 06511

Telephone 203-535-1456 Email lisa.sinclair@arvinas.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
University of Vermont		08/87 - 05/91	
Address	**City**	**State**	**Zip**
384 South Prospect Street	Burlington	VT	05405
Diploma/Degree obtained, if any			
BA			

School Name		From - To (MM/YY – MM/YY)	
Somers High School		08/83 - 06/87	
Address	**City**	**State**	**Zip**
120 Primrose St	Lincolndale	NY	10540
Diploma/Degree obtained, if any			
Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/14 - Current	[redacted]	Madison	CT	06443
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Arvinas, Inc.			08/22 - Present
Business Address	**City**	**State**	**Zip**
5 Science Park, 395 Winchester Ave, Suite NE 100	New Haven	CT	06511
Phone	**Title**	**Number of Employed Hours**	
203-535-1456	SVP Corporate Operations	4160	
Description of Duties			
See Attached			

Business Name			From - To (MM/YY – MM/YY)
RALLYBIO			10/19 – 07/22
Business Address	**City**	**State**	**Zip**
234 Church Street	New Haven	CT	06510
Phone	**Title**	**Number of Employed Hours**	
203-859-3820	Head of Corporate and Commercial Strategy	6240	
Description of Duties			
See Attached			

Business Name			From - To (MM/YY – MM/YY)
Springworks Therapeutics			08/18 – 10/19
Business Address	**City**	**State**	**Zip**
100 Washington Blvd	Stamford	CT	06902
Phone	**Title**	**Number of Employed Hours**	
203-883-9490	Head of Program and Alliance Management	2080	
Description of Duties			
See attached			

Business Name			From - To (MM/YY – MM/YY)
Alexion Pharmaceuticals			01/14 – 12/17
Business Address	**City**	**State**	**Zip**
100 College Street	New Haven	CT	06510
Phone	**Title**	**Number of Employed Hours**	
475-230-2596	Vice President of R&D Strategy, Portfolio and Project	6240	
Description of Duties			
See attached			

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

L. Sinclair
Original Signature (electronic, copies or stamps not accepted)

9/26/24
Date

I, Lisa Sinclair, **certify that as the designated representative for**

Arvinas Operations, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. LS I am at least 21 years of age;
3. LS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. LS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. LS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. LS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. LS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Lisa Sinclair

Print Name (First, Last)

Li Sinclair

Original Signature (electronic, copies or stamps not accepted)

9/26/24

Date

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

Lisa Sinclair

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/26/24

Date

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

State of Connecticut, ss. County of New Haven

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

Original Signature

9/26/24

Date

Subscribed and Sworn to before me this 26th day of September 2024.

Notary Public Signature

SANDRA CARLINO
NOTARY PUBLIC - CT 172583
MY COMMISSION EXPIRES OCT. 31, 2026

(Seal)

Curriculum Vitae

LISA R. SINCLAIR

[redacted]

Professional Experience:

Arvinas, Inc., New Haven, CT. 08/2022 - present

Title: Senior Vice President of Corporate Operations

Responsible for strategic leadership of Development Operations, Corporate Project and Program Management, Quality, Information Technology, and business performance metrics & analytics.

- Lead development of the Long-Range Operating Plan and optimization of the business model to ensure efficiency and scale flexibility.
- Translate the overall strategy into near-term/short range plans that align with the company's corporate and annual objectives and operating budgets.
- Accountable for integration of overarching corporate and functional strategies, strategic partnerships and business development initiatives, budget, and enterprise resource capacity management.
- Build a reliable and scalable business operations structure. Lead business capability, strategic and operational infrastructure planning in partnership with the LT.
- Develop and implement the governance and team operating model.

RALLYBIO, New Haven, CT > 10/2019 – 07/2022

Title: Head of Corporate and Commercial Strategy

Responsible for Accountable for corporate strategy, operational planning, and commercial strategy for a rare disease clinical stage portfolio biotech start-up. Engage with the Board of Directors, investors, thought leaders, diagnostic labs, and patient advocacy groups. Supported IPO $93M and Series B $145M financing.

- Lead development and evolution of the long-term corporate strategy and 3-year operating plan including market landscape assessment, sustainable pipeline analysis, approaches to portfolio growth, corporate goals and priorities, capability planning framework, scenario planning.
- Developed the initial commercial strategic plan for the portfolio. Generated commercial

models for different market and product archetypes in preparation for in-licensing and partnerships.
- Built the early commercial development and medical strategy for a first in class preventive therapeutic and diagnostic screening platform in Fetal & Neonatal Alloimmune Thrombocytopenia.
- Drove strategic evaluation of FNAIT portfolio assets to optimize value and offset investment risk. Proposal supported by the Board of Directors.
- Oversee the global partnership strategy for FNAIT commercial diagnostics.
- Created a cross-functional approach to challenge and diversify portfolio investment opportunities.

Springworks Therapeutics, Stamford, CT. 08/2018 – 10/2019

Title: Head of Program and Alliance Management

Responsible for building portfolio, program, and alliance management capabilities for a late-stage, clinical oncology biotech start-up. Managed rare oncology portfolio to achieve value-creation milestones through targeted scaling of operational capabilities. Reported to the CEO.

Delivered portfolio pipeline investment plan to $153M IPO and $125M Series B financing. Generated cross-functional scenario plans and risk analysis to inform investment and trade-offs.
- Led the corporate 3-year operating plan and secured endorsement from the Board of Directors.
- Built late-stage integrated product and investment plans that achieved Phase 3 and 2 milestones.
  Optimized value creation through lifecycle strategic plans for nirogacestat and mirdametinib.
- Formed and managed alliance teams; developed goals and milestone plan targets for GSK BCMA/ nirogacestat combination, Beigene lifirafenib/mirdametinib combination and MapKure joint venture.

Alexion Pharmaceuticals, New Haven, CT. 01/2014 – 12/2017

Title: Vice President of R&D Strategy, Portfolio and Project Management

Responsible for building a high-performing team of portfolio leaders, project managers, and business operations directors. Member of the R&D Leadership Team and Science & Innovation Committee of the Board of Directors.
- Generated objectives and integrated development plans to accelerate delivery of life-transforming medicines in rare and ultra-rare diseases.

- Achieved NME and lifecycle approvals on time – Strensiq, Kanuma, Soliris gMG.
- Accelerated execution of priority medicines – Ultomiris from FIH to Phase 3 in 28 months.
- Created focused disease area strategy to enable fast pivot from POC to registration.
- Partnered with R&D Leadership to develop the first 5-year strategic plan, portfolio prioritization, and operating plan. Secured endorsement from Executive Committee and the Board of Directors.
- Shaped the capability strategy with R&D Leadership to increase productivity and position the business to realize growth targets.
- Designed and implemented a new product development planning process with Commercial. Aligned cross-functional interdependencies, decision points, and cycle times from POC to launch.
- Developed and implemented R&D performance metrics and risk management plans. Conducted progress reviews with the Board of Directors.
- Collaborated with CEO and Executive Leadership on PV and Corporate Compliance performance improvement initiative. Executed change management with new Quality practices and measures.

ASTRAZENECA, Wilmington, DE 08/2011 – 12/2013

Title: Vice President, Global R&D Portfolio and Performance

Responsible for forming a global team of portfolio business leaders, analysts, and project managers to support operations across 4 R&D sites. Managed $4.8B R&D budget with R&D Leadership; R&D and lifecycle portfolio management; resource forecast and capacity planning.

- Transformed delivery of R&D portfolio management to accelerate execution of priority assets.
- Chaired the R&D One Portfolio Management Committee through close engagement with leaders across AZ and MedImmune R&D, Therapeutic Area (TA) Heads, Finance, product teams.
- Delivered the portfolio plan to rebuild the Ph 3 pipeline, increase value and reduce Phase 2 cycle times in partnership with TA Leadership and Finance.
- Led change management initiatives within R&D and TA organizations that simplified governance operations and decision-making across management, teams, and functions.
- Prepared and led therapeutic area strategy review process across TAs including objectives, prioritized investment options, resource allocation trade-off's, sustainability, and performance analyses against benchmarks.
- Co-led a 3-year portfolio performance & productivity target initiative with Corporate Strategy. Recommendations endorsed by Executive Leadership and the Board of Directors.

PFIZER Inc., Groton / New London, CT, and New York 08/1993 – 08/2011

Title: Portfolio Group Head, Primary Care Portfolio Operations & Project Management 2009 – 2011

Led a team of portfolio directors, project managers and business operations directors responsible for management of pipeline and alliance programs in Cardiovascular, Metabolic, Pain, & Women's Health and Business Unit functional operations for R&D, Global Commercial, and Global Medical Affairs.

- Co-led generation of the Primary Care disease area strategy and investment plan with Commercial.
- Developed 3-year operating plan and provided management support for $1.0B+ annual budget.
- Executed portfolio reviews, pipeline prioritization, and new team/governance operating model.

Title: Portfolio Lead, Senior Director, CV and Metabolic Disease Therapeutic Area 2006 – 2009

Managed portfolio goals, prioritization, resource allocation planning and governance operations.

- Developed efficiency options that realized ~$25M in savings against the R&D target.
- Supported Short-Term Achievement of Revenue initiative; assessed and identified top opportunities for revenue growth in 5 years. Investment proposal endorsed by corporate executive governance.

Title: Therapeutic Coordinator Role, CVMED Therapeutic Area Strategy Team 2002 – 2006

Partnered with TA Leadership and Product Decision Analysis to deliver pipeline, lifecycle management, and business development recommendations for the CVMED TA growth strategy.

- Assessment approach adopted as best practice and rolled out across 11 Therapeutic Areas.

Title: Global Program Manager, torcetrapib / atorvastatin Global Development Team 2001 – 2005

Managed global development plan from POC through Phase 3 and Morbidity & Mortality trial; $869M total R&D budget; 36 clinical trials across 19 countries.
Accelerated timelines and protected product value (~$8B) through active risk mitigation.

Title: Early Development Project Manager, Preclinical to Proof-of-Concept, R&D 1998 – 2001

Xeljanz / RA and transplant; CETP / CVMED; VEGF, Ras FTase / Oncology; Zithromax SR / anti-infective.

Title: Clinical Operations Lead, Norvasc Global Candidate Team, R&D 1994 – 1998

sNDA filing for CHF; record start-up of Phase 3b Morbidity & Mortality trial; oversight of academic CRO; established clinical operations metrics; presented performance outcomes to CEO and R&D Leadership.

Title: Norvasc US Marketing Internship 1994

Title: Pfizer Sales Representative, PRATT Pharmaceutical Sales 1993 – 1994

Designed and implemented franchise management strategy for Norvasc, Procardia XL, Zoloft, and Glucotrol XL. Achieved above plan targets in specialist, PCP, managed care, and VA market segments.

Education and Certifications:

Bachelor of Arts in Business Administration, Marketing concentration University of Vermont, Burlington, VT

Co-Chair, Executive Women in Bio CT Chapter
Leader, Bioscience Industry Collaborative for Greater New Haven Board Member, Greater New Haven Chamber of Commerce
Co-Chair, Alexion Women in Leadership Steering Committee
AstraZeneca Global Leadership Development Program, Harvard Business School Pfizer Advanced Management & Leadership Program
Pfizer Primary Care Women in Leadership Mentoring Program Pfizer Blue Ocean Strategy Executive Education Program, INSEAD

Publications:

N/A

Signature:

ARVINAS

Employee list –
Confidential Information - Do Not Distribute

Sam Abdelhamid
Stella Abudu
Timothy Ackerson
Nick Adams
Sergey Aksenov
Fahmi Al-Aqrabi
Diana Alicea
Miri Alon
Estevan Alonzo
Martha Altieri
Sharvari Apte
Erika Araujo
Gaurav Arora
Melissa Arzrouni-Dawson
Christina Bailey
Anthony Bang
Nicholas Barczak
Carol Barnabei
Christopher Beck
Halie Beckert
Miklos Bekes
James Belcastro
Brett Beno
Aimee Bergey-Reilly
Elmer Berghorn
Jason Berk
Noah Berkowitz
Michael Berlin
Prateek Bhargava
Joanna Bloom
Patrick Boamah
Courtney Bond
Mark Bookbinder
Elizabeth Bortolon
Andrew Bowler
Jeffery Boyle
Catherine Braine
Jingjing Bu
Michelle Budris
Jonathan Busby
William Butcher
Christine Butler
Devon Butler
Tim Bye
Angela Cacace
Juan Cadavid
Gregory Cadelina
Roodly Cadet
Joseph Calabro
Christina Calderwood
John Caldwell
Ann-Marie Campbell
Scott Campbell
Jennifer Cantley
Joseph Cantone
Sandra Carlino
Candy Carrano
Sharyn Carrasco
Britney Caso
Rudy Castro
Sanjukta Chakraborty
Edward Chan
David Chandiwana
Amanda Chapman
Juan Chavez
Xin Chen
Herman Chen
Doris Chen
Zhidong Chen
Sean Chen

ARVINAS

Dabing Chen
Renda Cheng
Ken Cheng
Srikanth Chougoni
Mee Kyung Chung
Lauren Ciesla
Jordan Clark
Brian Clas
Kaitlin Clinton
Nicholas Cockroft
Meghan Colasanto
Jennifer Coleman
Melissa Collins
Melissa Conners
Rebecca Conrad
Cathy Consolo
Ilaria Conti
John Corradi
Hilary Cortes
William Corwin
Ana Luiza Costa Zaninotto
Barbara Coughlin
Marci Crandall
Roberto Crespo
Lori Cykowski
Chaofeng Dai
Vivian Dai
Gregory Dalton-Kay
Barbara Daniels
Sayantan Dasgupta
Kim Davenport
Albert DeBerardinis
Lynn Decarr
Samantha Del Vecchio
Robin DeWalt
Shelley Diaz
Nicholas DiGiacomo
Katie Digianantonio
Erin Dominy
Hanqing Dong
Chuck Donnelly
Madeline Dorso Kelly
Connie Doss
Suzette Dowling
Brittany Driscoll
Jacqueline Dunn
Elizabeth Duperret
Laura Dusatko
Lydia Dwyer
Sarah Eaton
Thomas Eckland
Michelle Edwards
Christine Edwards
Lisa Evans
Samantha Falcioni
Kathleen Farmer
Dawn Farrell
Arman Fathizadeh
Caterina Ferraro
Melissa Fezer
Yetty Folami
Mary Ellen Foran
Patrick Fredericksen
Jared Freedberg
Jenny Frenette
Karem Friedman
Renee Galardy
Felipe Gallego
Samantha Galster
Cecile Galvin
Yosif Ganat
Sachita Ganesa
Yu-Jing Gao
Peter Gareiss
James Geib
Stacey Gellatly
Samuel Gerritz
Barbara Ghent

ARVINAS

Christopher Gilson
Raghav Giri
Theresa Gold
Lindsey Gomer
Jiachang Gong
Marc Goodman
Deborah Gordon
Dea Gorka
Sheryl Gough
Mangesh Goundalkar
Maria Grasic
James Gregory
John Grosso
Jeffrey Grotzke
Shiva Guduru
Valerie Guss
Rachel Hardy
Roy Haskell
Jerome Hayes
Diane Healey
Peter Hegan
Adam Hendricson
James Herrington
Jacob Herskowitz
Christopher Hickey
Rod Hill
Rebecca Hill
Matt Hitzeman
Keith Hornberger
John Houston
Yongqing Huang
Kari Hunter
Linus Hyun
Alexey Ishchenko
Bradford Ives
Susan Ivie
Bryan Jackson
Gardison Jean
Joanna Jennens
Yeontae Jeong
Zhirong Jiang
Jason Jiang
Terry Johnson
Christine Jones
Ignacio Juncadella
Jaejoon Jung
Brian Jurczyk
Denise Jurczyszak
Agnes Kairer
Puneet Kapoor
Janice Kapty
Rushad Karanjawala
Fazlul Karim
William Kattell
Stefanie Keenan
Kaela Kelly
Charles Kelly
Jeffrey Kessler
Seaho Kim
Crystal Kim
Ngaire Kimball
Lida Kimmel
Dana Klug
Elena Kostenko
Michael Krampitz
Jessica Kraus
Deborah Kroeger
Christopher Kuhlberg
Bob Kyne
Barbara Labbe
Michael Lachowicz
Guy Laidig
Sean Landrette
James Landro
Anna Langhorne
David Langley
Brad Lanoue
Sarah LeBoeuf

ARVINAS

Marie Leimkuhler
Mary Leung
Tong Li
David Liang
Renee Lichtenstein
Gwenda Ligon
Hannah Lin
Ram Lingamaneni
Xu Liu
Xu Liu
David Loomis
Andrea Lopez-Arroyo
Darin Lory
Haolan Lu
Christine Lubeski
Jessica Lucchina
Margit MacDougall
Lauren Main
Daisy Maldonado-Ortiz
Shelley Mandigo
Mahnaz Manouchehrabadi
Bernadette Martinez
Josefina Martinez-Webster
Kimberly Masi
Eric Masson
Michele Matchett
Elias Mattas
Kathleen McAvoy
Claire McCall
Michael McCarthy
Tim McCloskey
Katie Medici
Jesus Medina
Francesco Meghini
Nichole Melia
Jacques Mercier
Diana Mesnil
Gabriella Miklossy
Mike Mitchell

Jeffrey Montgomery
Lisa Moore
Russell Moore
Alexis Moran
Alicia Morgan
Patri-ca Morgan
Kathleen Murphy
Jim Myslik
Garrett Naumann
Morgan Neydorff
Chu Ngo
Debra Nickischer
Michelle Nophsker
John Northcott
Nicole Northrop
Peter Nower
John Obourn
Kristin Ocampo
Arthur O'Connor
Elsie Odishaw
Matthew Oliynik
Kayla Osbourne
Sobayo Osifeso
Kirsten Owens
Kelly Page
Darrin Parada
Janaki Parameswaran
Aaron Parent
Edward Park
Swapnil Parmar
Achal Pashine
Avani Patel
Nitin Patel
Parth Patel
Priya Patel
Guddi Patel
Vaibhav Patel
Bina Patel
Goutham Pattabiraman

ARVINAS

Jason Pattis
Shahar Pedahzur
Stephanie Pelkey
Amarilis Perez
Susan Perucci
Jamie Phillips
Odette Pirayev
Jennifer Pizzano
Lalitha Podila
Craig Polson
Jessica Pontbriand
Kerline Poulard
Richard Prejean
Sarah Prophet
Cynthia Purington
Connor Quinn
Shari Rabenstine
Vrushal Rakshe
Jennifer Ranciato
Madeleine Ratte
Kim Raymer
Max Reeve
Natalie Reinhardt
Stephanie Renzullo
Joseph Reo
Dustin Revell
Denis Reyna Ruiz
Robert Riccio
Eileen Rich
Paul Richardson
Lisa Ritz
Thania Rivera
Carlos Rivera
Zully Rivera-Pacheco
Kaitlynn Robling
Bianca Rodriguez
Daniel Rogoz
Charlie Romano
Emma Rousseau
Meghan Rubin
Brenda Ryan
Elizabeth Sachatello
Andrew Saik
Alex Santini
Andrew Sargent
Jennifer Schreiber
Jeremy Schreiner
Nicole Schroeder
Joe Sciacchitano
James Sciortino
Morena Scopel
Alexander Scott
Shiva Sekhar
Bassem Shebl
Dan Sherman
Matthew Silverman
Robert Simpson
Lisa Sinclair
Jennifer Singer
Anusha Sivaramakrishnan
Brian Slafer
Katie Smith
Dina Smith
Sierra Soletsky
Leofal Soto
Kristi Spitzmueller
Linda Stephens Stramiello
Cory Stiff
Thomas Storz
Chris Strom
Antonella Stroppa
Noelle Strzalkowski
Artur Sztyler
Molly Szymaszek
Brian Tanaka
Susan Tang
Marianne Tanious
Sarah Tannenbaum-Dvir

ARVINAS

Elizabeth Tanner
Jing Tao
Ian Taylor
Randy Teel
Jessica Teh
Siew Teo
Soweto Thomas
Towyana Thomas
Samantha Tice
Lyuben Tsvetkov
Brianna Tucker
Anika Tylek
Christopher Ullum
Chandravathi Vage
Anna Van Acker
Barbara van Leeuwen
Laura Vasu
Murti Vemuri
Krithika Venkataraman
Nick Vitale
Gan Wang
Joe Wang
Chenchi Wang
Yuhong Wang
Janet Wang
Robert Wdowik
Cathy Weber
Kimberly Wehger
Steve Weiss
Alexander Wellems
Victoria Wetherby
Tyler Whisman
Michelle Wieczorek
Rashaun Wilson
Scott Wirth
Elizabeth Wolf
Christine Woodard
Caroline Woodward
Eric Wright
Wendy Wu
Alissa Wynne
Hong Xiao
Michael Yan
Song Yang
Paul Young Jr
Tinghui Yu
Lin Yuan
Huda Zahid
George Zhang
Yuanyuan Zhang
Jin Zhang
Eric Zhi
Joe Zhou
Kurt Zimmermann
Min Zou

The content of this document is confidential and is not to be used beyond its intended use.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE TRANSITION PERIOD FROM TO .

Commission File Number: 001-38672

ARVINAS, INC.

(Exact name of registrant as specified in its Charter)

Delaware	**47-2566120**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
5 Science Park **395 Winchester Ave.** **New Haven, Connecticut**	**06511**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (203) 535-1456

Securities registered pursuant to Section 12(b) of the Act:

(Title of each class)	Trading Symbol(s)	(Name of each exchange on which registered)
Common stock, par value $0.001 per share	ARVN	The Nasdaq Global Select Market LLC

Securities registered pursuant to Section 12(g) of the Act:

None
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No x

As of June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the Common Stock held by non-affiliates of the registrant was approximately $1,293.4 million, based on the closing price of the registrant's Common Stock on such date. The number of shares of registrant's Common Stock, $0.001 par value per share, outstanding as of February 20, 2024 was 68,083,928.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report incorporates by reference information from the definitive Proxy Statement for the registrant's 2024 Annual Meeting of Stockholders, which is expected to be filed with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2023.

4J

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH Not applicable	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: BioMimetic Therapeutics, LLC

Physical Address: 389 Nichol Mill Lane

City: Franklin State: TN Zip: 37067

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

City: State: Zip:

Telephone: 214-287-4694 Website: www.stryker.com

Name of Designated Representative (DR): Russ Hancock

Licensing Company Email: statelicensing1@stryker.com DR Email: russ.hancock@stryker.com

Entitles the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Surgical Centers		■ Others: Virtual Manufacturer

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gr[illegible] including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) with at least 10% interest or partners with any interest, ever been denied a license, permit c[illegible]		✓
3. Has the corporation, any owner(s), share[illegible] with at least 10% interest or partners with any interest, ever been subject of an administr[illegible] the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholde[illegible] with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or er[illegible] nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or p[illegible]s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Not applicable

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

NATHAN W. PERRY STATE OF TENNESSEE NOTARY PUBLIC MAURY COUNTY, TENN.

Comm. Expires 5/21/2025

Original Signature (electronic, copies or stamps not accepted)

17 JUN 2024

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Not applicable - no pharmaceutical products

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): Wright Medical Technology Inc. and then publicly traded Stryker Corporation (SYK)

Corporation Name: BioMimetic Therapeutics, LLC

Mailing Address: 389 Nichol Mill Lane

City: Franklin State: TN Zip: 37067

Telephone: 214-257-4694 Email: austin.ke@stryker.com

Contact Person Name: Austin Ke

Date of SEC Registration: 1979 | SEC Registration Number: 001-13149 | Stock Exchange Symbol: SYK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/ **Not applicable; 100% corporate owned**		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** **Not applicable; no CS**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. **Not applicable; FDA Registered**		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. **FDA Registered; $25k bond attached**		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

BioMimetic Therapeutics, LLC

Facility Name

Russell Hancock

Print Name of Authorized Person Submitting Application

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

17 June 2024

Date

comm. expires 5/21/2025

NATHAN W. PERRY
STATE OF TENNESSEE
NOTARY PUBLIC
MAURY COUNTY, TENN

Board Use Only	Date Received: 10/7/24	Amount: $1000-ck 13170

Nevada Section 2: History of Company

Qualifiers:

3: Applicant does not manufacture/distribute pharmaceuticals.

4: Applicant does not manufacture/distribute controlled substances.

FDA

FDA Registration

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
BIOMIMETIC THERAPEUTICS,LLC
389 Nichol Mill Ln
FRANKLIN, TN 37067
Registration Number: 3003897776
FEI Number*: 3003897776
Status: Active
Date Of Registration Status: 2024

Owner/Operator:
STRYKER CORP.[6]
1901 Romence Pkwy
Portage, MI US 49002
Owner/Operator Number: 1811755[7]

Official Correspondent:
Leslie Fitch
1023 Cherry Road
Memphis, TN 38117
Phone: 1-901-4875295

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

---

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&Product
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&Product

Page Last Updated: 09/23/2024

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training an Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of **Health & Human Services**

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&Product
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperatorName=&Product

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BIOMIMETIC THERAPEUTICS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FIFTH DAY OF AUGUST, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "BIOMIMETIC THERAPEUTICS, LLC" WAS FORMED ON THE FIFTEENTH DAY OF NOVEMBER, A.D. 2012.

Jeffrey W. Bullock, Secretary of State

5242389 8300

SR# 20243502183

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204236679

Date: 08-25-24

BIOMIMETIC THERAPEUTICS, LLC
Officer List with Percent Owned

Name	Role	% Owned
Menon, Viju	Officer	0%
Stiles, Spencer S.	Officer	0%

BioMimetic Therapeutics LL
Ownership List with ercent Owne

Wright Medical Technology Inc. and then publicly traded Stryker Corporation (SYK) 100%

10542

08/31/2026

Home State License

BIOMIMETIC THERAPEUTICS, LLC
389 NICHOL MILL LANE
FRANKLIN, TN 37067

State of Tennessee
Department of Health

14066654

Renewal No 35445

Board of Pharmacy
Manufacturer

BIOMIMETIC THERAPEUTICS, LLC
389 NICHOL MILL LANE,
FRANKLIN, TN 37067

This is to certify that all requirements of the State of Tennessee have been met

ID NUMBER: 10542

EXPIRATION DATE: August 31, 2026

MEDICAL DEVICES

Commissioner, Dept. of Health

Jennifer L. Putnam, Esq
Assistant Commissioner, Health Licensure & Regulation

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 01/22/2024

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

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

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. MSC#17382 Aon PO Box 1447 Lincolnshire IL 60069 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Stryker Corporation & Subsidiaries 1941 Stryker Way Portage MI 49002 USA	INSURER A: Old Republic Insurance Company	24147
	INSURER B:	
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570103677315 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY31274724	02/01/2024	11/01/2024	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$100,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						MED EXP (Any one person)	Excluded
	X POLICY PRO-JECT LOC						PERSONAL & ADV INJURY	$2,000,000
	OTHER						GENERAL AGGREGATE	$3,000,000
							PRODUCTS - COMP/OP AGG	$3,000,000
A	AUTOMOBILE LIABILITY			MWTB 312744 24	02/01/2024	11/01/2024	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / HIRED AUTOS ONLY / X Phys Dmge-Self Insd						BODILY INJURY (Per accident)	
	SCHEDULED AUTOS / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			MWC31274324	02/01/2024	11/01/2024	X PER STATUTE OTH-ER	
	Y/N			AOS				
A	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) N	N/A		MWXS31274524	02/01/2024	11/01/2024	E.L. EACH ACCIDENT	$1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below			Excess WC - MI			E.L. DISEASE-EA EMPLOYEE	$1,000,000
				SIR applies per policy terms & conditions			E.L. DISEASE-POLICY LIMIT	$1,000,000

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

FOR INFORMATIONAL PURPOSES ONLY

CERTIFICATE HOLDER

Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central Inc.

Holder Identifier :

Certificate No : 570103677315

©1988-2015 ACORD CORPORATION. All rights reserved.

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: BioMimetic Therapeutics, LLC — MDEG License # (if applicable): Not Applicable

Physical Address: 389 Nichol Mill Lane

City: Franklin — State: TN — Zip: 37067

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

City: — State: — Zip:

Telephone: 629-899-3734 — Website: www.stryker.com

Licensing Company Email: statelicensing1@stryker.com

Section 2: Personal Information

First: Russell — Middle: J — Last: Hancock

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

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

Mailing Address: [redacted]

City: Franklin — State: TN — Zip: 37064

Telephone: 629-899-3734 — Email: russell.hancock@stryker.com

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

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

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? **Not applicable**		

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

School Name		From - To (MM/YY – MM/YY)	
New York University		8/2010 - 05/2015	
Address	City	State	Zip
44 West 4th Street	New York	NY	10012
Diploma/Degree obtained, if any			
Masters of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Arizona State UNiversity		8/2004 - 5/ 2007	
Address	City	State	Zip
1151 S Forest Ave,	Tempe	AZ	85281
Diploma/Degree obtained, if any			
Bachelors of Science - Supply Chain Management			

School Name		From - To (MM/YY – MM/YY)	
Mercer County Community College		8/2002-5/2004	
Address	City	State	Zip
1200 Old Trenton Rd	West Windsor Twnshp	NJ	08550
Diploma/Degree obtained, if any			
None			

School Name		From - To (MM/YY – MM/YY)	
West Windsor Plainsboro High School South		9/1999 - 6/2002	
Address	City	State	Zip
346 Clarksville Rd	Princeton Junction	NJ	08550
Diploma/Degree obtained, if any			
High School Diploma			

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2021-Current	[redacted]	Franklin	TN	37064
5/2020-10/2021		Boonton	NJ	07005
4/2018-5/2020		Fremont	CA	94536
10/2016-4/2018		Tuttlingen	Germany	78532
8/2007-10/2016		Boonton	NJ	07005
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
BioMemetic Therapeutics, LLC (Stryker Employment Company LLC)			10/2021-Current
Business Address	**City**	**State**	**Zip**
389 Nichol Mill Lane	Franklin	TN	37067
Phone	**Title**	**Number of Employed Hours**	
629-899-3734	Sr Director, F&A Division Operations Leader and Site Lead	5,200	
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Stryker Trauma and Extremities (Stryker Employment Company LLC)			6/2020-10/2021
Business Address	**City**	**State**	**Zip**
325 Corporate Drive Mahwah	Mahwah	NJ	07430
Phone	**Title**	**Number of Employed Hours**	
629-899-3734	Sr Manager. Global Manufacturing Integration Lead	2,950	
Description of Duties			
See attached Resume			

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

I, Russell Hancock, **certify that as the MDEG Administrator for**

BioMemetic Therapeutics, LLC,

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

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

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

Russell Hancock

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

17 JUN 2024

Date

Comm expires 5/21/2025

NATHAN W. PERRY STATE OF TENNESSEE NOTARY PUBLIC MAURY COUNTY, TENN.

Board Use Only	Date Received: 10/7/24

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

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

This is in response to Question # _____. Provide all the following *where applicable*: Not applicable

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

17 JUN 2024
Date

[redacted]

Russell J. Hancock

[redacted]
Franklin, TN

Accomplished manufacturing operations leader with 15+ years of experience in the medical device industry. Have led manufacturing operations in facilities across the US, as well as manufacturing integration roles in Europe and US, ranging in size from 60-250 employees.

Have led and influenced teams across time zones, geographies, and cultures. Specializing in operational strategic planning, change management, manufacturing and cultural integration of new acquisitions, and driving cost and efficiency improvements through operations excellence and lean principles.

Passionate about developing and mentoring talent by driving transparent and direct communication, while cultivating a culture of constant feedback and accountability across all levels, resulting in the team delivering high results through challenging and meaningful projects/tasks.

EXPERIENCE

Stryker, Global Quality & Operations – Trauma & Extremities **Franklin, TN** **April 2021 - Present**

Director – Division Operations Leader & Manufacturing Integration – Foot and Ankle

Serving as the single point of contact between the Foot and Ankle commercial division (Sales, Marketing, R&D) and the supply organization Global Quality and Operations (Manufacturing, Quality, Supply Planning, Sourcing, Advanced Ops, distribution). Leading a cross-functional team to drive alignment with the commercial team on strategy, priorities, and goals in order to remove obstacles and solve problems which will enable high quality supply of product and on-time NPIs to our customers. Also, serving as the site leader for the Franklin facility responsible for the planning, supply, and testing of our flagship biologics brand.

- Led GQO functions in preparation and ramp up for Foot &Ankle largest ever product launch - ASC platform
- Serve as GQO conduit on business development due diligence on company/asset acquisitions and distribution deals
- Align global supply chain on commercial priorities, through strategy deployment on site expansion/transfer, capex investments, product transfer for additional capacity, product lifecycle management/obsoletion, etc.
- Escalate and mitigate significant supply and backorder risks due to quality issues, underperforming suppliers, natural disasters, macro raw material supply disruptions

Stryker, Global Quality & Operations – Trauma & Extremities **Mahwah, NJ** **June 2020 - November 2022**

Global Manufacturing Integration Leader – Sr. Manager

Served as Stryker's Global Manufacturing Integration Leader for SYK's largest acquisition to date, a $5.5B deal. Responsible for fully integrating 7 manufacturing facilities across 3 countries into various SYK company programs, including: Organizational Design, EHS, Manufacturing Excellence, Financial reporting & acumen, employee engagement, automation and digitization.

- Led consolidation and transfer of two manufacturing sites into the SYK network
- Met all deal model deliverables in year 1 and 2 within Manufacturing workstream and roll-up of the global acquisition
- Implemented all organizational design changes required to meet the SYK standard structure, which included additions and eliminations of role, changes in roles and responsibilities, and interactions across the hybrid model.
- Served as integration partner on developing the newly acquired plant goals, strategy, and investment plans with the respective local plant leadership teams
- Conducted coaching and training sessions as well as mentorship to local leadership teams and front-line managers to shift culture, behavior, and process to that of the SYK standards
- Led team that developed, trained, and launched full MDI process, including Leader Standard Work, 6S, SPS toolkit

Stryker, Global Quality & Operations – Neurovascular **Fremont, CA** **April 2018 – June 2020**

Sr. Operations Manager/GQO Site Lead

Served as GQO site lead for Manufacturing and support teams of 60+ employees. Managed an absorption-based P&L of ~$22M per year in COGM.

- Operating Income results vs. Budget/Projection: 2018 - $5.5M / $1.8M favorable, 2019RR - $4M / $1.8M favorable
- 2019 Standard cost reduction on Extrusion portfolio of 47%, Stents +3% (scrap driven)
- Planned, facilitated, and executed workforce management ramp-down in coordination with manufacturing transfer to Salt Lake City Facility
- Served as conduit between operations and division with 3 successful NPIs in Extrusion/Expansion tubing in lieu of AO (advanced operations) organization
- Achieved increase in Q12 scores (engagement survey) in 2018/2019 (4.32) despite plant closure through direct, transparent communication and commitment to help employees land on their feet by transferring to new positions at other SYK locations
- Developed, trained, and launched partial MDI processes. Daily Tier meetings encompassing manufacturing employees
- Developed and launched visual management system for ENG resource management and task/project prioritization (Cloud)
- Mitigated $900k+ backorder by sponsoring critical Nitinol Supply project in which the team completed a supplier manufacturing transfer 6 months ahead of schedule

Stryker, Global Quality & Operations - Endoscopy **Tuttlingen, Germany** **October 2016 –April 2018**

Sr. Operations Manager, Berchtold (Acquisition)

Served as an integration leader, launching Stryker standards, processes, and norms through a multifaceted role including CI, Project Management and influencing to drive newly acquired site to SYK Culture

- Developed plant goals, strategy, and investment plans with plant leadership team
- Conducted coaching and training sessions with front-line and middle managers to shift culture, behavior, and process to that of the SYK standard
- Launched and implemented 6S program with actions tied to MDI process.
- Developed, trained, and launched full MDI process, including Leader Standard Work, daily Tier 1, 2, & 3, and engineering visual management system, encompassing all local SGS employees
- Implemented monthly recognition program (Tuttlingen CUP) for operators, showcasing improvements derived from MDI
- Facilitated implementation of KanBan systems resulting in 30% decrease in floor space needed for Table Assembly
- Implemented 4-Step cell (single-piece continuous flow) implementation at Light Head assembly, 46% increase in throughput without additional headcount

Project LIGHT - New Greenfield Facility

- Completed current state analysis of space, head count, product flow, employee commutes, etc. to identify opportunities
- Planned and facilitated "Programming" process (completed by SYK Architect), a needs assessment of all users, stakeholders, and decision makers to determine the future needs for the Communications business
- Planned and facilitated "Development Advisory" process (completed by SYK real estate partner) to determine the best strategy and location for additional manufacturing space
- Attended town development planning meetings with SYK team to secure plot of land for potential SYK greenfield site with prominent branding, significant option for expansion, and ideal location to aid in employee's quality of life
- Developed and designed the manufacturing space for increased efficiencies through product flow, equating to 12% reduction in headcount
- Performed data collection and compilation for capital expense request, executive summary, and strategy analysis

Stryker, Global Quality & Operations – Joint Replacement **Mahwah, NJ** **June 2007 – October 2016**

Operations Manager, Baseplate Manufacturing ***September 2012 – October 2016***

Manager of a team of 80+ employees in the manufacturing and support of Tibial Baseplate manufacturing, 1200+ units per day equating to an absorption-based P&L of $14M COGM per year

- Operating income of $700k and $2.5M favorable to budget in 2013 & 2014
- Delivered 2014/2015 standard cost reductions of 3.4% and 6.4% through waste elimination and productivity improvements
- Developed 5-year strategy for baseplate manufacturing and motivated team to execute on planned phases
- Reduced in-cell lead time 55% from 22 days to 10 days. Attained via waste elimination, excess inventory reduction, transport and motion waste reduction, eliminating the ability to overproduce, and allow decision making at the lowest level
- Implemented projects and processes to achieve an in-cell scrap reduction year over year, 23% and 27%, 2014 & 2015
- Increased customer service level from maximum of 81% pre-2012 and >98% in 2014 & 2015
- Championed the Mobile Equipment Critical Safety team
- Led backroom in FDA, BSI, Quality audits from 2012 to 2015
- Set cultural change and continuous improvement strategies by chairing on the Operational Excellence (OPEX) team

Associate Manager, Femoral Manufacturing (rotated between teams) ***October 2009 – August 2012***

Manager of 60+ hourly skilled manufacturing employees on both Femoral production teams across three shifts

- Coached operators on daily production attainment goals and subsequent resource planning
- Built and engaged the team by recruiting top talent, performance managing low performers and investing in training and development of operators
- Coordinated on a daily basis with team planner, operations engineers, and quality engineers to set production targets, expose obstacles, and work together to meet production targets to maintain high service level
- Led quarterly Continuous Improvement Kaizen Events usually lasting 3-5 days in effort to engage hourly operators by allowing them the opportunity to eliminate waste at the lowest level

Material Control Specialist/Planner, Femoral Manufacturing ***June 2007 – October 2009***

- Forecasted and analyzed hospital demand trends on a regular basis to produce and manage 300 knee part numbers ensuring minimal backorders while keeping optimal inventory levels
- Created and maintained various planning tools in Microsoft Excel to schedule, load, expedite, and resource plan based on customer demand and supply commitments. Standardized several tools plant-wide to other planners
- Led team in consistently producing 250 implants per day while decreasing lead time by 43%, from 54 days to 31 days
- Directed validations to approve new processes, equipment, and vendors for Triathlon TS product launches while managing launch commitments without taking customer backorders.

RNR Services, Owner/Advisor **Cranbury, NJ** **August 2005 - Present**

RNR Services, Owner/Operator **Cranbury, NJ** **September 1999 – August 2005**

- Started property maintenance company to include services of lawn care, fertilizing, hardscaping, decks, firewood, snow removal, lighting, and excavation.
- Developed and executed a business plan as a teenager, marketed middle to upper class homeowners in Central New Jersey
- Built business by handling Marketing, Customer Services, Finance/Accounting, Operations, and HR. Altered business plan based on VOC and expanded service offerings.
- Increased client book from 25 to 320 in 5 years, employing up to 14 employees, and grew sales from $14k to $531K in 5 years.
- Currently, business is still run by the family with father, mother, and brother all involved with the daily operations.

EDUCATION

New York University *Leonard Stern School of Business*	**MBA-Master's in Business Administration** Leadership & Change Management Business Management	**2015** GPA 3.5
Arizona State University *W.P. Carey School of Business*	**BS-Bachelor of Science** Supply Chain Management	**May 2007** GPA 3.7

Leadership Training:

Stryker	DE&I - Active Inclusion	2020
Bell Leadership Institute	Great Leaders / Achievers II	2016
Stryker	GQO Academy	2014
Bell Leadership Institute	Achievers I	2013
Gallup Organization	Great Managers Program II	2012
Gallup Organization	Great Managers Program I	2010

ADDITIONAL INFORMATION

- **Systems:** Excel, Power BI, PowerPoint, Oracle, SAP, OneSource, Windchill, ComplianceWire, WorkDay, Kronos
- Environmental Management Systems (ISO) Certified Internal Auditor
- Front Room Facilitator & Backroom Coordinator for Quality Management System audits (FDA, BSI, etc.)
- Stryker Wellbeing Champion
- Stryker Talent Scout – university recruiting and relations
- CPR / First Aid Certified
- Intermediate German
- Global Student Entrepreneur Awards: First Place Student Entrepreneur of 2004 for the East Coast.

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: BioMimetic Therapeutics, LLC

Pharmacy/Wholesaler License # (if applicable): Not applicable; applied for

Physical Address: 389 Nichol Mill Lane

City: Franklin State: TN Zip: 37067

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

City: State: Zip:

Telephone: 629-899-3734 Website: www.stryker.com

Licensing Company Email: statelicensing1@stryker.com

Section 2: Personal Information

First: Russell Middle: J Last: Hancock

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

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

Mailing Address: [redacted]

City: Franklin State: TN Zip: 37064

Telephone: 629-899-3734 Email: russell.hancock@stryker.com

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

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

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? **Not applicable**		

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

School Name		From - To (MM/YY – MM/YY)	
New York University		8/2010 - 05/2015	
Address	City	State	Zip
44 West 4th Street	New York	NY	10012
Diploma/Degree obtained, if any			
Masters of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Arizona State UNiversity		8/2004 - 5/ 2007	
Address	City	State	Zip
1151 S Forest Ave	Tempe	AZ	85281
Diploma/Degree obtained, if any			
Bachelors of Science - Supply Chain Management			

School Name		From - To (MM/YY – MM/YY)	
Mercer County Community College		8/2002-5/2004	
Address	City	State	Zip
1200 Old Trenton Rd	West Windsor Twnshp	NJ	08550
Diploma/Degree obtained, if any			
None			

School Name		From - To (MM/YY – MM/YY)	
West Windsor Plainsboro High School South		9/1999 - 6/2002	
Address	City	State	Zip
346 Clarksville Rd	Princeton Junction	NJ	08550
Diploma/Degree obtained, if any			
High School Diploma			

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2021-Current	[redacted]	Franklin	TN	37064
5/2020-10/2021		Boonton	NJ	07005
4/2018-5/2020		Fremont	CA	94536
10/2016-4/2018		Tuttlingen	Germany	78532
8/2007-10/2016		Boonton	NJ	07005
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
BioMemetic Therapeutics, LLC (Stryker Employment Company LLC)			10/2021-Current	
Business Address		City	State	Zip
389 Nichol Mill Lane		Franklin	TN	37067
Phone	Title		Number of Employed Hours	
629-899-3734	Sr Director, F&A Division Operations Leader and Site Lead		5,200	
Description of Duties				
See attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Stryker Trauma and Extremities (Stryker Employment Company LLC)			6/2020-10/2021	
Business Address		City	State	Zip
325 Corporate Drive Mahwah		Mahwah	NJ	07430
Phone	Title		Number of Employed Hours	
629-899-3734	Sr Manager, Global Manufacturing Integration Lead		2,950	
Description of Duties				
See attached resume				

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? Not applicable		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

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

This is in response to Question # _____. Provide all the following *where applicable*: Not applicable

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

17 JUN 2024
Date

I, Russell Hancock, **certify that as the designated representative for**

BioMimetic Therapeutics, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Russell Hancock

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

17 JUN 2024

Date

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

Russell Hancock

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

17 JUN 2024

Date

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

State of Tennessee, ss. County of Williamson

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

Original Signature Russ Hancock

17 JUN 2024

Date

Subscribed and Sworn to before me this 17th day of June 2024.

Notary Public Signature

NATHAN W. PERRY STATE OF TENNESSEE NOTARY PUBLIC MAURY COUNTY, TENN.

comm. expires 5/21/2025

(Seal)

Russell J. Hancock

[redacted]

[redacted]
Franklin, TN

Accomplished manufacturing operations leader with 15+ years of experience in the medical device industry. Have led manufacturing operations in facilities across the US, as well as manufacturing integration roles in Europe and US, ranging in size from 60-250 employees.

Have led and influenced teams across time zones, geographies, and cultures. Specializing in operational strategic planning, change management, manufacturing and cultural integration of new acquisitions, and driving cost and efficiency improvements through operations excellence and lean principles.

Passionate about developing and mentoring talent by driving transparent and direct communication, while cultivating a culture of constant feedback and accountability across all levels, resulting in the team delivering high results through challenging and meaningful projects/tasks.

EXPERIENCE

Stryker, Global Quality & Operations – Trauma & Extremities **Franklin, TN** **April 2021 - Present**

Director – Division Operations Leader & Manufacturing Integration – Foot and Ankle

Serving as the single point of contact between the Foot and Ankle commercial division (Sales, Marketing, R&D) and the supply organization Global Quality and Operations (Manufacturing, Quality, Supply Planning, Sourcing, Advanced Ops, distribution). Leading a cross-functional team to drive alignment with the commercial team on strategy, priorities, and goals in order to remove obstacles and solve problems which will enable high quality supply of product and on-time NPIs to our customers. Also, serving as the site leader for the Franklin facility responsible for the planning, supply, and testing of our flagship biologics brand.

- Led GQO functions in preparation and ramp up for Foot &Ankle largest ever product launch - ASC platform
- Serve as GQO conduit on business development due diligence on company/asset acquisitions and distribution deals
- Align global supply chain on commercial priorities, through strategy deployment on site expansion/transfer, capex investments, product transfer for additional capacity, product lifecycle management/obsoletion, etc.
- Escalate and mitigate significant supply and backorder risks due to quality issues, underperforming suppliers, natural disasters, macro raw material supply disruptions

Stryker, Global Quality & Operations – Trauma & Extremities **Mahwah, NJ** **June 2020 - November 2022**

Global Manufacturing Integration Leader – Sr. Manager

Served as Stryker's Global Manufacturing Integration Leader for SYK's largest acquisition to date, a $5.5B deal. Responsible for fully integrating 7 manufacturing facilities across 3 countries into various SYK company programs, including: Organizational Design, EHS, Manufacturing Excellence, Financial reporting & acumen, employee engagement, automation and digitization.

- Led consolidation and transfer of two manufacturing sites into the SYK network
- Met all deal model deliverables in year 1 and 2 within Manufacturing workstream and roll-up of the global acquisition
- Implemented all organizational design changes required to meet the SYK standard structure, which included additions and eliminations of role, changes in roles and responsibilities, and interactions across the hybrid model.
- Served as integration partner on developing the newly acquired plant goals, strategy, and investment plans with the respective local plant leadership teams
- Conducted coaching and training sessions as well as mentorship to local leadership teams and front-line managers to shift culture, behavior, and process to that of the SYK standards
- Led team that developed, trained, and launched full MDI process, including Leader Standard Work, 6S, SPS toolkit

Stryker, Global Quality & Operations – Neurovascular **Fremont, CA** **April 2018 – June 2020**

Sr. Operations Manager/GQO Site Lead

Served as GQO site lead for Manufacturing and support teams of 60+ employees. Managed an absorption-based P&L of ~$22M per year in COGM.

- Operating Income results vs. Budget/Projection: 2018 - $5.5M / $1.8M favorable, 2019RR - $4M / $1.8M favorable
- 2019 Standard cost reduction on Extrusion portfolio of 47%, Stents +3% (scrap driven)
- Planned, facilitated, and executed workforce management ramp-down in coordination with manufacturing transfer to Salt Lake City Facility
- Served as conduit between operations and division with 3 successful NPIs in Extrusion/Expansion tubing in lieu of AO (advanced operations) organization
- Achieved increase in Q12 scores (engagement survey) in 2018/2019 (4.32) despite plant closure through direct, transparent communication and commitment to help employees land on their feet by transferring to new positions at other SYK locations
- Developed, trained, and launched partial MDI processes. Daily Tier meetings encompassing manufacturing employees
- Developed and launched visual management system for ENG resource management and task/project prioritization (Cloud)
- Mitigated $900k+ backorder by sponsoring critical Nitinol Supply project in which the team completed a supplier manufacturing transfer 6 months ahead of schedule

Stryker, Global Quality & Operations - Endoscopy **Tuttlingen, Germany** **October 2016 –April 2018**

Sr. Operations Manager, Berchtold (Acquisition)

Served as an integration leader, launching Stryker standards, processes, and norms through a multifaceted role including CI, Project Management and influencing to drive newly acquired site to SYK Culture

- Developed plant goals, strategy, and investment plans with plant leadership team
- Conducted coaching and training sessions with front-line and middle managers to shift culture, behavior, and process to that of the SYK standard
- Launched and implemented 6S program with actions tied to MDI process.
- Developed, trained, and launched full MDI process, including Leader Standard Work, daily Tier 1, 2, & 3, and engineering visual management system, encompassing all local SGS employees
- Implemented monthly recognition program (Tuttlingen CUP) for operators, showcasing improvements derived from MDI
- Facilitated implementation of KanBan systems resulting in 30% decrease in floor space needed for Table Assembly
- Implemented 4-Step cell (single-piece continuous flow) implementation at Light Head assembly, 46% increase in throughput without additional headcount

Project LIGHT - New Greenfield Facility

- Completed current state analysis of space, head count, product flow, employee commutes, etc. to identify opportunities
- Planned and facilitated "Programming" process (completed by SYK Architect), a needs assessment of all users, stakeholders, and decision makers to determine the future needs for the Communications business
- Planned and facilitated "Development Advisory" process (completed by SYK real estate partner) to determine the best strategy and location for additional manufacturing space
- Attended town development planning meetings with SYK team to secure plot of land for potential SYK greenfield site with prominent branding, significant option for expansion, and ideal location to aid in employee's quality of life
- Developed and designed the manufacturing space for increased efficiencies through product flow, equating to 12% reduction in headcount
- Performed data collection and compilation for capital expense request, executive summary, and strategy analysis

Stryker, Global Quality & Operations – Joint Replacement **Mahwah, NJ** **June 2007 – October 2016**

Operations Manager, Baseplate Manufacturing ***September 2012 – October 2016***

Manager of a team of 80+ employees in the manufacturing and support of Tibial Baseplate manufacturing. 1200+ units per day equating to an absorption-based P&L of $14M COGM per year

- Operating income of $700k and $2.5M favorable to budget in 2013 & 2014
- Delivered 2014/2015 standard cost reductions of 3.4% and 6.4% through waste elimination and productivity improvements
- Developed 5-year strategy for baseplate manufacturing and motivated team to execute on planned phases
- Reduced in-cell lead time 55% from 22 days to 10 days. Attained via waste elimination, excess inventory reduction, transport and motion waste reduction, eliminating the ability to overproduce, and allow decision making at the lowest level
- Implemented projects and processes to achieve an in-cell scrap reduction year over year, 23% and 27%, 2014 & 2015
- Increased customer service level from maximum of 81% pre-2012 and >98% in 2014 & 2015
- Championed the Mobile Equipment Critical Safety team
- Led backroom in FDA, BSI, Quality audits from 2012 to 2015
- Set cultural change and continuous improvement strategies by chairing on the Operational Excellence (OPEX) team

Associate Manager, Femoral Manufacturing (rotated between teams) ***October 2009 – August 2012***

Manager of 60+ hourly skilled manufacturing employees on both Femoral production teams across three shifts

- Coached operators on daily production attainment goals and subsequent resource planning
- Built and engaged the team by recruiting top talent, performance managing low performers and investing in training and development of operators
- Coordinated on a daily basis with team planner, operations engineers, and quality engineers to set production targets, expose obstacles, and work together to meet production targets to maintain high service level
- Led quarterly Continuous Improvement Kaizen Events usually lasting 3-5 days in effort to engage hourly operators by allowing them the opportunity to eliminate waste at the lowest level

Material Control Specialist/Planner, Femoral Manufacturing ***June 2007 – October 2009***

- Forecasted and analyzed hospital demand trends on a regular basis to produce and manage 300 knee part numbers ensuring minimal backorders while keeping optimal inventory levels
- Created and maintained various planning tools in Microsoft Excel to schedule, load, expedite, and resource plan based on customer demand and supply commitments. Standardized several tools plant-wide to other planners
- Led team in consistently producing 250 implants per day while decreasing lead time by 43%, from 54 days to 31 days
- Directed validations to approve new processes, equipment, and vendors for Triathlon TS product launches while managing launch commitments without taking customer backorders.

RNR Services, Owner/Advisor **Cranbury, NJ** **August 2005 - Present**

RNR Services, Owner/Operator **Cranbury, NJ** **September 1999 – August 2005**

- Started property maintenance company to include services of lawn care, fertilizing, hardscaping, decks, firewood, snow removal, lighting, and excavation.
- Developed and executed a business plan as a teenager, marketed middle to upper class homeowners in Central New Jersey
- Built business by handling Marketing, Customer Services, Finance/Accounting, Operations, and HR. Altered business plan based on VOC and expanded service offerings.
- Increased client book from 25 to 320 in 5 years, employing up to 14 employees, and grew sales from $14k to $531K in 5 years.
- Currently, business is still run by the family with father, mother, and brother all involved with the daily operations.

EDUCATION

New York University	**MBA-Master's in Business Administration**	**2015**
Leonard Stern School of Business	Leadership & Change Management	GPA 3.5
	Business Management	
Arizona State University	**BS-Bachelor of Science**	**May 2007**
W.P. Carey School of Business	Supply Chain Management	GPA 3.7

Leadership Training:

Stryker	DE&I - Active Inclusion	2020
Bell Leadership Institute	Great Leaders / Achievers II	2016
Stryker	GQO Academy	2014
Bell Leadership Institute	Achievers I	2013
Gallup Organization	Great Managers Program II	2012
Gallup Organization	Great Managers Program I	2010

ADDITIONAL INFORMATION

- **Systems:** Excel, Power BI, PowerPoint, Oracle, SAP, OneSource, Windchill, ComplianceWire, WorkDay, Kronos
- Environmental Management Systems (ISO) Certified Internal Auditor
- Front Room Facilitator & Backroom Coordinator for Quality Management System audits (FDA, BSI, etc.)
- Stryker Wellbeing Champion
- Stryker Talent Scout – university recruiting and relations
- CPR / First Aid Certified
- Intermediate German
- Global Student Entrepreneur Awards: First Place Student Entrepreneur of 2004 for the East Coast.

Biomimetic Employee List

First Name	Last Name
Bedilu	Allo
Lee	Bateman
Julie	Bonomo
Jackson	Booth
Rusty	Colvin
Peter	Di Benedetto
Kaitlin	Dickerson
Michael	Flowers
BETSY	GAVITT
Tamara	Geraci
Russell	Hancock
John	Haywood
Heather	Hensley
Robert	Hinkle
Kayla	Hunt
Michael	Irwin
Corey	Jackson
Michael	Linebach
Rachel	Purdy
Jovelyn	Quiton
Nancy	Rodriguez
Benjamin	Salcido
Amanda	Seidl
Robert	Shockley
Tessa	Trento
Jeremy	Warnick
Fred	Weber
Bezawit	Wodajo

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 001-13149

stryker

STRYKER CORPORATION
(Exact name of registrant as specified in its charter)

Michigan	38-1239739
(State of incorporation)	(I.R.S. Employer Identification No.)
1941 Stryker Way, Portage, Michigan	49002
(Address of principal executive offices)	(Zip Code)

(269) 385-2600
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $.10 Par Value	SYK	New York Stock Exchange
0.250% Notes due 2024	SYK24A	New York Stock Exchange
2.125% Notes due 2027	SYK27	New York Stock Exchange
3.375% Notes due 2028	SYK28	New York Stock Exchange
0.750% Notes due 2029	SYK29	New York Stock Exchange
2.625% Notes due 2030	SYK30	New York Stock Exchange
1.000% Notes due 2031	SYK31	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Emerging growth company	☐
Non-accelerated filer	☐	Small reporting company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $109,722,902,589 at June 30, 2023. There were 380,264,036 shares outstanding of the registrant's common stock, $0.10 par value, on January 31, 2024.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement to be filed with the U.S. Securities and Exchange Commission relating to the 2024 Annual Meeting of Shareholders (the 2024 proxy statement) are incorporated by reference into Part III.

TABLE OF CONTENTS

PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	4
Item 1B.	Unresolved Staff Comments	10
Item 1C.	Cybersecurity	10
Item 2.	Properties	11
Item 3.	Legal Proceedings	11
Item 4.	Mine Safety Disclosures	11
PART II		
Item 5.	Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	11
Item 6.	Selected Financial Data	12
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	21
Item 8.	Financial Statements and Supplementary Data	23
	Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	23
	Consolidated Statements of Earnings	24
	Consolidated Statements of Comprehensive Income	24
	Consolidated Balance Sheets	25
	Consolidated Statements of Shareholders' Equity	26
	Consolidated Statements of Cash Flows	27
	Notes to Consolidated Financial Statements	28
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	41
Item 9A.	Controls and Procedures	41
Item 9B.	Other Information	42
Item 9C.	Disclosure Regarding Foreign Jurisdictions That Prevent Inspections	42
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	42
Item 11.	Executive Compensation	42
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	42
Item 13.	Certain Relationships and Related Transactions, and Director Independence	42
Item 14.	Principal Accountant Fees and Services	42
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	43
Item 16.	Form 10-K Summary	46

PART I

ITEM 1. BUSINESS.

Stryker Corporation (Stryker or the Company) is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually.

Our core values guide our behaviors and actions and are fundamental to how we execute our mission.



Stryker was incorporated in Michigan in 1946 as the successor company to a business founded in 1941 by Dr. Homer H. Stryker, a prominent orthopaedic surgeon and inventor of several medical products. Our products are sold in approximately 75 countries through company-owned subsidiaries and branches as well as third-party dealers and distributors, and include surgical equipment and surgical navigation systems, endoscopic and communications systems, patient handling, emergency medical equipment and intensive care disposable products; clinical communication and workflow solutions; neurosurgical and neurovascular devices; implants used in joint replacement and trauma surgeries; Mako Robotic-Arm Assisted technology, spinal devices, as well as other products used in a variety of medical specialties. Most of our products are marketed directly to doctors, hospitals and other healthcare facilities.

As used herein, and except where the context otherwise requires, "Stryker," "we," "us," and "our" refer to Stryker Corporation and its consolidated subsidiaries.

Business Segments and Geographic Information

We segregate our operations into two reportable business segments: (i) MedSurg and Neurotechnology and (ii) Orthopaedics and Spine. Financial information regarding our reportable business segments and certain geographic information is included under "Consolidated Results of Operations" in Item 7 of this report and Note 14 to our Consolidated Financial Statements.

Net Sales by Reportable Segment

	2023		2022		2021	
MedSurg and Neurotechnology	$ 11,836	58 %	$ 10,611	58 %	$ 9,538	56 %
Orthopaedics and Spine	8,662	42	7,838	42	7,570	44
Total	$ 20,498	100 %	$ 18,449	100 %	$ 17,108	100 %

MedSurg and Neurotechnology

MedSurg products include surgical equipment, patient and caregiver safety technologies, and navigation systems (Instruments), endoscopic and communications systems and reprocessed and remanufactured medical devices (Endoscopy), and patient handling, emergency medical equipment, intensive care disposable products and clinical communication and workflow solutions (Medical). Neurotechnology includes neurosurgical, neurovascular and craniomaxillofacial implant products. Our neurotechnology offering includes products used for minimally invasive endovascular procedures; a comprehensive line of products for traditional brain and open skull based surgical procedures; orthobiologic and biosurgery products, including synthetic bone grafts and vertebral augmentation products (Neuro Cranial); and minimally invasive products for the treatment of acute ischemic and hemorrhagic stroke (Neurovascular). The craniomaxillofacial implant offering includes cranial, maxillofacial and chest wall devices as well as dural substitutes and sealants.

We are one of five leading global competitors in Instruments; the other four being Zimmer Biomet Holdings, Inc. (Zimmer), Medtronic plc (Medtronic), Johnson & Johnson and ConMed Linvatec, Inc. (a subsidiary of CONMED Corporation). We are one of seven leading global competitors in Endoscopy; the other six being Karl Storz GmbH & Co., Olympus Optical Co. Ltd., Smith & Nephew plc (Smith & Nephew), ConMed Linvatec, Arthrex, Inc. and STERIS plc. We are one of five leading global competitors in Medical; the other four being Baxter International Inc., Zoll Medical Corporation, Medline Industries and Ferno-Washington, Inc. We are one of five leading global competitors in Neurotechnology; the other four being Medtronic, Johnson & Johnson, Terumo Corporation and Penumbra, Inc.

Composition of MedSurg and Neurotechnology Net Sales

	2023		2022		2021	
Instruments	$ 2,569	22 %	$ 2,279	21 %	$ 2,111	22 %
Endoscopy	3,033	26	2,725	26	2,418	25
Medical	3,459	29	3,031	29	2,607	27
Neurovascular	1,226	10	1,200	11	1,188	13
Neuro Cranial	1,549	13	1,376	13	1,214	13
Total	$ 11,836	100 %	$ 10,611	100 %	$ 9,538	100 %

In 2023 Instruments launched the Neptune S, which is the only constantly closed low-fluid waste management system on the market. Instruments also saw continued momentum from the launch of the System 9 total joint power tool.

Endoscopy expanded its product offering with the launch of the 4K 1788 Camera platform that features several enhancements for a broader range of clinical applications and specialties, including urology, neurology and ear, nose and throat. In addition, 1788 can be used to visualize indocyanine green and Cytalux.

Medical launched the Xpedition powered stair chair, designed with an integrated workflow for first responders, maintaining the same storage footprint as Stryker's Stair-PRO and enhanced user interface for ease of use. Xpedition allows caregivers to safely and ergonomically move patients over a variety of terrains.

Neurovascular completed the acquisition of Cerus Endovascular Limited (Cerus), a leader in the design and development of neurointerventional devices for the treatment of intracranial aneurysms. The acquisition of Cerus is highly complementary to our Neurovascular business and strengthens our hemorrhagic portfolio globally. Neurovascular also launched the Target Tetra coil in the United States, Japan, Korea and Europe, Middle East, Africa for the treatment of small aneurysms and the Vecta 46 Intermediate Catheter in the United States, Japan and Korea.

Orthopaedics and Spine

Orthopaedics products consist primarily of implants used in total joint replacements, such as hip, knee and shoulder, and trauma and extremities surgeries. We bring patients and physicians advanced implant designs and specialized instrumentation that make orthopaedic surgery and recovery simpler, faster and more effective. We support surgeons with the technology and services they need as they develop new surgical techniques. The Mako Robotic-Arm Assisted Surgical System was designed to help surgeons provide patients with a personalized surgical experience based on their specific diagnosis and anatomy. The Mako System currently offers three applications supporting Partial Knee, Total Hip and Total Knee procedures. Mako is the only robotic-arm assisted technology enabled by 3D CT-based pre-operative planning and, with AccuStop™ haptic technology, Mako provides surgeons the ability to know more about their patients' anatomy so they can cut less in bone preparation and implant placement with intra-operative haptic guidance.

Our spinal implant offering includes cervical and thoracolumbar systems that include fixation, minimally invasive and interbody systems used in spinal injury, complex spine and degenerative therapies. Our spine enabling technologies portfolio includes best in class imaging solutions, image-guided surgical technology, patient specific implants and digital health solutions supporting surgeons and their patients throughout the continuum of care.

We are one of four leading global competitors for joint replacement and trauma and extremities products and robotics, the other three being Zimmer, DePuy Synthes (a Johnson & Johnson company) and Smith & Nephew. We are one of four leading global competitors in Spine; the other three being Medtronic Sofamor Danek, Inc. (a subsidiary of Medtronic), Globus Medical, Inc. (including Nuvasive) and DePuy Synthes.

Composition of Orthopaedics and Spine Net Sales

	2023		2022		2021	
Knees	$ 2,273	26 %	$ 1,997	25 %	$ 1,848	25 %
Hips	1,544	18	1,413	18	1,342	18
Trauma and Extremities	3,147	36	2,807	36	2,664	35
Spine	1,169	14	1,146	15	1,167	15
Other	509	6	475	6	549	7
Total	$ 8,662	100 %	$ 7,838	100 %	$ 7,570	100 %

In 2023 we continued our full commercial launch of the Insignia hip stem. Insignia received approval in Japan from the Pharmaceuticals and Medical Devices Agency and clinical cases occurred in December 2023. With the addition of Japan, Insignia is now being used clinically in six countries worldwide (United States, Canada, Japan, New Zealand, Singapore and Hong Kong). We also saw our first clinical use of the Triathlon Hinge revision knee system in August 2023. The Hinge product helps restore patient mobility in challenging cases and we anticipate moving towards full commercial launch in 2024. In 2023 we celebrated the 10th anniversary of the Triathlon Tritanium Baseplate. Since its introduction in 2013, Triathlon Cementless, which includes the Triathlon Tritanium Baseplate, has delivered a decade of positive patient impact, demonstrated impressive survivorship data and has become a trusted solution for surgeons across the globe.

In 2023 we celebrated the 10-year anniversary of the Mako Surgical Corp. acquisition and the Mako SmartRobotics™ technology. Over the past ten years, this groundbreaking technology has transformed the orthopaedics landscape, resulting in tremendous patient impact for surgeons and their patients. Additionally, we reached the milestone of 1 million Mako SmartRobotics™ procedures performed globally.

Raw Materials and Inventory

Raw materials essential to our business are generally readily available from multiple sources; however, certain of our raw materials are currently sourced from single suppliers. Substantially all products we manufacture are stocked in inventory, while certain MedSurg products are assembled to order.

Patents and Trademarks

Patents and trademarks are significant to our business to the extent that a product or an attribute of a product represents a unique design or process. Patent protection of such products restricts competitors from duplicating these unique designs and features. We seek to obtain patent protection on our products whenever appropriate for protecting our competitive advantage. On December 31, 2023 we owned approximately 5,200 United States patents and approximately 7,700 patents in other countries.

Seasonality

Our business is generally not seasonal in nature; however, the number of orthopaedic implant surgeries is typically lower in the summer months, and sales of capital equipment are generally higher in the fourth quarter.

Competition

In each of our product lines we compete with local and global companies. The development of innovative products is important to our success in all areas of our business. Competition in research involving the development and improvement of new and existing products and processes is particularly significant. The competitive environment requires substantial investments in continuing research and maintaining sales forces.

We believe our commitment to innovation, quality and service and our reputation differentiates us in the highly competitive product categories in which we operate and enables us to compete effectively. We believe that our competitive position in the future will depend to a large degree on our ability to develop new products and make improvements to existing products.

Regulation

Our businesses are subject to varying degrees of governmental regulation in the countries in which we operate, and the general trend is toward increasingly stringent regulation. We are required to comply with the unique regulatory requirements of each country in which we market and sell our products.

In the United States the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act and its subsequent amendments and the regulations issued and proposed thereunder provide for federal regulation by the United States Food and Drug Administration (FDA) of the design, manufacture and marketing of medical devices, including most of our products. In addition, state licensing requirements often apply to certain of our business operations and products. On the federal level, many of our new products fall into FDA classifications that require notification submitted as a 510(k) and review by the FDA before we begin marketing them. Certain of our products require extensive clinical testing, consisting of safety and efficacy studies, followed by pre-market approval applications for specific surgical indications. Certain of our products also fall under other FDA classifications, such as drugs and Human Cells, Tissues, and Cellular and Tissue-Based Products.

The FDA's Quality System regulations set forth standards for our product design and manufacturing processes, require the maintenance of certain records and provide for inspections of our facilities by the FDA. There are also certain requirements of

state, local and foreign governments that must be complied with in the manufacture and marketing of our products.

The European Union enacted the European Union Medical Device Regulation in May 2017 with an original effective date of May 2021, which imposes stricter requirements for the marketing and sale of medical devices, including in the areas of clinical evaluation requirements, quality systems, labeling and post-market surveillance. Extended transition timelines were published in 2023 which range from May 2026 through December 2028 depending on the type of device and our implementation is on track to meet these timelines.

Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. It is not possible to predict at this time the long-term impact of such cost containment measures on our future business. In addition, business practices in the healthcare industry are scrutinized, particularly in the United States, by federal and state government agencies. The resulting investigations and prosecutions carry the risk of significant civil and criminal penalties.

Environment

We are subject to various rules and regulation in the United States and internationally related to the protection of human health and the environment. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe our policies, practices and procedures are properly designed to comply, in all material respects, with applicable environmental laws and regulations. We do not expect compliance with these requirements to have a material effect on purchases of property, plant and equipment, cash flows, net earnings or competitive position.

Employees

On December 31, 2023 we had approximately 52,000 employees globally, with approximately 27,000 employees in the United States. Our talented employees are an integral reason for our standing as a global leader in medical technologies where, together with our customers, we are driven to make healthcare better. Our company values of integrity, accountability, people and performance are a key component of that mission. Our people, as one of our core values, continue to be a key focus.

Our success depends on our ability to attract the best talent. To do so, we continue to focus on creating and maintaining a great workplace. We believe in attracting the right people, maintaining and building employee engagement and developing our employees. We believe when people are able to do what they do best, they will look forward to coming to work and, in turn, will deliver great business results.

Our leadership team and Board of Directors receive regular updates on our people and culture strategy and provide feedback on our strategy and goals, including alignment to our mission and values, peer benchmarking and stakeholder feedback.

Employee Development

Our employee development is extensive and exists at all levels of the organization, including company-wide training on our Code of Conduct, job-related technical training and management and leadership training. Our development programs include on-the-job learning, coaching and mentoring, management and leadership development courses, team building and collaboration training and immersive experiences with expert partners.

We encourage all employees to establish development objectives, in partnership with their manager, to help employees gain the needed development experience to grow their careers.

Employee Engagement

An engaged workplace culture that drives performance and business outcomes is central to our mission. Listening to and learning from our employees forms the foundation of an engaging culture. More than 90% of our employees participate in our annual engagement survey, which provides a valued platform for listening and allows us to take action based on the feedback collected.

We supplement our annual engagement survey with targeted pulse surveys to gather feedback on topics relevant to the current climate. In addition, we establish forums for collecting qualitative feedback to gain insights and identify actions we can take so that employees feel included, engaged and able to achieve their full potential.

We also provide tools and resources that enable managers and teams to act on the insights we gain from our surveys and to drive employee engagement and strong business outcomes.

Diversity, Equity and Inclusion (DE&I)

An essential part of our culture is respecting each individual's strengths and values. Building on this foundation, we are focused on maintaining an inclusive, engaging work environment and prioritizing DE&I in keeping with our values of integrity and people. Our DE&I strategy is centered around these three commitments:

- Strengthen the diversity of our workforce
- Advance a culture of inclusion, engagement and belonging
- Maximize the power of inclusion to drive innovation and growth

We are advancing our commitments through the following actions, among others:

- Increasing access to talent through strategic partnerships and campaigns
- Growing and engaging talent with a range of opportunities to learn and develop
- Aligning our employee resource groups to focus on creating community and belonging

As of December 31, 2023 approximately 38.1% of our employees were women and 27.9% of our employees in the United States identified as racially or ethnically diverse.

Attracting and Hiring

We understand that every employee drives our success. We focus on attracting, identifying and selecting strong candidates who will be successful at Stryker and ensuring that each person we hire brings the talent, expertise and passion we need to continue to be successful.

Health and Safety

Ensuring our employees' safety is a top priority. It is a responsibility that we share throughout the company and one that has evolved to meet the needs of our workforce. Employees' safety risks vary depending on the roles they perform, so we tailor our safety efforts accordingly.

Competitive Pay and Benefits

Our compensation and benefits programs are designed to attract and retain top talent and to incentivize performance and alignment to our mission and values.

We offer market-competitive base pay and benefits to our employees in countries around the world. We regularly evaluate our compensation and benefit offerings and levels, using recognized outside consulting firms to ensure internal fairness and competitiveness in our offerings.

Most of our employees also have variable components to their compensation packages that reward employees based on individual, business unit and/or company-wide performance.

Our proxy statement provides more detail on the competitive compensation programs we offer.

Information about our Executive Officers

As of January 31, 2024

Name	Age	Title	First Became an Executive Officer
Kevin A. Lobo	58	Chair, Chief Executive Officer and President	2011
Yin C. Becker	60	Vice President, Chief Corporate Affairs Officer	2016
William E. Berry Jr.	58	Vice President, Chief Accounting Officer	2014
Glenn S. Boehnlein	62	Vice President, Chief Financial Officer	2016
M. Kathryn Fink	54	Vice President, Chief Human Resources Officer	2018
Robert S. Fletcher	53	Vice President, Chief Legal Officer	2019
Viju S. Menon	56	Group President, Global Quality and Operations	2018
J. Andrew Pierce	50	Group President, MedSurg and Neurotechnology	2021
Spencer S. Stiles	47	Group President, Orthopaedics and Spine	2021

Each of our executive officers was elected by our Board of Directors to serve in the office indicated until the first meeting of the Board of Directors following the annual meeting of shareholders in 2024 or until a successor is chosen and qualified or until his or her resignation or removal. Each of our executive officers held the position above or served Stryker in various executive or administrative capacities for at least five years, except for Mr. Fletcher. Prior to joining Stryker in April 2019, Mr. Fletcher held various legal leadership roles with Johnson & Johnson for the previous 14 years, most recently as the Worldwide Vice President, Litigation.

Available Information

Our main corporate website address is *www.stryker.com*. The information on our website is not incorporated by reference into this report. Copies of our filings with the United States Securities and Exchange Commission (SEC) are available free of charge on our website within the "Investors Relations" section as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*.

ITEM 1A. RISK FACTORS.

This report contains statements that are not historical facts and are considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on current projections about operations, industry conditions, financial condition and liquidity. Words that identify forward-looking statements include, without limitation, words such as "may," "could," "will," "should," "possible," "plan," "predict," "forecast," "potential," "anticipate," "estimate," "expect," "project," "intend," "believe," "may impact," "on track," "goal," "strategy" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, an acquisition or our businesses. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Those statements are not guarantees and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results could differ materially and adversely from these forward-looking statements, historical experience or our present expectations. Some important factors that could cause our actual results to differ from our expectations in any forward-looking statements include:

- weakening of economic conditions, or the anticipation thereof, that could adversely affect the level of demand for our products;
- geopolitical risks, including from international conflicts and upcoming elections in the United States and other countries, which could, among other things, lead to increased market volatility;
- pricing pressures generally, including cost-containment measures that could adversely affect the price of or demand for our products;
- changes in foreign currency exchange markets;
- legislative and regulatory actions;
- unanticipated issues arising in connection with clinical studies and otherwise that affect approval of new products by the FDA and foreign regulatory agencies;
- inflationary pressures;
- increased interest rates or interest rate volatility;
- supply chain disruptions;
- changes in labor markets;
- changes in reimbursement levels from third-party payors;
- a significant increase in product liability claims;
- the ultimate total cost with respect to recall-related and other regulatory and quality matters;
- the impact of investigative and legal proceedings and compliance risks;
- resolution of tax audits;
- changes in tax laws and regulations;
- the impact of legislation to reform the healthcare system in the United States or other countries;
- costs to comply with medical device regulations;
- changes in financial markets;
- changes in our credit ratings;
- changes in the competitive environment;
- our ability to integrate and realize the anticipated benefits of acquisitions in full or at all or within the expected timeframes;
- our ability to realize anticipated cost savings;
- potential negative impacts resulting from climate change or other environmental, social and governance and sustainability related matters;
- the impact on our operations and financial results of any public health emergency and any related policies and actions by governments or other third parties;
- breaches or failures of our or our vendors' or customers' information technology systems or products, including by cyber-attack, data leakage, unauthorized access or theft; and
- other risks detailed in our filings with the SEC.

While we believe that the assumptions underlying such forward-looking statements are reasonable, there can be no assurance that future events or developments will not cause such statements to be inaccurate. All forward-looking statements

contained in this report are qualified in their entirety by this cautionary statement. We expressly disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that affect the likelihood that actual results will differ from those contained in the forward-looking statements.

Our operations and financial results are subject to various risks and uncertainties discussed below that could materially and adversely affect our business, cash flows, financial condition and results of operations. Additional risks and uncertainties not currently known to us or that we currently deem not to be material or that could apply to any company may also materially and adversely affect our business, cash flows, financial condition or results of operations. If any of the risks discussed below or other risks actually occur or continue to occur, our business, financial condition, operating results or cash flows could be materially adversely affected. Accordingly, you should carefully consider the following risk factors, as well as other information contained in or incorporated by reference in this report.

BUSINESS AND OPERATIONAL RISKS

We use a variety of raw materials, components, devices and third-party services in our global supply chains, production and distribution processes; significant shortages, price increases or unavailability of third-party services have in the past increased, and could in the future increase, our operating costs and could require significant capital expenditures or adversely impact the competitive position of our products: Our reliance on certain suppliers to secure raw materials, components and finished devices, and on certain third-party service providers, such as sterilization service providers, exposes us to product shortages and unanticipated increases in prices, whether due to inflationary pressure, regulatory changes, litigation exposure, geopolitical tensions or otherwise. For example, in the past we experienced limited product availability due to an electronic components shortage in certain product lines. If a similar shortage occurs in the future with respect to other raw materials or components, we may not be able to obtain them from our suppliers on a timely basis, or at all, or identify alternative suppliers. In addition, several raw materials, components, finished devices and services are procured from a sole source due to the quality considerations, unique intellectual property considerations or constraints associated with regulatory requirements. If sole-source suppliers or service providers are unable or unwilling to deliver these materials or services as a result of financial difficulties, acquisition by a third party, natural disasters or otherwise, we may not be able to manufacture or have available one or more products during such period of unavailability and our business could suffer. In certain cases, we may not be able to establish additional or replacement suppliers for such materials or service providers for such services in a timely or cost-effective manner, often as a result of FDA and other regulations that require, among other things, validation of materials, components and services prior to their use in or with our products. In certain instances we have been unable to meet demand due to supply chain challenges, which has led to loss of sales. Although the impacts have not been material to date, an inability to meet demand due to supply chain challenges in the future could materially adversely impact our reputation, the competitive position of our products and our business. Any of the foregoing risks could have a material adverse impact on our profitability and results of operations.

In addition, since 2022 the market has experienced increasing inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts following the COVID-19 pandemic. We expect these inflationary pressures will continue. Inflation in the United States and in many of the countries where we conduct business has resulted in, and may continue to result in, higher interest rates and increased capital, energy, shipping and labor costs, weakening or strengthening exchange rates against the United States Dollar and other similar effects. We have experienced, and may continue to experience, inflationary increases in manufacturing costs and operating expenses, as well as negative impacts from weakening or strengthening exchange rates against the United States Dollar. Although we have been able to pass certain cost increases on to our customers, we have not been able to pass along all cost increases and we cannot guarantee that we will be able to do so in the future. Inflation, higher interest rates or interest rate volatility may also cause our customers to reduce or delay orders for our products and services. Any of the foregoing could have a material adverse impact on our sales, profitability and results of operations.

We are subject to pricing pressures as a result of cost containment measures in the United States and other countries and other factors: Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets in which we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. For example, China has implemented a volume-based procurement process designed to decrease prices for medical devices and other products. This has already impacted our joint replacement and spine businesses on a national level, and our trauma and certain neurovascular products on a provincial level, and we expect further adoption of volume-based procurement provincially or nationally in China in 2024. Pricing pressure has also increased due to continued consolidation among healthcare providers, trends toward managed care, the shift toward governments becoming the primary payers of healthcare expenses, reduction in reimbursement levels and medical procedure volumes and government laws and regulations relating to sales and promotion, reimbursement and pricing generally. We have also reduced prices for certain products due to increased competition and if we further reduce prices, we could become less profitable. In addition, due to healthcare industry consolidation in recent years, competition to provide goods and services to industry participants has become, and may continue to become, more intense, and this consolidation has produced, and may continue to produce, larger enterprises with more bargaining power. Pricing pressures related to any of the foregoing or other factors have impacted and could in the future impact our results of operations and profitability.

We operate in a highly competitive industry in which competition in the development and improvement of new and existing products is significant: The markets in which we compete are highly competitive, and a significant element of our strategy is to increase revenue growth by focusing on innovation and new product development. New business models, products and surgical procedures are introduced on an ongoing basis and our present or future products could be rendered obsolete or uneconomical by internal or external technological advances, as we continue to innovate to address physician and patient needs, or by our existing competitors and new market entrants. Our existing competitors and new market entrants may respond more quickly to or integrate new or emerging technologies such as robotics, artificial intelligence and machine learning in their product offerings, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch

new products, our ability to maintain or expand our market position in the markets in which we participate may be negatively impacted.

We may be unable to maintain adequate working relationships with healthcare professionals: We seek to maintain close working relationships with respected physicians and medical personnel in healthcare organizations, such as hospitals and universities, who assist in product research and development. We rely on these professionals to assist us in the development and improvement of proprietary products. If we are unable to maintain these relationships due to regulatory restrictions, hospital access restrictions for non-patients or for other reasons, our ability to develop, market and sell new and improved products could be adversely affected. For example, China's National Health Commission has launched an anti-corruption campaign focused on investigating government officials and individuals employed by state-owned entities and public institutions in the healthcare sector, which has resulted in us seeing some limitations to physician and surgeon access. Although this has not had a material impact on our business, if other jurisdictions were to take this approach, our business could be adversely impacted.

We rely on indirect distribution channels and major distributors that are independent of Stryker: In many markets we rely on indirect distribution channels to market, distribute and sell our products. These indirect channels often are the main point of contact for the healthcare professionals and healthcare organization customers who buy and use our products. Our ability to continue to market, distribute and sell our products may be at risk if the indirect channels become insolvent, choose to sell competitive products, choose to stop selling medical technology, fail to adhere to Stryker requirements or are subject to new or additional government regulation.

We are subject to risks associated with our extensive global operations: We develop, manufacture and distribute our products globally. Our global operations are subject to risks and costs related to, among other things, changes in reimbursement; changes in regulatory requirements (such as the staggered phase-in period for manufacturers to comply with the European Union Medical Device Regulation (MDR) through December 2028); differing local product preferences and product requirements; diminished protection of intellectual property in some countries; tariffs and other trade protection measures, as well as increasing localization and protectionism policies in certain jurisdictions; international trade disputes and import or export requirements; difficulty in staffing and managing foreign operations; introduction of new internal business structures and programs; political and economic instability; current or potential geopolitical conflicts, such as the tensions between China and Taiwan and the wars in Ukraine and the Middle East, and related sanctions and other developments; disruptions of transportation, including port closures, increased border controls or border closures or reduced transportation availability, due to military conflicts, a global pandemic of contagious diseases like COVID-19 or otherwise; increased energy or transportation costs; fluctuations in currency exchange rates and financial markets; and increased security threats to our supply chain. Many of these risks are rapidly evolving and subject to an accelerating pace of change. Our business could be adversely impacted if we are unable to successfully manage these and other risks of global operations in an increasingly volatile environment. In addition, in many countries, the laws and regulations applicable to us or our industry are evolving, and we have in certain cases become subject to divergent and conflicting laws and regulations across our operations, which could increase risk over time.

We may be unable to capitalize on previous or future acquisitions: In addition to internally developed products, we invest in new products and technologies through acquisitions, including our acquisition of Cerus in 2023. Such investments are inherently risky, and we cannot guarantee that any acquisition will be successful or will not have a material unfavorable impact on us. The risks include the activities required and resources allocated to integrate new businesses, diversion of management time that could adversely affect management's ability to focus on other projects, the inability to realize the expected benefits, savings or synergies from the acquisition, the loss of key personnel, litigation resulting from the acquisition and exposure to unexpected liabilities of acquired companies. Certain acquisitions are subject to antitrust and competition laws, and antitrust scrutiny by regulatory agencies and changes to the regulatory approval process in the United States and foreign jurisdictions may cause approvals to take longer than anticipated to obtain, not be obtained at all, or contain burdensome conditions, which may jeopardize, delay or reduce the anticipated benefits of acquisitions to us and could impede the execution of our business strategy. In addition, we cannot be certain that the businesses we acquire will become or remain profitable.

We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site: We rely extensively on information technology (IT) systems to conduct business. In addition, we rely on networks and services, including internet sites, cloud and software-as-a-service solutions, data hosting and processing facilities and tools and other hardware, software (including open-source software) and technical applications and platforms, some of which are managed, hosted, provided and/or used by third parties or their vendors, to assist in conducting our business. Numerous and evolving cybersecurity threats have posed, and will continue to pose, risks to the security of our IT systems, networks and product offerings, as well as the confidentiality, availability and integrity of our data. Some of our products and services, and information technology systems, contain or use open-source software, which poses particular risks, including potential security vulnerabilities, licensing compliance issues and quality issues. We, our customers and third-party hosting services have experienced, and expect to continue to experience, security breaches of, or unauthorized access to, products or systems. While such breaches or unauthorized access have not been material to date, we cannot guarantee that any future breach or unauthorized access will not be material and any breach or unauthorized access could impact the use of such products and systems and the security of information stored therein. Although we have made investments and expect to continue to make investments seeking to address these threats, including monitoring of networks and systems, use of artificial intelligence, hiring of experts, employee training and security policies for employees and third-party providers, the techniques used in these attacks change frequently and may be difficult to detect for periods of time and we may face difficulties in anticipating and implementing adequate preventative measures.

When cybersecurity incidents occur, we follow our incident response protocols and address them in accordance with applicable governmental regulations and other legal requirements. Our response to these incidents and our investments to protect our product offerings and information technology infrastructure and data may not shield us from significant losses and potential liability or prevent any future interruption or breach of our systems. Moreover, given the increasing complexity and sophistication of the techniques used by threat actors to obtain unauthorized access or disable or degrade systems, a cyberattack could occur and persist for an extended period of time before being detected, and we may not anticipate these acts or mitigate them adequately or timely, which may compound damages before the incident is discovered or remediated. The extent of a particular cyber incident and the steps that we may need to take to investigate the incident may

not be immediately clear, and it may take a significant amount of time before such investigation can be completed and full and reliable information about the incident is known. New regulations may require us to disclose information about a material cybersecurity incident before it has been resolved or fully investigated. Additionally, as threats continue to evolve and increase, and as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, we may be required to devote significant additional resources to modify and enhance our security controls and to identify and remediate any security vulnerabilities, which could adversely impact our net income. In addition, a significant number of our employees working remotely has exposed us, and may continue to expose us, to greater risks related to cybersecurity and cyber-liability. If our IT systems are damaged or cease to function properly, the networks or service providers we rely upon fail to function properly, or we or one of our third-party providers suffer a loss or disclosure of our business or stakeholder information due to any number of causes ranging from catastrophic events or power outages to improper data handling or security breaches or unauthorized access and our business continuity plans do not effectively address these failures on a timely basis, we may be exposed to reputational, competitive and business harm as well as litigation and regulatory action.

An inability to successfully manage the implementation of our new commercial global enterprise resource planning (ERP) system could adversely affect our operations and operating results: We are in the process of implementing a new commercial ERP system. This system will replace many of our existing operating and financial systems. The implementation is a major undertaking, both financially and from a management and personnel perspective. Any material disruptions, delays or deficiencies in the design and implementation of our new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

We may be unable to attract, develop and retain executives and key employees: Our sales, technical and other key personnel play an integral role in the development, marketing and selling of new and existing products. Our future performance also depends in large part on the continued services of our senior management. If we are unable to recruit, hire, develop and retain a talented, competitive work force in our highly competitive industry, or if we are unable to plan effective succession for the future, we may not be able to meet our strategic business objectives. Inflationary pressures, labor demand and shortages and other macroeconomic factors have increased and could further increase the cost of labor and could harm our ability to recruit, hire and retain talented employees. In addition, increased unionization could negatively impact our labor costs and ability to create an engaging, connected culture, which could adversely affect our ability to recruit, hire, develop and retain a talented, competitive workforce. Further, if we are unable to maintain competitive and equitable compensation and benefit programs, including incentive programs which reward financial and operational performance, our ability to recruit, hire, engage, motivate and retain talent could be negatively affected. Additionally, if we are unable to maintain an inclusive culture that aligns our diverse workforce with our mission and values, it could adversely impact our ability to recruit, hire, develop and retain key talent. Further, our remote and hybrid work practices, ability to provide flexible and alternative work arrangements, and our practices relating to corporate responsibility may not meet the needs or expectations of our employees, including senior management or other key employees, which could negatively impact our ability to attract and retain highly skilled employees, or may harm our culture and/or decrease employee engagement, which could adversely impact our ability to recruit, hire, develop and retain a talented, competitive workforce.

Effective succession planning is also important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transitions involving executives and other key employees could hinder our strategic planning and execution. Changes in our management team may be disruptive to our business, and any failure to successfully integrate key new hires or promoted employees could adversely affect our business and results of operations. The loss of the services of any of our senior management or other key personnel, or our inability to attract highly qualified senior management and other key personnel, could harm our business. Our ability to execute our business strategy could be impaired if we are unable to replace such persons timely. In addition, recent legal and regulatory changes affect our ability to enforce post-termination obligations from certain employees with respect to non-competition, non-solicitation and protection of confidential information. This may negatively impact our ability to retain employees and protect our information and relationships with customers and other third parties.

Interruption of manufacturing operations could adversely affect our business: We and our suppliers have manufacturing and supply sites all over the world. However, the manufacturing of certain of our product lines is concentrated in one or more plants or geographic regions. We have principal manufacturing and distribution facilities in the United States in Arizona, California, Florida, Illinois, Indiana, Michigan, Minnesota, New Jersey, Puerto Rico, Tennessee, Texas, Utah, Virginia and Washington, and outside the United States in China, France, Germany, Ireland, Mexico, the Netherlands, Poland, Switzerland and Turkey. Damage to our facilities, to our suppliers' or service providers' facilities, or to our central distribution centers as a result of natural disasters, fires, explosions or otherwise, as well as issues in our manufacturing arising from a failure to follow specific internal protocols and procedures, compliance concerns relating to the quality systems regulation, equipment breakdown or malfunction, IT system failures or cybersecurity incidents, environmental hazard incidents or changes to environmental regulations or other factors, could adversely affect the availability of our products. In the event of an interruption in manufacturing, we may be unable to move quickly to alternate means of producing and distributing affected products to meet customer demand. In the event of a significant interruption, we may experience lengthy delays in resuming production or distribution of affected products due to the need for regulatory approvals, and we may experience loss of market share, additional expense and harm to our reputation.

Our insurance program may not be adequate to cover future losses: We maintain third-party insurance to cover our exposure to certain property and casualty losses and are self-insured for claims and expenses related to other property and casualty losses, including product liability, intellectual property infringement and enforcement, environmental, and cybersecurity and data privacy losses. We manage a portion of our exposure to self-insured losses through a wholly-owned captive insurance company. Insurance coverage limits provided by third-party insurers and/or our captive insurance company may not be sufficient to fully cover certain losses we may experience.

We have experienced, and may continue to experience, a significant and unpredictable need to adjust our operations as market demand for certain of our products has shifted and continues to shift or as may be mandated by governmental authorities: Some of our products are particularly sensitive to reductions in elective medical procedures. Elective medical procedures were suspended or reduced at various times during the COVID-19 pandemic in many of the markets where our products are marketed and sold, which negatively affected

our business, cash flows, financial condition and results of operations. It is not possible to predict whether elective medical procedures will again be suspended or reduced in the future and, to the extent individuals and customers are required to delay or cancel elective procedures, our business, cash flows, financial condition and results of operations could be negatively affected. Further, our customers have experienced, and could continue to experience, staffing shortages that may result in decreased demand for our products, which could negatively affect our business and financial results.

In addition, during the COVID-19 pandemic our products in certain divisions, such as Medical, experienced higher demand as our customers were focused on treating COVID-19 patients and preparing for future public health emergencies. Unpredictable increases in demand for certain of our products have exceeded in the past, and could exceed in the future, our capacity to meet such demand timely, which could adversely affect our customer relationships and result in negative publicity. In this regard, the accelerated development and production of products and services to address medical and other requirements could increase the risk of regulatory enforcement actions, product defects or related claims or reputational harm.

Pandemics and public health emergencies, and the fear thereof, have in the past materially adversely affected and could in the future materially adversely affect, our operations, supply chain, manufacturing, product distribution, customers and other business activities: In connection with COVID-19, governmental authorities and private enterprises implemented, and may in the future implement in connection with another pandemic or public health emergency (or in response to the fear thereof), measures, such as travel bans and restrictions, quarantines, shelter-in-place orders and shutdowns. Our customers, global suppliers, distributors and manufacturing facilities have in the past been, and could in the future be, materially affected by restrictive measures implemented in response to a pandemic or public health emergency, which has in the past caused and could in the future cause them to be unable to hire and retain employees, distribute or use our products or provide required services. We have as a result experienced, and could in the future experience, delays in, or the suspension of, our manufacturing operations, sales activities, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions, which may result in our inability to satisfy consumer demand for our products in a timely manner or at all and which could harm our reputation, future sales and profitability. The extent of any future pandemic or public health emergency's effect on our business and industry will depend on, among other things, the severity of the disease, the successful development, distribution and acceptance of vaccines for diseases, future resurgences and/or the spread of disease variants, all of which are uncertain and difficult to predict. The COVID-19 pandemic materially impacted us, and any future pandemic or public health emergency could materially impact us and would heighten many of the other risks described in this report.

LEGAL AND REGULATORY RISKS

Current economic and political conditions make tax rules in jurisdictions subject to significant change: Our future results of operations could be affected by changes in the effective tax rate as a result of changes in tax laws, regulations and judicial rulings. We are continuing to evaluate the impact of tax reform in the countries in which we operate as new guidance is published and new regulations are adopted. In addition, further changes in the tax laws could arise, including as a result of the base erosion and profit shifting project undertaken by the Organisation for Economic Cooperation and Development (OECD). The OECD, which represents a coalition of member countries, has put forth two proposed frameworks—Pillar One and Pillar Two—that revise the existing profit allocation and nexus rules and ensure a minimal level of taxation, respectively. On December 12, 2022, the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15%, and various countries (both within and outside the European Union) have enacted new laws implementing Pillar Two or have proposed legislation. The OECD continues to release additional guidance on the two-pillar framework, with widespread implementation anticipated by 2024. These changes, and any additional contemplated changes, could increase tax expense.

We could be negatively impacted by future changes in the allocation of income to each of the income tax jurisdictions in which we operate: We operate in multiple income tax jurisdictions both in the United States and internationally. Accordingly, our management must determine the appropriate allocation of income to each jurisdiction based on current interpretations of complex income tax regulations. Income tax authorities regularly perform audits of our income tax filings. Income tax audits associated with the allocation of income and other complex issues, including inventory transfer pricing and cost sharing, product royalty and foreign branch arrangements, may require an extended period to resolve and may result in significant income tax adjustments.

The impact of healthcare reform legislation on our business remains uncertain: Several markets where we sell our products are making efforts to expand access to health care or health insurance coverage while decreasing costs. These efforts may have a direct or unintended negative impact on access to medical technology and could have a significant effect on our business. We cannot predict what healthcare programs and regulations could ultimately be implemented at the federal or state level or the effect that any future legislation or regulation in the United States may have on our business. Similarly, we cannot predict the impact that healthcare reform legislation in other countries where we sell our products may have on our business.

We are subject to extensive governmental regulation relating to the classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products: The classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products are subject to extensive and evolving regulations and rigorous regulatory enforcement by the FDA, state governments, European Union and other governmental authorities in the United States and internationally. These governmental authorities may impose additional requirements or limits on the methods, procedures or agents we use to manufacture and sterilize our products, which could have a negative impact on our business. In addition, the process of obtaining licenses, regulatory clearances and/or approvals to market and sell our products can be costly and time consuming and the clearances and/or approvals might not be granted timely. We have ongoing responsibilities under the laws and regulations applicable to the manufacturing of products within our facilities and those contracted by third parties that are subject to periodic inspections by the FDA, state Boards of Pharmacy and other governmental authorities to determine compliance with the quality system, medical device reporting regulations and other requirements. We incur significant costs to comply with regulations, including the MDR. If we fail to comply with applicable regulatory requirements, we may be subject to a range of sanctions, including substantial fines, warning letters that require corrective action, product seizures, recalls, import restrictions, the suspension of product manufacturing or sales, revocation of approvals, exclusion from future participation in government healthcare programs, substantial fines and criminal prosecution.

We are subject to federal, state and foreign healthcare regulations, including anti-bribery, anti-corruption, anti-kickback and false claims laws, globally and could face substantial penalties if we fail to comply with such regulations and laws: The relationships that we, and third parties that market and/or sell our products, have with healthcare professionals, such as physicians, hospitals, healthcare organizations and others, are subject to scrutiny under various state and federal laws often referred to collectively as healthcare fraud and abuse laws. In addition, the United States and foreign government regulators have increased the enforcement of the Foreign Corrupt Practices Act (FCPA) and other anti-bribery and anti-kickback laws. We also must comply with a variety of other laws that impose extensive tracking and reporting related to all transfers of value provided to certain healthcare professionals and others. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to investigate, audit and monitor compliance or to alter our practices. Violations or alleged violations of these laws could result in litigation and we may be subject to criminal or civil penalties and sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in governmental healthcare programs. In 2013 and 2018 we settled claims brought by the SEC related to the FCPA. Pursuant to these settlements, we paid fines and penalties and retained an independent compliance consultant. We continue to implement recommendations that resulted from the independent compliance consultant's review of our commercial practices to enhance our commercial business practices. In addition, we are currently investigating whether certain business activities in certain foreign countries violated provisions of the FCPA and have been contacted by the SEC, United States Department of Justice and certain other regulatory authorities. Although we are currently unable to predict the outcome of the investigations or the potential impact, if any, on our financial statements, the impacts could potentially be significant.

We are subject to privacy, data protection and data security regulations and laws globally, and could face substantial penalties if we fail to comply with such regulations and laws: We are subject to a variety of laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personally identifiable healthcare information. For example, in the United States, privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, including the expanded requirements under the Health Information Technology for Economic and Clinical Health Act of 2009, establish comprehensive standards with respect to the use and disclosure of protected health information (PHI), by covered entities, in addition to setting standards to protect the confidentiality, integrity and security of PHI. Regulators are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the European Union's General Data Protection Regulation (GDPR) established rules regarding the handling of personal data. Non-compliance with the GDPR may result in monetary penalties of up to 4% of total company revenue. Various U.S. states and other governmental authorities around the world have imposed or are considering similar types of laws and regulations, data breach reporting and penalties for non-compliance and increasing security requirements. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to monitor compliance or to alter our practices. As new privacy-related laws and regulations are implemented, the time and resources needed for us to comply with such laws and regulations, as well as our potential liability for non-compliance and reporting obligations in the case of data breaches, have increased and may further increase.

We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements: We are exposed to potential product liability risks inherent in the design, manufacture and marketing of medical devices, many of which are implanted in the human body for long periods of time or indefinitely. We are currently defendants in a number of product liability matters, including those relating to our Rejuvenate and ABGII Modular-Neck hip stems, LFIT Anatomic CoCr V40 Femoral Heads and the product liability lawsuits and claims relating to Wright Medical Group N.V. (Wright) legacy hip products discussed in Note 7 to our Consolidated Financial Statements. These matters are subject to uncertainties and outcomes are not predictable. Further, the European Representative Actions Directive (the Collective Redress Directive), which became effective in 2023, mandates a class action regime in each EU member state to facilitate domestic and cross-border class actions in a wide range of areas, including product liability claims with medical devices. The Collective Redress Directive could result in additional litigation risks and significant legal expenses. In addition, we may incur significant legal expenses or reputational damage for product liability claims regardless of whether we are found to be liable.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products: The medical device industry is characterized by extensive intellectual property litigation and, from time to time, we are the subject of claims of infringement or misappropriation. Regardless of the outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and/or royalty payments or negatively impact our ability to sell current or future products in the affected category.

Dependence on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may impact offerings in our product portfolios: Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, it could allow others to sell products that directly compete with proprietary features in our product portfolio. Also, our issued patents may be subject to claims challenging their validity and scope and raising other issues. In addition, currently pending or future patent applications may not result in issued patents.

MARKET RISKS

We have exposure to exchange rate fluctuations on cross border transactions and translation of local currency results into United States Dollars: We report our financial results in United States Dollars and approximately 25% of our net sales are denominated in foreign currencies, including the Australian Dollar, British Pound, Canadian Dollar, Euro and Japanese Yen. Cross border transactions with external parties and intercompany relationships result in increased exposure to foreign currency exchange effects. While we use derivative instruments to manage the impact of currency exchange, our hedging strategies may not be successful, and our unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the United States Dollar results in favorable or unfavorable translation effects when the results of our foreign locations are translated into United States Dollars.

Additional capital that we may require in the future may not be available to us or may only be available to us on unfavorable terms, which could negatively affect our liquidity: Our future capital requirements will depend on many factors, including operating requirements, current and future

acquisitions and the need to refinance existing debt. Our ability to issue additional debt or enter into other financing arrangements on acceptable terms could be adversely affected by our debt levels, unfavorable changes in economic conditions or uncertainties that affect the capital markets. Changes in credit ratings issued by nationally recognized credit rating agencies could also adversely affect our access to and cost of financing. Higher borrowing costs or the inability to access capital markets could adversely affect our ability to support future growth and operating requirements. In addition, we have experienced, and could in the future experience, loss of sales and profits due to delayed payments or insolvency of healthcare professionals, hospitals and other customers and suppliers facing liquidity issues due to the current macroeconomic environment, type and number of conditions being treated or for other reasons. As a result, we may be compelled to take additional measures to preserve our cash flow, including through the reduction of operating expenses or suspension of dividend payments.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE RISKS

We could be negatively impacted by corporate responsibility and sustainability-related matters: Governments, investors, customers, employees and other stakeholders have been increasingly focused on corporate responsibility practices and disclosures, and expectations in this area continue to rapidly evolve. On occasion, we announce new initiatives, including goals, under our corporate responsibility framework. This framework is aligned with our areas of interest, which include environment and sustainability, social impact, diversity, equity and inclusion and supply chain management, among others. Implementation of these goals and initiatives involves risks and uncertainties, requires investments and depends in part on third-party performance or data that is outside our control. We cannot guarantee that we will achieve our announced corporate responsibility goals and initiatives. The criteria by which our corporate responsibility practices are assessed may change due to the quickly evolving landscape, which could result in greater regulatory requirements or expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Moreover, the increasing attention to corporate responsibility initiatives could also result in reduced demand for our products, reduced profits and increased investigations and litigation. If we are unable to satisfy evolving criteria, investors and other stakeholders may conclude that our policies and/or actions with respect to corporate responsibility matters are inadequate. If we fail or are perceived to have failed to achieve previously announced initiatives or goals, comply with corporate responsibility laws and regulations, meet evolving expectations or accurately disclose our progress, we could face legal and regulatory proceedings and our reputation, business, financial condition and results of operations could be adversely impacted.

Physical effects of climate change or legal, regulatory or market measures intended to address climate change could adversely affect our operations and operating results: Risks associated with climate change are subject to increasing societal, regulatory and political focus in the United States and globally. Shifts in weather patterns caused by climate change are expected to increase the frequency, severity or duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures or flooding, which could cause more significant business and supply chain interruptions, damage to our products and facilities as well as the infrastructure of hospitals, medical care facilities and other customers, reduced workforce availability, increased costs of raw materials and components, increased liabilities and decreased revenues than what we have experienced in the past from such events. In addition, increased public concern over climate change has resulted in certain, and could result in additional, new legal or regulatory requirements designed to mitigate the effects of climate change, which could include the adoption of more stringent environmental laws and regulations or stricter enforcement of existing laws and regulations. Such developments could result in increased compliance costs and adverse impacts on raw material availability and sourcing, manufacturing operations and the distribution of our products, which could adversely affect our operations and operating results.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY.

RISK MANAGEMENT AND STRATEGY

We review cybersecurity risk as part of our overall enterprise risk management program. This ensures that cybersecurity risk management remains a top priority in our business strategy and operations.

MANAGEMENT'S ROLE IN MANAGING RISK

Primary management responsibility for assessing, monitoring and managing our cybersecurity risks rests with our chief information security officer ("CISO"). Our current CISO has over 30 years of experience in information technology including over 20 years in cybersecurity and oversees a team of cybersecurity professionals with over 140 security, risk, and compliance certifications. The CISO is regularly informed about recent developments in cybersecurity, including potential threats and innovative risk management techniques.

The CISO implements and oversees processes for the regular monitoring of our information systems. We use various tools and methodologies to manage cybersecurity risk that are tested regularly. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, penetration tests and threat intelligence feeds. In addition, we engage third-party consultants to conduct annual cybersecurity assessments and to conduct audits for compliance with regulatory, Sarbanes-Oxley Act, Service Organization Control Type 2 and International Organization for Standardization standards. We also engage third parties to assess our cybersecurity maturity and risk management programs.

We use a cross-departmental approach to addressing cybersecurity risk, with our cybersecurity, product security and legal teams presenting quarterly on key topics to a committee of leaders in finance, regulatory, and corporate affairs functions. This leadership committee meets quarterly to ensure that we have input and oversight from critical stakeholders into our cybersecurity program and evolving issues.

The CISO oversees a training and awareness program for employees to take part in protecting the Company against cybersecurity risks. We have implemented annual mandatory security education to help employees understand cybersecurity risks and comply with our cybersecurity policies. Additionally, we provide frequent communications around pertinent cybersecurity topics and policies to all employees. We also provide additional cybersecurity and data protection training to employees in certain roles.

As part of our cybersecurity risk management program, we also conduct cybersecurity and privacy assessments on all third parties who integrate with Stryker's data, network, systems and products. We use a combination of internal and external tools to confirm that these third parties meet our security requirements. We leverage standard industry threat model and privacy impact assessment concepts to confirm that data minimization and adequate data protections are in place. We perform supplemental reviews as necessary, commensurate with the risk associated with each vendor.

In the event of a cybersecurity incident, we have an incident response plan that includes immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents. The cybersecurity and product security teams routinely practice this plan with functions across the organization. We conduct tabletop exercises with senior management, during which we practice the procedures in place to ensure that potentially material cybersecurity risks and incidents are escalated to management and the Board of Directors where applicable.

GOVERNANCE

Cybersecurity risks are overseen by the full Board of Directors and the Audit Committee. The Audit Committee is central to the Board of Directors' oversight of cybersecurity risks and bears the primary responsibility for overseeing cybersecurity risk. The Audit Committee actively participates in strategic decisions related to cybersecurity, offering guidance and approval for major cybersecurity initiatives. This involvement ensures that cybersecurity considerations are integrated into our broader strategic objectives.

Our CISO provides comprehensive updates to the Audit Committee quarterly and the full Board of Directors at least annually. These briefings include a range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events;
- Metrics demonstrating company and industry-standard prevention of common threats; and
- Regulatory changes impacting cybersecurity requirements and strategy.

The Board of Directors is aware of the critical nature of managing risks associated with cybersecurity threats and is actively engaged in our cybersecurity risk management strategy.

RISKS FROM CYBERSECURITY THREATS

Although cybersecurity risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we face numerous and evolving cybersecurity threats in our business. For more information about the cybersecurity risks we face, see the risk factor entitled "We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site" in Item 1A. Risk Factors.

ITEM 2. PROPERTIES.

We have approximately 28 company-owned and 294 leased locations worldwide including 43 manufacturing locations. We believe that our properties are in good operating condition and adequate for the manufacture and distribution of our products. We do not anticipate difficulty in renewing existing leases as they expire or in finding alternative facilities.

ITEM 3. LEGAL PROCEEDINGS.

We are involved in various proceedings, legal actions and claims arising in the normal course of business, including proceedings related to product, labor and intellectual property, and the matters described in more detail in Note 7 to our Consolidated Financial Statements.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the New York Stock Exchange under the symbol SYK.

Our Board of Directors considers payment of cash dividends at its quarterly meetings. On January 31, 2024 there were 2,501 shareholders of record of our common stock.

We did not repurchase any shares in the three months ended December 31, 2023 and the total dollar value of shares that could be acquired under our authorized repurchase program at December 31, 2023 was $1,033.

In the fourth quarter 2023 we issued 5 shares of our common stock as performance incentive awards to employees. These shares were not registered under the Securities Act of 1933 based on the conclusion that the awards were not events of sale within the meaning of Section 2(a)(3) of the Act.

The following graph compares our total returns (including reinvestment of dividends) against the Standard & Poor's (S&P) 500 Index and the S&P 500 Health Care Index. The graph assumes $100 (not in millions) invested on December 31, 2018 in our common stock and each of the indices.



Company / Index	2018	2019	2020	2021	2022	2023
Stryker Corporation	$ 100.00	$ 135.33	$ 159.91	$ 176.26	$ 163.19	$ 202.03
S&P 500 Index	$ 100.00	$ 131.49	$ 155.68	$ 200.37	$ 164.08	$ 207.21
S&P 500 Health Care Index	$ 100.00	$ 120.82	$ 137.07	$ 172.89	$ 166.51	$ 173.00

ITEM 6. SELECTED FINANCIAL DATA.

Statement of Earnings Data	2023	2022	2021	2020	2019
Net sales	$ 20,498	$ 18,449	$ 17,103	$ 14,351	$ 14,884
Cost of sales	7,440	6,871	6,140	5,294	5,188
Gross profit	$ 13,058	$ 11,578	$ 10,968	$ 9,057	$ 9,696
Research, development and engineering expenses	1,388	1,454	1,235	984	971
Selling, general and administrative expenses	7,129	6,455	6,427	5,361	5,356
Recall charges, net	18	(15)	103	17	192
Amortization of intangible assets	635	627	619	472	464
Goodwill impairment	—	216	—	—	—
Total operating expenses	$ 9,170	$ 8,737	$ 8,384	$ 6,834	$ 6,983
Operating income	**$ 3,888**	**$ 2,841**	**$ 2,584**	**$ 2,223**	**$ 2,713**
Other income (expense), net	(215)	(158)	(303)	(269)	(151)
Earnings before income taxes	**$ 3,673**	**$ 2,683**	**$ 2,281**	**$ 1,954**	**$ 2,562**
Income taxes	508	325	287	355	479
Net earnings	$ 3,165	$ 2,358	$ 1,994	$ 1,599	$ 2,083
Net earnings per share of common stock:					
Basic	$ 8.34	$ 6.23	$ 5.29	$ 4.26	$ 5.57
Diluted	$ 8.25	$ 6.17	$ 5.21	$ 4.20	$ 5.48
Dividends declared per share of common stock	$ 3.050	$ 2.835	$ 2.585	$ 2.355	$ 2.135
Balance Sheet Data					
Cash, cash equivalents and current marketable securities	$ 3,053	$ 1,928	$ 3,019	$ 3,024	$ 4,425
Accounts receivable, net	3,765	3,565	3,022	2,701	2,893
Inventories	4,843	3,995	3,314	3,494	2,980
Property, plant and equipment, net	3,215	2,970	2,833	2,752	2,567
Total assets	$ 39,912	$ 36,884	$ 34,631	$ 34,330	$ 30,167
Accounts payable	1,517	1,413	1,129	810	675
Total debt	12,995	13,048	12,479	13,991	11,090
Shareholders' equity	$ 18,593	$ 16,616	$ 14,877	$ 13,084	$ 12,807
Cash Flow Data					
Net cash provided by operating activities	$ 3,711	$ 2,624	$ 3,263	$ 3,277	$ 2,191
Purchases of property, plant and equipment	575	588	525	487	649
Depreciation	393	371	371	340	314
Acquisitions, net of cash acquired	390	2,563	339	4,222	802
Amortization of intangible assets	635	627	619	472	464
Payments of dividends	1,139	1,051	950	863	778
Repurchase of common stock	—	—	—	—	307
Other Data					
Number of shareholders of record	2,518	2,533	2,551	2,597	2,636
Approximate number of employees	52,000	51,000	46,000	43,000	40,000

Dollar amounts in millions except per share amounts or as otherwise specified.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

About Stryker

Stryker is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually. Our goal is to achieve sales growth at the high-end of the medical technology (MedTech) industry and maintain our long-term capital allocation strategy that prioritizes: (1) Acquisitions, (2) Dividends and (3) Share repurchases.

Macroeconomic Environment

The global economy continues to experience increased inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts of the macroeconomic environment which we anticipate will continue. Higher interest rates and capital costs, higher shipping costs, increased costs of labor, fluctuating foreign currency exchange rates and the military conflicts in Russia and Ukraine and the Middle East create additional economic challenges and uncertainties. These conditions may cause our customers to decrease or delay orders for our products and services, and the higher interest rates may impact deal mix for our capital products.

Overview of 2023

In 2023 we achieved reported net sales growth of 11.1%. Excluding the impact of acquisitions and divestitures, sales grew 11.5% in constant currency. We reported net earnings of $3,165 and net earnings per diluted share of $8.25. Excluding the impact of certain items, we achieved adjusted net earnings[1] of $4,066 and adjusted net earnings per diluted share[1] of $10.60 representing growth of 13.5%.

We continued our capital allocation strategy by investing $390 in acquisitions and paying $1,139 in dividends to our shareholders.

In May 2023 we acquired Cerus for net cash consideration of $289 and up to $225 in future milestone payments. Cerus designs, develops and manufactures neurovascular products used for the treatment of hemorrhagic stroke. Cerus is part of our Neurovascular business within MedSurg and Neurotechnology. Refer to Note 6 to our Consolidated Financial Statements for further information.

During 2023 we made payments of $850 to extinguish the remaining balance on the $1.5 billion term loan scheduled to mature February 22, 2025.

In August 2023 we issued €500 of floating rate senior notes due November 16, 2024. The notes bear interest at a rate based on the three-month Euro Interbank Offered Rate (EURIBOR) plus 0.3%. The notes are callable at February 16, 2024, May 16, 2024 or October 16, 2024 either by us or at the option of the notes holders.

In November 2023 we repaid the outstanding €550 principal amount of 1.125% senior unsecured notes due November 30, 2023 and in December 2023 we repaid the outstanding $600 principal amount of 0.600% senior unsecured notes due December 1, 2023. We subsequently issued $600 of 4.850% senior unsecured notes due December 8, 2028 and €600 of 3.375% senior unsecured notes due December 11, 2028.

[1] Refer to "Non-GAAP Financial Measures" for a discussion of non-GAAP financial measures used in this report and a reconciliation to the most directly comparable GAAP financial measure.

CONSOLIDATED RESULTS OF OPERATIONS

				Percent Net Sales			Percentage Change	
	2023	2022	2021	2023	2022	2021	2023 vs. 2022	2022 vs. 2021
Net sales	$ 20,498	$ 18,449	$ 17,108	100.0 %	100.0 %	100.0 %	11.1 %	7.8 %
Gross profit	13,058	11,578	10,968	63.7	62.8	64.1	12.8	5.6
Research, development and engineering expenses	1,388	1,454	1,235	6.8	7.9	7.2	(4.5)	17.7
Selling, general and administrative expenses	7,129	6,455	6,427	34.8	35.0	37.6	10.4	0.4
Recall charges, net	18	(15)	103	0.1	(0.1)	0.6	nm	nm
Amortization of intangible assets	635	627	619	3.1	3.4	3.6	1.3	1.3
Goodwill impairment	—	216	—	—	1.2	—	nm	nm
Other income (expense), net	(215)	(158)	(303)	(1.0)	(0.9)	(1.8)	36.1	(47.9)
Income taxes	508	325	287	nm	nm	nm	56.3	13.2
Net earnings	$ 3,165	$ 2,358	$ 1,994	15.4 %	12.8 %	11.7 %	34.2 %	18.3 %
Net earnings per diluted share	$ 8.25	$ 6.17	$ 5.21				33.7 %	18.4 %
Adjusted net earnings per diluted share[1]	$ 10.60	$ 9.34	$ 9.09				13.5 %	2.8 %

nm - not meaningful

Dollar amounts in millions except per share amounts or as otherwise specified.

4K

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

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

Section 1: General Information

Facility Name: GE Medical Systems Information Technologies, INC.

Physical Address: 465 Pan American Dr. Suite 10

City: El Paso State: TX Zip: 79907

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 915-206-0047 Website: www.gehealthcare.com

Name of Designated Representative (DR): Luis G Guajardo

Licensing Company Email: luis.guajardo@gehealthcare.com DR Email: _____

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	■ Repacker
■ Hospitals	■ [3]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Getemed Medizin-und-Informationstech AG
Address: Oderstraße 77 City: Teltow State: GERM Zip: 14513
Name: Arrow Electronics Inc - OEM Computing Solutions Group (OCS)
Address: 1955 E Sky Harbor Circle N City: Phoenix State: AZ Zip: 85034
Name: Critikon de Mexico S.R.L. de C.V.
Address: Calle Valle del Cedro 1551 City: Juarez State: MX Zip:
Name: WIPRO
Address: No. 4, Kadugodi Industrial Area, Sadaram City: Bangalore State: INDIA Zip: 560067

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): GE HealthCare Technologies INC.
Corporation Name: GE HealthCare Technologies INC.
Mailing Address: 500 West Monroe Street
City: Chicago State: IL Zip: 60661
Telephone: 1-203-360-4369 Email:
Contact Person Name:

Date of SEC Registration: Dec 29, 2022	SEC Registration Number: 001-41528	Stock Exchange Symbol: GEHC

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

GE Medical Systems Information Technologies INC, El Paso TX

Facility Name

Luis G Guajardo

Print Name of Authorized Person Submitting Application

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

12 - Jul - 2024

Date

Board Use Only	Date Received: 7/24/24	Amount: $1000.00

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing
New Search Back To Search Results

Establishment:
GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES
Business Trade Name:
GE Healthcare

465 PAN AMERICAN DR STE 11
EL PASO, TX 79907
Registration Number: 1651104
FEI Number*: 3002737156
Status: Active
Initial Distributer/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2024

Verified 11/5/24 MS

Owner/Operator:
GE HealthCare Technologies Inc.[6]
3000 N. Grandview Blvd
Waukesha, WI US 53188
Owner/Operator Number: 9912004[7]

Official Correspondent:
Tracey Holevas
3000 N. Grandview BLVD
Waukesha, WI 53188
Phone: 262-3092157

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9912004&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishm
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9912004&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishm

Page Last Updated: 06/03/2024

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of Health & Human Services

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9912004&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishm
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9912004&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishm

Summary News Chart Community Statistics Historical Data Profile Financials Analysis Options Holders Sustainability

NasdaqGS - Delayed Quote • USD

GE HealthCare Technologies Inc. (GEHC)

☆ Follow

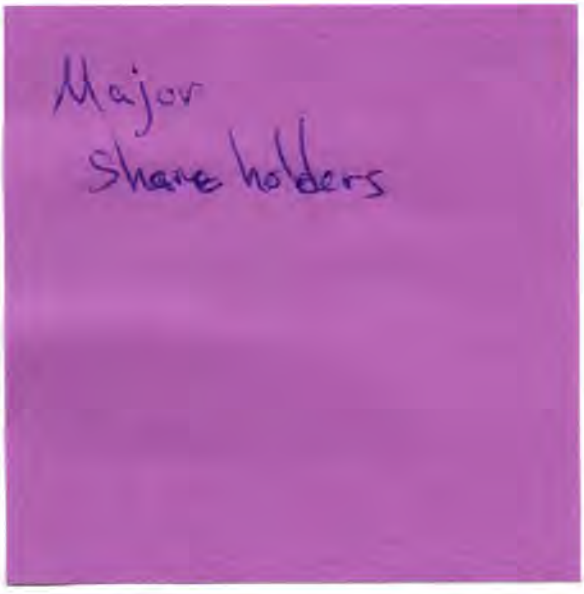
75.97 +1.23 (+1.65%)

At close: 4:00 PM EDT

75.97 0.00 (0.00%)

After hours: 4:05 PM EDT

Major Holders Insider Roster Insider Transactions Insider Sentiment



Major Holders

Breakdown	
6.93%	% of Shares Held by All Insider
77.36%	% of Shares Held by Institutions
83.12%	% of Float Held by Institutions
1,621	Number of Institutions Holding Shares

Top Institutional Holders

Holder	Shares	Date Reported	% Out	Value
Capital Research Global Investors	53.99M	Mar 31, 2024	11.83%	4,101,766,456
Vanguard Group Inc	48.52M	Mar 31, 2024	10.63%	3,686,014,319
Blackrock Inc.	31.05M	Mar 31, 2024	6.80%	2,358,551,970
General Electric Company	30.53M	Mar 31, 2024	6.69%	2,319,463,050
State Street Corporation	19.56M	Mar 31, 2024	4.29%	1,486,007,410
Dodge & Cox Inc	16.81M	Mar 31, 2024	3.68%	1,277,343,191
Price (T.Rowe) Associates Inc	9.96M	Mar 31, 2024	2.18%	756,776,534
Egerton Capital (UK) LLP	8.71M	Mar 31, 2024	1.91%	661,459,709
Geode Capital Management, LLC	8.56M	Mar 31, 2024	1.87%	650,194,877
T. Rowe Price Investment Management, Inc.	8.08M	Mar 31, 2024	1.77%	614,141,337

Top Mutual Fund Holders

Holder	Shares	Date Reported	% Out	Value
Investment Company Of America	21.06M	Mar 31, 2024	4.61%	1,599,897,078
Growth Fund Of America Inc	13.61M	Mar 31, 2024	2.98%	1,034,206,292
Vanguard Total Stock Market Index Fund	13.61M	Mar 31, 2024	2.98%	1,033,841,712
Dodge & Cox Stock Fund	10.71M	Mar 31, 2024	2.35%	813,484,190
Vanguard 500 Index Fund	10.67M	Mar 31, 2024	2.34%	810,749,042
Vanguard Mid-Cap Index Fund	9.4M	Mar 31, 2024	2.06%	714,338,324
Invesco ETF Tr-Invesco QQQ Tr, Series 1 ETF	8.57M	Apr 30, 2024	1.88%	651,048,020
Price (T.Rowe) Capital Appreciation Fund	5.25M	Mar 31, 2024	1.15%	398,492,208
Fidelity 500 Index Fund	5.13M	Apr 30, 2024	1.12%	389,655,682
SPDR S&P 500 ETF Trust	5.01M	Apr 30, 2024	1.10%	380,887,224

Related Tickers

SOLV	VEEV	TDOC	GDRX	DOCS	SDGR	WAY	TXG	HQY
Solventum Corporation	Veeva Systems Inc.	Teladoc Health, Inc.	GoodRx Holdings, Inc.	Doximity, Inc.	Schrödinger, Inc.	Waystar Holding Corp.	10x Genomics, Inc.	HealthEquity, Inc.
56.20 -0.60%	188.91 +0.48%	10.20 -2.30%	8.85 -0.45%	29.66 -0.72%	21.64 +3.05%	21.70 -4.49%	21.35 -1.07%	83.07 -4.42%

yahoo!finance

Copyright © 2024 Yahoo.
All rights reserved.

POPULAR QUOTES
- Dow Jones
- S&P 500
- DAX Index
- Nvidia
- Tesla
- DJT

EXPLORE MORE
- Mortgages
- Credit Cards
- Sectors
- Crypto Heatmap
- Biden Economy
- Financial News

ABOUT
- Data Disclaimer
- Help
- Feedback
- Sitemap
- What's New
- Premium Plans

Board of Directors

H. Lawrence Culp, Jr.

Chairman

Risa Lavizzo-Mourey

Director

Peter J. Arduini

President and CEO

Rodney F. Hochman

Director

Lloyd W. Howell, Jr.

Director

Catherine Lesjak

Director

Anne T. Madden

Director

Tomislav Mihaljevic

Director

William J. Stromberg

Director

Phoebe L. Yang

Director

United States of America

State of Wisconsin

DEPARTMENT OF FINANCIAL INSTITUTIONS

Division of Corporate & Consumer Services

To All to Whom These Presents Shall Come, Greeting:

I, Craig Heilman, Administrator of the Division of Corporate and Consumer Services, Department of Financial Institutions, do hereby certify that

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC.

is a domestic corporation or a domestic limited liability company organized under the laws of this state and that its date of incorporation or organization is July 08, 1965.

I further certify that said corporation or limited liability company has, within its most recently completed report year, filed an annual report required under ss. 180.1622, 180.1921, 181.0214 or 183.0212 Wis. Stats., but that it has not filed a statement or articles of dissolution.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the official seal of the Department on June 18, 2024.

CRAIG HEILMAN, Administrator
Division of Corporate and Consumer Services
Department of Financial Institutions

DFI/Corp/33

To validate the authenticity of this certificate

Visit this web address: https://apps.dfi.wi.gov/apps/ccs/verify/

Enter this code: **391575-5B1F1931**



License Number: 0068094 ***Current Date: 06/12/2024 03:52 PM***

Name:	**GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES**
License Type:	**Dev Manufacturer**
License Status:	**Current**
Expiry Date:	**05/31/2026**
Effective Rank Date:	**04/30/2003**

Addresses

Mailing Address	Address	GE HEALTHCARE EL PASO , TX EL PASO 79907 US
Physical Loc	Address	GE HEALTHCARE 465 PAN AMERICAN DR STE 11 EL PASO , TX EL PASO 79907 US

Food & Drug Owner

Licensee's Role:	**Food & Drug License**
Related Party Role:	**Food & Drug Owner**

Related Party Name	**License**	**Address**
GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES	**Owner #A047481** **Status:** **Current** **Expiration Date:**	EL PASO , TX EL PASO 79907 US

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
12/29/2023

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

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

PRODUCER MARSH USA, LLC. 1166 Avenue of the Americas New York, NY 10036 CN1382335--GAWP-24-24 Y	**CONTACT NAME:** **PHONE (A/C, No, Ext):** **FAX (A/C, No):** **E-MAIL ADDRESS:**
INSURED GE HealthCare Technologies Inc. Including GE Precision Healthcare LLC and all subsidiaries and affiliates 500 West Monroe Chicago, IL 60661	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A :** ACE American Insurance Company — 22667 **INSURER B :** N/A — N/A **INSURER C :** Indemnity Insurance Company of North America — 43575 **INSURER D :** ACE Fire Underwriters Insurance Company — 20702 **INSURER E :** Illinois Union Insurance Company — 27960 **INSURER F :**

COVERAGES **CERTIFICATE NUMBER:** NYC-011538376-10 **REVISION NUMBER:** 10

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			HDO G48332791	01/03/2024	11/01/2024	EACH OCCURRENCE	$	2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						MED EXP (Any one person)	$	10,000
	X POLICY PRO-JECT LOC						PERSONAL & ADV INJURY	$	2,000,000
	OTHER:						GENERAL AGGREGATE	$	4,000,000
							PRODUCTS - COMP/OP AGG	$	EXCLUDED
								$	
A	**AUTOMOBILE LIABILITY**			ISA H10778839	01/03/2024	11/01/2024	COMBINED SINGLE LIMIT (Ea accident)	$	5,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$	
	DED RETENTION $							$	
C	**WORKERS COMPENSATION AND EMPLOYERS' LIABILITY** Y/N			WLR C52075373 (AOS)	01/03/2024	11/01/2024	X PER STATUTE OTH-ER		
A	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N	N/A		WLR C52075300 (AZ)	01/03/2024	11/01/2024	E.L. EACH ACCIDENT	$	2,000,000
D	**(Mandatory in NH)** If yes, describe under DESCRIPTION OF OPERATIONS below			SCF C52075427 (WI)	01/03/2024	11/01/2024	E.L. DISEASE - EA EMPLOYEE	$	2,000,000
							E.L. DISEASE - POLICY LIMIT	$	2,000,000
E	Product Liability(Claims Made)			SPL G47372616 002	01/03/2024	11/01/2024	Per Occ/Combined Single Agg		5,000,000

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

This document to be used for Evidence of Insurance

CERTIFICATE HOLDER

GE HealthCare Evidence of Coverage
GE HealthCare Technologies Inc.
and all subsidiaries and affiliates
500 West Monroe Street
Chicago, IL 60661

CANCELLATION

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

AUTHORIZED REPRESENTATIVE
of Marsh USA LLC

Marsh USA LLC

© 1988-2016 ACORD CORPORATION. All rights reserved.

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG GE Medical Systems Information Technologies INC MDEG License # (if applicable) _____

Physical Address 465 Pan American Dr

City El Paso State TX Zip 79907

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 915-206-0047 Website www.gehealthcare.com

Licensing Company Email luis.guajardo@gehealthcare.com

Section 2: Personal Information

First Luis Middle Gilberto Last Guajardo

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

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

Mailing Address 465 Pan American Dr

City El Paso State TX Zip 79907

Telephone [redacted] Email luis.guajardo@gehealthcare.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Instituto Tecnologico y de Estudios Superiores de Monterrey		Jan 2000 - Dec 2001	
Address	**City**	**State**	**Zip**
Bulevar Tomás Fernández 8945	Juarez	MEXICO	32470
Diploma/Degree obtained, if any			
Master Degree in Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Instituto Tecnologico y de Estudios Superiores de Monterrey		Aug 1994 - Dec 1998	
Address	**City**	**State**	**Zip**
Av. Eugenio Garza Sada 2501 Sur,	Monterrey	MEXICO	64849
Diploma/Degree obtained, if any			
Bachelor degree in Mechanical Engineering			

School Name		From - To (MM/YY – MM/YY)	
Instituto Tecnologico y de Estudios Superiores de Monterrey		Aug 1991 - Jun 1994	
Address	**City**	**State**	**Zip**
Juan de La Barrera 1241	Saltillo	MEXICO	25270
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2019 - present	[redacted]	Juarez	MEXICO	32543
11/2003 - 06/2019		Juarez	MEXICO	32543
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
GE Medical Systems Information Technologies			Apr/2017 - Present day	
Business Address		**City**	**State**	**Zip**
465 Pan American Dr		El Paso	TX	79907
Phone	**Title**		**Number of Employed Hours**	
915-206-0047	QA Site Leader		14,560	
Description of Duties				
See attached				

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

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

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

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

Continue on next page if additional space is needed.

GE Healthcare

JOB TITLE/TYPE: QA SITE LEADER-HC

Function: Quality **Family:** Quality Assurance **Band:** LPB

Description:
A Site Quality Leader is responsible for ensuring quality and regulatory compliance of the facility, while driving process effectiveness and efficiency. The Site Quality Leader represents GE Healthcare to external agencies and champions the evolution of the quality culture for the site.

Key responsibilities include:

- Directing the Site Quality Management System, fully integrated into the GE Global Quality Management System, including cross-functional and site-specific processes. The role is responsible for facility compliance covering voluntary, regulatory and company quality requirem ents and will champion quality initiatives at all levels of the organization.
- Maintaining and improving all aspects of Site Quality Planning.
- Overseeing all Quality-related communications and training requirements for all site employees
- Establishing positive relationships with outside agencies.
- Hosting Quality System audits and inspections.
- Overseeing the Corrective Action / Preventive Action activities and Complaint Handling Programs, and in some cases, Quality Engineering.
- Report on Quality System effectiveness and requirements to management team as required including preparing and executing facility Quality Management Reviews.
- Driving the definition of site quality objectives, metrics, reporting and operating mechanisms.
- Participating in selected global initiatives to share best practices and leverage quality synergies.
- Supporting local R&D programs and quality issue resolution.
- Acting as Management Representative for Quality at the Site.
- Operates a Local Inspection program and manages f/up activities to close NCs.

Quality Specific Goals:

1. Aware of and comply with the GEHC Quality Manual, Quality Management System, Quality Management Policy, Quality Goals, and applicable laws and regulations as they apply to this job type/position.
2. Complete all planned Quality & Compliance training within the defined deadlines.
3. Identify and report any quality or compliance concerns and take immediate corrective action as required.
4. Maintain full Quality System Regulations and Current Good Manufacturing Practices Requirements ensuring compliance to regulations and legal requirements through successful and effective quality management systems.
5. Identify and ensure timely closure of corrective and preventive actions for the site.
6. Participate and represent the Site in external Audits.
7. Mentor and coach direct reports to successful understanding and implementation of Quality System Requirements.
8. Timely communication of all quality concerns, initiatives, and information to the site Management team.
9. Meet specific quality metrics and/or milestones as defined in annual business objectives.

Qualifications:

1. Bachelor's degree in Engineering, Medical Device Technology or Scientific Field (or High School diploma/GED and a minimum of 7 years work experience and understanding of product development, manufacturing, quality control and servicing in a medical equipment environment).
2. Minimum 3 years professional experience and understanding of product development, manufacturing, quality control and servicing in the medical equipment or pharmaceutical industry.
3. Minimum 1 years supervisory/ management experience, including hiring, training, coaching and performance management activities.
4. Hands-on experience with FDA, QSR, ISO, MDD and/or other international quality systems requirements.
5. Proven track record in performing external and internal audits.
6. Ability to read, analyze, and interpret business plans, technical procedures and governmental regulations.
7. Effective report, business correspondence and procedure writing skills.
8. Good problem identification, multivariable analysis and creative resolution aptitude.
9. Proven process development and project management skills.
10. Strong computer skills.
11. Ability to communicate using English.

Preferred Qualifications:

1. Demonstrated experience working in a cross-functional environment and proven ability to influence and build consensus among multiple functions.
2. Experience in a global, matrixed organization structure.
3. Professional certification as a Lead Auditor.
4. Six Sigma training and/or certification.
5. Team player with a global mindset.
6. Strong Change Acceleration skills.
7. Experience in building a Quality System from ground up.
8. Front line operational responsibility in Engineering, Manufacturing or Sourcing.

Electronic Signature Information

Name	DOC2005274
Revision	4
Type	Controlled Document
Title	Appointment Letter Site QA Leader El Paso
Reason For Change	Update for Lisa Sullivan Signature
Originator	212043391_luis__guajardo
Release Date	07/24/2023 05:33:08 PM
Obsolete Date	

File Name	File Description	File Size (Bytes)
DOC2005274- Luis Guajardo delegation of authority.docx	DOC2005274- Luis Guajardo delegation of authority	27957

Route	Signer	Function	Status	Comments	Completion Date
R-10750671	212027835_thomas_j_westrick		Approve	Approved as a Task Assignee	20 Jul 2023 17:11:55 GMT
R-10750671	212060346_lisa_m_sullivan		Approve	Reviewed and Approved	30 May 2023 00:56:58 GMT

Periodic Review

There are no signatures or routes related to this business object.

Obsolesence Approval

There are no signatures or routes related to this business object.

* Printed versions are For Reference Only *
+ Indicates a task was reassigned from an original assignee

Released

GE HealthCare

Delegation of Responsibility for QA Management Representative for Border Operations – El Paso Site

I, Lisa Sullivan, hereby delegate the responsibility for QA site leader and QA management representative for the Border Operations – El Paso, TX site to Luis Guajardo.

This delegation of responsibility is effective May 26, 2023 and shall be valid until further notice.

In this capacity, Luis Guajardo is the representative for and has the authority to:

- Develop, implement, and maintain the local quality system and its associated documentation in accordance with the applicable quality system standards and regulations.
- Report on the performance of the local quality system to management, for review and improvement.
- Ensuring the promotion of awareness of regulatory and customer requirements throughout the organization.
- Represent the GEHC Border Operations – El Paso site on all quality matters within the scope of and pertinent to the quality system.
- Ensuring that the quality policy is understood, implemented, and maintained.
- Direct access to the local executive management.

Tom Westrick
President & CEO, Patient Care Solutions
(Refer to MWS for electronic signature)

Lisa Sullivan

QA Executive, Patient Care Solutions
(Refer to MWS for electronic signature)

Released

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

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

I, Luis G Guajardo, **certify that as the MDEG Administrator for**

GE Medical Systems Information Technologies INC.,

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

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

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

Luis G Guajardo
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12-Jul-2024
Date

Board Use Only	Date Received: 7/24/24

GE Medical Systems Information Technologies in El Paso TX

Employee ID	Full Name	Employee Type	Business Title
212711873	Adrian Salazar	Regular	Material Handler Shipping & Receiving
212041611	Adriana Martinez	Regular	Lead Engineer, Supplier Quality & Development,
212681646	Alan Arreola	Regular	Materials Specialist
212789551	Alejandro Marquez	Regular	Quality Assurance Technician
212057784	Alejandro Oropeza	Regular	Quality Assurance Technician
212026536	Alfonso Carranco	Regular	Configuration Technician
212035147	Alfonso Hernandez	Regular	Material Handler Shipping & Receiving
212044325	Alfonso Reza	Regular	Configuration Technician
212023078	Alfredo Benitez	Regular	Operations Manager
223112549	Ana Conner	Regular	Order Fulfillment Specialist
223100157	ANDREW NGUYEN	Regular	Manufacturing Engineer
212041883	Angel Lerma	Regular	Production Team Leader
212067886	Angel Sanchez	Regular	Shipping Coordinator
223094863	ANNE GUTIERREZ	Regular	Material Handler Shipping & Receiving
212027781	Armando Gonzalez	Regular	Director, Quality, Juarez Site
212418478	Arturo Herrera	Regular	Shipping Coordinator
223081281	Benigno Chavez	Regular	Material Handler Shipping & Receiving

223067814	Bernardo Carrasco	Regular	Fulfillment Coordinator
223052574	BIBIANA HERNANDEZ	Regular	Fulfillment Coordinator
223094760	Bob Oswald	Regular	Material Handler Shipping & Receiving
212761574	Bobby Reynolds	Regular	Material Handler/Cycle Counter
250010370	Carlos Alvarado	Regular	Lead Manufacturing Specialist - Prod Process
212707327	Carlos Barroteran	Regular	Fulfillment Coordinator
208027349	Carlos Escalera	Regular	Manufacturing Engineer I
250004314	CARLOS HERNANDEZ	Regular	Biomedical Technician 1
212577372	Cesar Martinez	Regular	Production Team Leader
223075185	CLIFFORD TANKUH	Regular	Material Handler Shipping & Receiving
250004747	Cuauhtonale Castro	Regular	Materials Handler
212607088	Danny Martinez	Regular	Material Handler Shipping & Receiving
250005200	David Enriquez	Regular	Materials Handler
223110895	David Munoz Ayala	Regular	Sr HR Business Partner, PCS Integrated Supply
212761934	Dionicio Santos	Regular	Material Handler Shipping & Receiving
212029232	Dolores Case	Regular	Fulfillment Manager, ICAR
223102847	Ed Salas	Regular	Operations Manager
212026537	Eduardo Ramirez	Regular	Material Handler Shipping & Receiving
223050517	EDUARDO SAUCEDO	Regular	Material Handler/Cycle Counter

250010951	Eli Montero	Regular	Install Cart Implementation Specialist
212452427	Eloy Chavez	Regular	Manufacturing Engineering Leader
212065282	Emilio Pacheco	Regular	Materials Control Coordinator
212063977	Enrique Pineda	Regular	Executive - Plant Leader Border Operations
212057785	Ernesto Garcia	Regular	Material Handler Shipping & Receiving
212607192	Fernando Bravo	Regular	Global Fulfillment Leader
212681665	Fernando Ponce	Regular	Senior Materials Leader
212021763	Florencio Bermudez	Regular	Material Handler Shipping & Receiving
223036602	Francisco Moreno	Regular	Material Handler Shipping & Receiving
223023433	Francisco Ruiz	Regular	Materials Control Coordinator
212042872	Gilberto Franco	Regular	Demand Planning Leader - Patient Care Solutions
212722417	Gregoria Martinez	Regular	Material Handler Shipping & Receiving
212030266	Irma Ceballos	Regular	Quality Assurance Technician
212769379	Irvin Ibarra	Regular	Material Handler Shipping & Receiving
212363719	Ivan Baylon	Regular	Order Fulfillment Specialist
223080950	James Castrejon	Regular	Material Handler Shipping & Receiving
223110182	Jennifer Chavira	Regular	Fulfillment Coordinator
212022964	Jesus Barraza	Regular	Configuration Technician
212711880	Jose Hernandez	Regular	Quality Assurance Technician

223025290	Jose Montiel	Regular	Material Handler Shipping & Receiving
212323182	Jose Salazar	Regular	Shipping Coordinator
212041930	Jose Sandoval	Regular	Material Handler Shipping & Receiving
223109703	Jose Soto	Regular	Material Handler Shipping & Receiving
212037626	Juan Durand	Regular	Manufacturing Specialist - Material Plan & Execution
223096796	Juan Villa	Regular	Quality Assurance Technician
212432230	Julian Occelli	Regular	Manufacturing Specialist - Material Plan & Execution
223036155	JULIO CASTRO	Regular	Material Handler Shipping & Receiving
223081487	LEONARDO GARCIA	Regular	Material Handler Shipping & Receiving
212037630	Lorenzo Medina	Regular	Material Handler Shipping & Receiving
223080792	Luis Chavez	Regular	Material Handler Shipping & Receiving
212043391	Luis Guajardo	Regular	Sr. Manager, Quality, El Paso Site
212744417	Marco Garcia	Regular	Materials Control Coordinator
212735904	Marisol Tinajero Sanmiguel	Regular	Human Resources Specialist- GE Healthcare
212044233	Martha Cardenas	Regular	Configuration Technician
212364597	Martha Solis	Regular	Material Handler Shipping & Receiving
250004890	Mauricio Olivas	Regular	Materials Handler
212489263	Mayra Rios	Regular	Fulfillment Coordinator
212692662	Memo Arguelles	Regular	Materials Control Coordinator

212037762	Monica Torres	Regular	Director, Supplier Quality & Development, LATAM PCS
212600558	Nadab Veliz	Regular	Lead - Order Fulfillment and Logistics
212021732	Noel Pallares	Regular	Order Fulfillment Leader
212815208	Norma Loya	Regular	Materials Specialist I
223038159	OMAR ALVARADO	Regular	Lead Engineer, Supplier Quality & Development,
212037791	Omar Avila Vazquez	Regular	Lean Operations Manager
212695892	Orlando Rios	Regular	Patient Care Solutions Service Process Leader -
212480208	Pablo Arreola-Galvan	Regular	Lead Quality Assurance Engineer
212450849	Pedro Gonzalez	Regular	Quality Assurance Coordinator
250000961	Pedro Velazco	Regular	Engineering and Design Manager
223048018	Raul Bueno	Regular	Quality Assurance Technician
212329865	Raul Hernandez	Regular	Material Handler Shipping & Receiving
250004748	Raul Montanez	Regular	Materials Handler
212025931	Ricardo Burrola	Regular	Senior Manufacturing Finance Analyst
212026538	Robert Wallace Wallace	Regular	Lead IT Analyst
223088866	SAMUEL MENDOZA	Regular	Material Handler Shipping & Receiving
212068884	Sandra Lozano Rodriguez	Regular	Manufacturing Finance Manager, GEHC Border
212044235	Sheila Ochoa	Regular	Fulfillment Coordinator
212025127	Shirley Robles	Regular	Fulfillment Coordinator

212685547	Stacy Zavala	Regular	Shipping Coordinator
212065954	Steve Ballinger	Regular	Manufacturing Engineering Leader
250003391	Susana Sotelo Novela	Regular	Manufacturing Quality and Inspection Tech
250004821	Teresa Thompson	Regular	Materials Handler
223101190	Timothy McWilliams	Regular	Material Handler Shipping & Receiving
212680024	Veronica Rodriguez	Regular	Material Handler Shipping & Receiving
212558867	Victor Sanchez	Regular	Order Fulfillment Specialist
223015888	Walter Chavez	Regular	Quality Assurance Coordinator
212041634	William Pereyra	Regular	Quality Assurance Coordinator
250004749	Yakin Gonzalez	Regular	Materials Handler

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

☑ ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2023
Commission file number 001-41528



GE HEALTHCARE TECHNOLOGIES INC.

(Exact name of registrant as specified in its charter)

Delaware	**88-2515116**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
500 W. Monroe Street, Chicago, IL	**60661**
(Address of principal executive offices)	(Zip Code)

(Registrant's telephone number, including area code) **(833) 735-1139**

Securities Registered Pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.01 per share	GEHC	The Nasdaq Stock Market LLC

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☑

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☑

The aggregate market value of the outstanding common stock of the Registrant held by non-affiliates as of June 30, 2023, the last day of the registrants most recently completed second fiscal quarter, was approximately $32 billion. There were 455,357,229 shares of common stock with a par value of $0.01 per share outstanding as of January 30, 2024.

DOCUMENTS INCORPORATED BY REFERENCE

The definitive proxy statement relating to the registrant's Annual Meeting of Shareholders, to be held May 21, 2024, is incorporated by reference into Part III of this Annual Report on Form 10-K to the extent described therein.

Table of Contents

		Page
Forward-Looking Statements		3
Part I.		
Item 1.	Business	4
Item 1A.	Risk Factors	15
Item 1B.	Unresolved Staff Comments	44
Item 1C.	Cybersecurity	44
Item 2.	Properties	45
Item 3.	Legal Proceedings	45
Item 4.	Mine Safety Disclosures	45
Part II.		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	45
Item 6.	[Reserved]	46
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	47
Item 7A.	Quantitative and Qualitative Disclosures about Market Risk	62
Item 8.	Financial Statements and Supplementary Data	64
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	116
Item 9A.	Controls and Procedures	116
Item 9B.	Other Information	117
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	117
Part III.		
Item 10.	Directors, Executive Officers and Corporate Governance	117
Item 11.	Executive Compensation	117
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	117
Item 13.	Certain Relationships and Related Transactions, and Director Independence	117
Item 14.	Principal Accountant Fees and Services	117
Part IV.		
Item 15.	Exhibits and Financial Statement Schedules	117
Item 16.	Form 10-K Summary	120
Signatures		121

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. These forward-looking statements might be identified by words, and variations of words, such as "will," "expect," "may," "would," "could," "plan," "believe," "anticipate," "intend," "estimate," "potential," "position," "forecast," "target," "guidance," "outlook," and similar expressions. These forward-looking statements may include, but are not limited to, statements about our business; information related to our business segment portfolios and strategies; human capital management and environmental, social, and governance ("ESG") strategies and initiatives; financial performance, financial condition, and results of operations, including revenue, revenue growth, profit, taxes, earnings per share, and cash flows; the impacts of macroeconomic and market conditions and volatility on our business operations, financial results, and financial position and on supply chains and the world economy; our strategy, innovation, and investments, including research and development activities; our cost structure; our funding and liquidity; the impacts on our business of manufacturing, sourcing, and supply chain management; the Russia and Ukraine conflict; our operations as a stand-alone company; and risks related to foreign currency exchange, interest rates, and commodity price volatility. These forward-looking statements involve risks and uncertainties, many of which are beyond our control. Factors that could cause our actual results to differ materially from those described in our forward-looking statements include, but are not limited to, operating in highly competitive markets; our ability to successfully complete strategic transactions; the actions or inactions of third parties with whom we partner and the various collaboration, licensing, and other partnerships and alliances we have with third parties; demand for our products, services, or solutions and factors that affect that demand; management of our supply chain and our ability to cost-effectively secure the materials we need to operate our business; disruptions in our operations; changes in third-party and government reimbursement processes, rates, contractual relationships, and mix of public and private payers, including related to government shutdowns; our ability to attract and/or retain key personnel and qualified employees; global geopolitical and economic instability, including as a result of the conflict between Ukraine and Russia, the conflict in Israel and surrounding areas, and the actions in the Red Sea region; public health crises, epidemics, and pandemics, such as the Coronavirus Disease 2019 ("COVID-19") and their effects on our business; maintenance and protection of our intellectual property ("IP") rights, as well as maintenance of successful research and development efforts with respect to commercially successful products and technologies; the impact of potential information technology, cybersecurity, or data security breaches; compliance with the various legal, regulatory, tax, privacy, and other laws to which we are subject, such as the Foreign Corrupt Practices Act (the "FCPA") and similar anti-corruption and anti-bribery laws globally, and related changes, claims, inquiries, investigations, or actions; our ability to control increases in healthcare costs and any subsequent effect on demand for our products, services, or solutions; the impacts related to our increasing focus on and investment in cloud, edge, artificial intelligence ("AI"), and software offerings; the impact of potential product liability claims; ESG matters; our ability to operate effectively as an independent, publicly traded company; and our level of indebtedness, as well as our general ability to comply with covenants under our debt instruments, and any related effect on our business. Please also see the "Risk Factors" section of this Annual Report on Form 10-K filed with the United States ("U.S.") Securities and Exchange Commission ("SEC") and any updates or amendments we make in future filings. There may be other factors not presently known to us or which we currently consider to be immaterial that could cause our actual results to differ materially from those projected in any forward-looking statements we make. We do not undertake any obligation to update or revise our forward-looking statements except as required by applicable law or regulation.

PART I
ITEM 1. BUSINESS

GE HealthCare Technologies Inc. ("GE HealthCare," the "Company," "our," or "we") is a leading global medical technology, pharmaceutical diagnostics, and digital solutions innovator. We have approximately 51,000 colleagues dedicated to our mission to create a world where healthcare has no limits. We operate at the center of the healthcare ecosystem, enabling precision care by increasing health system capacity, enhancing productivity, digitizing healthcare delivery, and improving clinical outcomes while serving patients' demand for greater efficiency, access, and personalized medicine. Our products, services, and solutions are designed to enable clinicians to make more informed decisions quickly and efficiently, improving patient care from diagnosis to therapy to monitoring. We have more than 125 years of experience and one of the strongest reputations in the global healthcare industry, built from our demonstrated record of delivering industry-defining innovation. This is complemented by our broad service capabilities and dedication to quality and integrity with a strong operational culture, deeply embedded in lean continuous improvement.

We generate revenue from the sale of medical devices, consumable products, service capabilities, and digital solutions. Precision care is expected to drive continued demand and the need for novel technologies and future innovation, as healthcare providers and researchers seek new solutions and tools for managing existing and new care pathways. The pursuit of precision care opportunities significantly expands our addressable industries to include integrated diagnostics, AI and machine learning-based clinical decision support, highly personalized therapies enabled by more precise diagnostics, and remote patient monitoring. The scale and breadth of our portfolio, combined with our innovation capabilities, position us to be a leading enabler of precision care.

GE HealthCare has extensive reach throughout the global healthcare system for medical technology, pharmaceutical diagnostics, and digital solutions, underpinned by resilient, sustainable practices and products, and a commitment to growing access to care. We serve customers in approximately 160 countries with a global team of 9,900 sales professionals, 8,100 field service engineers, and a network of 43 manufacturing, assembly, and pharmaceutical production sites across 17 countries.

Our customers are healthcare providers and researchers, including public, private, and academic institutions. We are organized into four business segments that are aligned with the industries we serve: Imaging, Ultrasound, Patient Care Solutions ("PCS"), and Pharmaceutical Diagnostics ("PDx"). Our portfolio of solutions addresses the biggest challenges facing healthcare providers and patients today, including helping to drive better patient outcomes and improved productivity for customers. These qualities foster strong trust, loyalty, and partnership with our global customer base.

GE HealthCare Technologies Inc. is a Delaware corporation with corporate headquarters in Chicago, Illinois. On January 3, 2023, the General Electric Company ("GE") completed the previously announced spin-off of GE HealthCare (the "Spin-Off"). Refer to Note 1, "Organization and Basis of Presentation" for further information regarding the Spin-Off.

OUR SEGMENTS

We develop, manufacture, and market a broad portfolio of products, services, and complementary digital solutions used in the diagnosis, treatment, and monitoring of patients. We have a large, global installed base of medical imaging, ultrasound, and patient monitoring systems.

Our business is comprised of four segments:

IMAGING.

GE HealthCare is a global leader in medical imaging with a comprehensive portfolio of scanning devices, clinical applications, service capabilities, and digital solutions. Our Imaging portfolio spans the care continuum and provides critical tools for physicians, from initial screening and diagnosis, through therapeutic decision-making and monitoring of patient progression. Our products support providers in the delivery of care for a broad spectrum of clinical specialties, including oncology, cardiology, neurology, nuclear medicine, orthopedics, women's health, pediatrics, and surgery.

Our Imaging portfolio is comprised of six product lines and associated service capabilities: Molecular Imaging, Computed Tomography, Magnetic Resonance, Image-Guided Therapies, Women's Health, and X-ray. We manage our Molecular Imaging and Computed Tomography product lines together ("MI/CT") and our Women's Health and X-ray product lines together ("WH/XR").

- Molecular imaging ("MI") enables the visualization, characterization, and quantification of functional processes taking place at the cellular and subcellular levels within patients. The images produced by MI systems allow clinicians to study the cellular and molecular pathways and mechanisms of disease in patients. We offer a complete MI solution from cyclotrons, chemistry synthesis, positron emission tomography ("PET"), computed tomography ("PET/CT"), PET/MR, and nuclear medicine to advanced digital solutions. Our Molecular Imaging team works closely with the PDx segment and their innovations and collaborations with pharmaceutical companies.
- Computed tomography ("CT") scans render 3D anatomical images of structures, such as bone, soft tissue, and air cavities using an X-ray tube that rotates around a patient. The images are used in a wide variety of applications, including the detection of tumors or lesions, blocked blood vessels in the brain, abnormal heart conditions, complex bone fractures, and internal injuries from trauma. Our comprehensive Computed Tomography portfolio includes multi-purpose and specialty scanners.

- Magnetic resonance ("MR") is a non-invasive imaging technology that produces detailed anatomical images of almost every internal structure in the human body, such as the brain, spinal cord, heart, breast, kidneys, muscles, ligaments, and tendons. MR can also be used for functional imaging, and it is well-suited for disease detection, diagnosis, and treatment monitoring of a variety of conditions, including stroke, cancer, trauma, aneurysm, multiple sclerosis, cardiomyopathy, and congenital disorders. Our Magnetic Resonance portfolio includes scanners for a range of clinical capabilities through different bore sizes, magnetic field strengths, and scalable platforms.
- Our Image-Guided Therapies business provides technologies that assist clinicians and surgeons during open surgeries and minimally-invasive endovascular procedures. Intraoperative imaging systems are used to visualize procedures that involve implants and devices, such as stents, balloons, pacemakers, and artificial joints. Our Image-Guided Therapies business includes two business lines: interventional systems and surgery systems. Our interventional systems are comprised of a broad portfolio of products that provide real-time advanced X-ray imaging and integrate with other imaging and diagnostic technologies that support clinicians in planning, guiding, and assessing minimally-invasive procedures. Our surgical systems are comprised of a broad portfolio of mobile surgical C-arms that meet the varying clinical and environmental needs for surgical imaging around the world.
- Women's Health products use X-ray technology to help clinicians screen for and diagnose breast cancer as well as bone and metabolic diseases in women. The product portfolio includes imaging and biopsy positioning systems designed to image the breast and dual energy X-ray absorptiometry scanners designed to image bones with low mineral density.
- X-ray systems are used by clinicians to perform first-line diagnostic imaging examinations of anatomical structures in the body, such as bones, lungs, and the gastrointestinal tract. Our X-ray product portfolio includes systems for three distinct clinical situations: fixed room radiography products installed in hospitals and imaging centers; mobile radiography products used for bedside or other point-of-care imaging needs; and fluoroscopy products installed in hospitals for dynamic or "moving" X-ray imaging in applications like gastrointestinal examinations.

We also offer a suite of software and applications that help radiology teams improve productivity, address staff shortages, and deliver better patient outcomes. These software solutions and applications are upgradable through the lifecycle of the equipment and are especially beneficial for multi-site, multi-disciplinary networks that have complex operations. We also offer Picture Archiving and Communication Systems and Radiological Information Systems to manage the storage and reporting of radiology images.

In addition to our core products, digital solutions, and service offerings, we provide complementary enterprise solutions, such as education and training and data integration services. Our broad enterprise solutions used along the imaging continuum enable us to drive connectivity across healthcare systems and throughout the product lifecycle.

ULTRASOUND.

GE HealthCare is a global leader in ultrasound medical devices and solutions with a broad portfolio that spans the continuum of care, including screening, diagnosis, treatment, and monitoring of certain diseases. Our Ultrasound business' focus is on designing solutions that are aligned by specialties or care areas for specific clinical workflows to better serve the unique needs of our customers and improve patient outcomes, while lowering the overall cost of care. We continue to deliver innovative ultrasound probes, consoles, and digital and AI solutions that increase diagnostic accuracy and simplify clinical and operational workflows.

Our Ultrasound equipment portfolio, digital and AI solutions, and associated service capabilities serve customers across five clinical areas: Radiology and Primary Care, Women's Health, Cardiovascular, Point of Care and Handheld, and Surgical Visualization and Guidance:

- Radiology and Primary Care Ultrasound is comprised of systems that produce images to support precise diagnoses and treatment across the whole body, including liver, thyroid, renal, breast, vascular, and transcranial applications. Our systems combine high image quality with comprehensive clinical tools, including measurement quantification, workflow automation, cross-modality networking, portability, and cloud-based technologies.
- Women's Health Ultrasound is comprised of obstetrics, gynecology, assisted reproductive medicine, and supplemental breast cancer screening. These care areas require specially-designed ultrasound products that account for patient comfort and workflow constraints to enable practitioners to provide higher-quality screening, exams, and procedural care.
- Cardiovascular Ultrasound is used in the diagnosis, treatment, and monitoring of patients with suspected or known heart disease. Diagnostic exams assess the structure and function of the heart. Our Ultrasound solutions are also used for guidance during interventional, electrophysiology, and surgical procedures.
- Point of Care and Handheld Ultrasound technologies are portable devices that produce high-quality images, whether in a hospital, ambulance, or remote geographic location. Clinicians use our Point of Care and Handheld Ultrasound devices to diagnose, monitor, and treat patients' conditions throughout various care pathways to help improve outcomes while also reducing procedure time and required resources. Our portfolio contains consoles, laptops, and handheld devices.

- Our suite of Surgical Visualization and Guidance products helps surgeons visualize anatomy and lesions, guide interventions, and navigate inside the human body. Intraoperative imaging expands the use of ultrasound beyond diagnostics by providing real-time information throughout surgical procedures that can be used to confirm or amend surgical plans, monitor progress, and validate the execution of a procedure.

Each clinical area is supported with our digital and AI Ultrasound solutions that are designed to deliver optimal, simplified, and scalable clinical and operational workflows. They are designed to increase efficiencies that support higher scan volume and billing opportunities by: providing AI-guided ultrasound to help experienced to novice clinicians acquire quality diagnostic images; eliminating keystrokes to shorten exam time; and providing clinical decision support tools. Clinicians are further supported by our broad probe portfolio which includes specialized probes for surgical intervention and transesophageal procedures. Our equipment, digital, and AI solutions are complemented by service offerings that are highly regionalized according to local requirements, varying customer needs, and cross-modality service strategies.

PATIENT CARE SOLUTIONS.

The Patient Care Solutions business is a leading global provider of medical devices, consumables, services, and digital solutions that acquire and transform complex clinical data into real-time visualization and clinical decision support to ease the way to more confident patient care and improve patient outcomes. Our devices, digital solutions, and service solutions form a broad and integrated portfolio that support patient care needs and care teams within and beyond most acute healthcare environments.

Our portfolio is comprised of Patient Monitoring, Anesthesia Delivery and Respiratory Care, Diagnostic Cardiology, Maternal Infant Care, and Consumables and Services connected by and differentiated with our digital solutions.

- Our flexible Patient Monitoring solutions enable clinicians to flex care based on a patient's acuity and across all the acute care continuum. Our portfolio ranges from spot-check to continuous patient monitoring, including comprehensive multi-parameter monitors; central stations; continuous, wearable, and mobile monitors; transport monitors; cardiac telemetry solutions; spot-check monitors; and visualization, alarm distribution, and care team collaboration solutions. Our Patient Monitoring business includes proprietary parameters and complementary consumables as well as original equipment manufacturer ("OEM") parameters that are integrated into our monitoring fleet, of which a significant portion represents recurring revenue streams.
- Anesthesia and Respiratory Care products offer life support solutions via ventilation technology. Products in our Anesthesia portfolio are used by anesthesiologists and nurse anesthetists to ventilate and deliver general anesthetic drugs to patients during surgeries. Our products are installed in many operating rooms, non-operating room anesthesia environments and ambulatory surgical centers across the world. Our respiratory devices are designed to ventilate critically ill patients, generally in ICUs.
- In Diagnostic Cardiology, we offer electrocardiogram ("ECG" or "EKG") solutions, that are usually the first diagnostic tool to detect cardiovascular disease, a leading cause of death across the world. We provide resting ECG devices, stress ECG devices, and ECG management digital solutions, including interpretation algorithms. Our ECG ecosystem obtains, interprets, and stores ECGs captured from devices in both hospital and home settings, supporting patients and clinicians along the continuum of care for cardiology.
- Our Maternal Infant Care products are used in the labor and delivery department to monitor important maternal and fetal parameters, and in neonatal intensive care to assist in critical care for newborns. Our product portfolio includes neonatal incubators, infant warmers, resuscitation devices, phototherapy equipment, maternal and fetal monitors, and digital offerings, such as maternal and fetal heart rate surveillance software. Our products have added innovation in design, including integrated scales, hands-free alarm silencing, angled radiant heating, and thermoregulation.
- Our Consumables and Services portfolio consists of approximately 1,000 consumables that are used primarily with our monitoring solutions patient parameters, such as blood pressure, ECG, pulse, temperature, respiratory rate, blood oxygen level, and brain activity, and are used throughout the hospital. Our service offerings are flexible and can range from preventative maintenance to comprehensive, onsite biomedical service engineering contracts. Both our consumables and services provide our customers with ongoing clinical impact and protect their capital investment while providing us with recurring revenue streams.

The Patient Care Solutions portfolio also includes digital solutions that provide timely and accurate clinical decision support in acute and other care settings, simplifying clinical and operational workflows to drive efficiencies and improving delivery of precision medicine and patient outcomes. These solutions aggregate and integrate clinical data from various devices across care settings in real time and simplify visualization to guide clinical and operational decisions, enabling efficient care team collaboration, virtually. These solutions are interoperable and vendor-agnostic to integrate with customer environments in a multi-vendor setting and provide a recurring revenue stream.

Our broad product and digital solution portfolio is complemented by a comprehensive suite of service offerings, including parts, labor, and training, as well as emerging data, analytics, and networking solutions to aid our customers in improving uptime and efficiency of their medical technology fleets.

PHARMACEUTICAL DIAGNOSTICS.

GE HealthCare is a leading supplier of diagnostic agents to the global radiology and nuclear medicine industry. These diagnostic agents help clinicians assess patients to enable more precise diagnoses and better therapy selection. We distribute products globally, providing on-time delivery of quality products that help meet patient and procedural needs across a multitude of modalities. PDx's diagnostic agents are complementary to the imaging and ultrasound devices we offer, including CT, angiography and X-ray, MR, single-photon emission computed tomography ("SPECT") and PET, and are also compatible with systems from other equipment vendors.

PDx operates within a strictly regulated industry with unique operational needs. Diagnostic agents require a sophisticated supply chain for manufacturing, supported by a global infrastructure of commercial, marketing, medical affairs, market access, application, regulatory, and pharmacovigilance teams that help monitor products. Customers require timely and reliable supply of diagnostic agents as shortages or delays can be highly disruptive to workflows and even cause exam cancellations.

Our PDx business is comprised of two business lines: Contrast Media and Molecular Imaging.

- Contrast media are pharmaceuticals that are administered to a patient prior to certain diagnostic scans in order to increase the visibility of tissues or structures during imaging exams. Contrast media increase the diagnostic value of imaging and can be critical in the visualization of small or nuanced areas of diagnostic interest, such as cancer lesions or vascular structures, and to plan medical interventions, such as angioplasties, biopsies, or radiation therapy. We offer contrast media to three imaging modality groups: (1) CT, angiography, and X-ray, (2) MR, and (3) Ultrasound. Our Contrast Media business also includes contrast injection devices that are automated devices used to monitor and control the injection of contrast into patients, providing valuable productivity benefits in the imaging suite. We offer contrast injectors through collaborations with third-party original equipment manufacturers.
- Molecular imaging agents, or radiopharmaceuticals, are molecular tracers labeled with radioisotopes that are injected into a patient prior to a diagnostic imaging scan. These agents work by accumulating in an area of diagnostic interest, such as a tumor, and emitting energy that is detected by a SPECT or PET scanner. Because they have specific molecular targets, they allow visualization and assessment of cell function, providing a more detailed dimension of biological activity. Our radiopharmaceuticals support diagnosis and therapy selection in various care areas, such as neurology, cardiology, and oncology, and are also used by pharmaceutical companies and researchers in selecting target populations for clinical trials.

Our strong portfolio of diagnostic agents and advanced global supply chain, combined with our imaging, cyclotron, and advanced visualization software, positions our Company to grow in existing markets as well as emerging adjacencies.

ACQUISITIONS

Our business strategy includes the acquisition of technologies and businesses that expand or complement our existing business. Refer to Note 8, "Acquisitions, Goodwill, and Other Intangible Assets" for information about our acquisitions.

RESEARCH AND DEVELOPMENT ACTIVITIES

Our research and development ("R&D") efforts focus on creating new products and solutions, developing new applications for products, and enhancing our existing products to help improve outcomes for customers and their patients. We employ approximately 10,300 engineers and scientists worldwide, including hardware, systems, and software engineers and personnel focused on clinical research. We engage in and sponsor clinical research and product development through collaborations with universities, medical centers, and other organizations. We occasionally enter into agreements with third parties related to collaboration on R&D activities associated with the development of new or innovative products. See Note 18, "Supplemental Financial Information" for further information.

INTELLECTUAL PROPERTY

We have a substantial portfolio of IP. We rely on a combination of patent, design, utility model, trademark, copyright, trade secret and regulatory exclusivity period protections, as well as confidentiality agreements to protect our IP. Our IP team collaborates with our R&D and product teams to develop product-line-focused IP strategies and secure IP rights as appropriate. We generally file patent applications in the United States and foreign countries that have strong technology patent protections. We also license from third parties a variety of IP that complements our internal R&D efforts and our product offerings. While, in aggregate, our patents and other IP are vital to our operations, we do not consider any single IP asset or group of assets to be of material importance to any segment or to the business as a whole; rather, we believe understanding our customers' needs, technology expertise, and manufacturing know-how are critical for our business.

We rely on confidentiality agreements with colleagues, contractors, consultants, and third parties to help protect our trade secrets, proprietary technology, and other confidential information. We also monitor development and commercialization activities of third parties so our IP rights are not infringed upon. In addition, we make infrastructure investments to secure our IP assets and conduct audits to assess the effectiveness of our IP protection program.

We believe that invention leads to value for our customers and stakeholders, and that a culture of innovation across GE HealthCare is a core element of our business.

As part of the Spin-Off from GE, we secured IP specific to our business, and GE granted us a license to use other IP required for our business of which GE retained ownership. We also entered into a long-term trademark license with GE that enables GE HealthCare to continue building upon our brand.

COMPETITORS

The global medical technology industry is highly competitive and comprised of global and regional participants of all sizes that can vary by product line. Because of the diversity of our products and offerings, we face a wide variety of competitors, including a broad range of manufacturers, third-party distributors, and service providers. In the industries we serve, we believe our primary global competitors include Siemens Healthineers, Philips Healthcare, Canon, Mindray, and United Imaging, among others. In our PDx business segment, we primarily compete with Bayer, Bracco, Guerbet, Lantheus, and Curium.

While key competitive factors and trends vary among our segments, these typically include value, quality and performance, safety, delivery speed, service and support, technology and innovation, software offering, and brand reputation. For a further discussion of risks related to competition, please refer to Item 1A. "Risk Factors."

HUMAN CAPITAL

We are a purpose-driven global workforce of approximately 51,000 colleagues with a significant average tenure reflecting a strong, engaged culture. Our colleagues are committed to serving our customers and enabling them to provide the highest quality patient care. Our values emphasize safety for patients, customers, and colleagues; servant leadership with unyielding integrity; and fostering an inclusive culture and diverse team with a mission to deliver precision care innovation. We monitor our human capital priorities throughout the year, including as a part of our monthly business operating reviews. Our senior leadership is a diverse and global team of industry veterans with the skills and expertise required to lead a large, publicly listed medical technology, pharmaceutical diagnostics, and digital solutions company. We embrace a diverse workplace where every voice makes a difference and every difference builds a healthier world.

Below are our human capital priorities:

- ***Protect the health and safety of our workforce***: Safety is integrated into everything we do, from manufacturing to installation, operation, and service. We are committed to prioritizing safety over delivery and cost. We have established and maintain health and safety standard protocols across our businesses that are designed to align with regulatory requirements, industry practices, and company values. Our efforts extend to promoting the mental and emotional health and wellness of our workforce.

- ***Transform our culture***: Our senior management team is leading our company through a transformational period having completed the Spin-Off in January 2023 and now executing on our next phase of growth. We have aligned the organization around Cultural Operating Principles, which represent a shared understanding of how we expect colleagues to work with each other and interact with stakeholders to enable our growth strategy, deliver on our purpose, and create value for our colleagues, customers, patients, shareholders, and communities. These Cultural Operating Principles are:
    - Serve our people, patients, and customers;
    - Lead with a lean mindset;
    - Empower entrepreneurial spirit;
    - Deliver the future of healthcare; and
    - Win together and have fun.

- ***Attract, develop, and cultivate our talent***: GE HealthCare's approach to talent management is to cultivate strong individual and company performance. A key pillar of our talent strategy is senior management-led annual organization and talent reviews focused on critical roles, succession plans, and talent development. Learning and the professional development of our colleagues continue to be foundational priorities for the organization as a whole.

- ***Retain, motivate, and reward our talent:*** GE HealthCare's approach to total rewards is underpinned by a philosophy designed to provide programs that attract, retain, and motivate our people to fulfill our purpose to create a world where healthcare has no limits. Our philosophy is further supported by four principles that guide the total rewards we provide, which are:
    - Business-focused and differentiated by performance;
    - Ownership-oriented;
    - Competitive, motivating, and fair; and
    - Simple and transparent.

- ***Promote inclusion and diversity across the enterprise***: We believe in the value of each person's unique identity, background, and experiences. We are committed to fostering an inclusive culture in which all colleagues feel empowered to do their best work because they feel accepted, respected, and a sense of belonging.

We have approximately 16,700 colleagues in the United States and approximately 7,300 colleagues in China, our next largest geography. We have approximately 1,000 union-represented manufacturing colleagues in the United States, approximately 700 of whom are covered by four-year collective bargaining agreements that were ratified in 2023 and expire in June 2027. GE HealthCare's relationship with employee-representative organizations outside the United States takes many forms, including in Europe where GE HealthCare engages the representative bodies for colleagues, such as works councils and trade unions, in accordance with local law. We strive to unlock the ambition of all our people so they can innovate, grow, and reach their full potential. Our well-established colleague development strategy allows us to attract and retain innovative leaders, which is instrumental to our long-term success.

ENVIRONMENTAL, SOCIAL, AND GOVERNANCE

GE HealthCare is committed to delivering products and solutions that build a healthier and more sustainable world for this and future generations. We have an ESG program and governance structure that is aligned with our business strategy, the priorities of our stakeholders, our goals and ambitions, and our need to adapt to changes in societal, environmental, and regulatory expectations.

The Board of Directors oversees management's establishment and execution of corporate strategy, along with our ESG program and activities. Our Enterprise Stewardship Program Committee, a committee of our management team, works in partnership with all segments, regions, and functions to support GE HealthCare's ongoing goals in connection with environmental stewardship, corporate social responsibility, human capital, governance, and sustainability. It proactively identifies, assesses, and responds to risks and opportunities that could impact the company's business and operations, and has begun implementing GE HealthCare's ESG strategy, including priorities, initiatives, goals, and disclosures, while maintaining transparent and open communication with stakeholders.

We have five focus areas that build upon our long-standing commitments to innovation, product quality, and integrity. They are:

- Expanding access to healthcare;
- Promoting inclusion and diversity across the enterprise;
- Mitigating our climate impact and improving resiliency;
- Advancing the circular economy and environmental design; and
- Protecting patient data and cybersecurity

More information on our ESG program can be found in our annual Sustainability Report available on our website (which is not incorporated by reference herein).

SALES AND DISTRIBUTION MODEL

GE HealthCare deploys a global multi-channel commercial model consisting of approximately 9,900 sales professionals and a network of approximately 5,000 indirect third-party partners. Our reach into top hospitals and health systems is evidenced by our long-standing collaborations with leading institutions around the world. Our commercial model is organized according to the needs of our customers and includes global and regional marketing, regional inside sales teams, field-based sales teams, and sales agents and distributors. Our equipment sales representatives partner closely with their service sales counterparts to position both equipment contracts and long-term maintenance agreements along with system upgrades and software as a service ("SaaS") agreements. We complement our direct and indirect sales channels with end-to-end virtual sales teams. Our direct and indirect channel mix helps us expand our market coverage, increase customer satisfaction, and win more business in broad geographies and emerging markets. In developed markets, we supplement our commercial model with strategic account executive and collaboration teams that bring the depth and breadth of our overall portfolio to the senior leadership of our top customers to deliver long-term commercial collaborations, which can be tied to specific outcomes.

GLOBAL INTEGRATED SUPPLY CHAIN, SOURCING, AND LOGISTICS

Our sourcing, production, and distribution network is managed globally while our products are manufactured at and distributed by facilities serving specific regions. We believe our global scale, complemented by local focus, allows us to provide our customers with improved supply chain security, reduced costs, and compliance with regional or national trade and marketing requirements. We have manufacturing, assembly, and pharmaceutical production in 43 facilities across 17 countries. We use globally managed and coordinated quality assurance programs across our manufacturing and distribution facilities, and we regularly inspect and audit our sites. We hold our suppliers to the same rigorous operating standards.

REGULATION

The development, manufacturing, marketing, sale, promotion, and distribution of medical devices and pharmaceutical products are subject to stringent government regulation globally. We commit extensive resources to maintain compliance with these regulations.

The U.S., European Union ("EU"), and China are our most significant regions based on revenue and the regulatory landscape within these regions. Sales of medical devices and pharmaceuticals outside of these regions are subject to requirements that vary from country to country. Our ability to market and sell our products globally depends upon our compliance with the laws and regulations in each jurisdiction. This requires, among other things, receiving specific marketing authorization from the appropriate regulatory authorities, and maintaining our Quality Management System, which is compliant with the applicable local regulatory requirements, and ISO 13485 certification that is recognized by many regulators. Complying with requirements imposed on our products and business is an ongoing process as we introduce additional products and/or product modifications and seek to comply with changing legal and regulatory requirements. The time required to obtain authorization to market and sell products varies by country. The ability to comply with global post-market requirements requires extensive and ongoing resources.

The International Medical Device Regulators Forum, which includes a number of country regulators, has implemented a global approach to auditing medical device manufacturers. The Medical Device Single Audit Program ("MDSAP") provides for a single annual audit of a medical device manufacturer by a MDSAP-recognized auditing organization to satisfy the requirements of ISO 13485 and the regulatory requirements of the authorities that participate in MDSAP (currently the U.S., Canada, Australia, Brazil, and Japan). While the U.S. Food and Drug Administration ("FDA") accepts MDSAP audit reports as a substitute for routine agency inspections, it considers the following types of inspections to fall outside the scope of MDSAP: for-cause or compliance follow-up inspections; pre-approval or post-approval inspections; and inspections to assess compliance with Electronic Product and Radiation Control regulations, which apply to Molecular Imaging, X-ray, Women's Health, Interventional, and Surgery products.

UNITED STATES OF AMERICA.

Food and Drug Law
Under the Food, Drug, and Cosmetic Act ("FDCA"), we must comply with regulations governing the design, development, testing, manufacturing, packaging, labeling, distribution, import/export, sale, servicing, and marketing of medical products, including medical devices and pharmaceuticals. U.S. FDA product approvals and clearances may be withdrawn or suspended if compliance with regulations is not maintained or if product issues are discovered. Some of our products are also subject to the Radiation Control for Health and Safety Act and the Electronic Product and Radiation Control Regulations, administered by the FDA, which imposes performance standards, record keeping, reporting, product testing, and product labeling requirements on radiation-emitting electronic products, such as X-ray devices. We must also comply with the Mammography Quality Standards Act for our mammography products. Further, clinical studies of medical devices and pharmaceuticals are subject to regulation and inspection. In addition, we are subject to applicable laws and regulations of state and local authorities.

Devices
The FDCA classifies medical devices into three classes based on risk, including Class I (lowest risk), Class II (moderate risk), and Class III (highest risk), with more stringent regulatory requirements applicable to higher-risk devices. Commercial sales of our Class II (except for Class II exempt devices) and Class III medical devices in the U.S. must be preceded by either a pre-market notification filing pursuant to Section 510(k) of the FDCA for Class II or the granting of a premarket approval for Class III. The development of a medical device typically requires extensive non-clinical testing and, for some of our devices, clinical testing involving human subjects.

For all our medical devices, we must comply with the FDA's requirements governing, among other things, device site registration and listing, labeling, post-market record keeping and reporting, and the Quality System Regulation. These requirements are detailed, comprehensive, and require extensive investment and resources to comply with legal and regulatory requirements.

Pharmaceutical Products
Our pharmaceutical products are subject to the FDA's pre-market approval process. The pharmaceutical product development and approval process typically begins with extensive pre-clinical R&D, followed by approval of an Investigational New Drug ("IND"), and then, upon successful completion of several phases of clinical trials, the filing and request for FDA approval of a New Drug Application. We also are subject to the FDA's requirements, including drug establishment registration and listing, labeling and advertising, and current Good Manufacturing Practice ("cGMP") regulations, which set forth minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing pharmaceutical products. Post-approval, we must maintain and submit to the FDA reports of product quality defects and adverse events. The FDA's generic drug program requires filing of an Abbreviated New Drug Application for a generic drug application that does not include preclinical or clinical data to establish safety and effectiveness, but must demonstrate equivalency to the innovator drug.

EUROPEAN UNION.

Devices
There is no pre-market approval of medical devices in the EU. All new medical devices placed on the market or put into service in the EU must be compliant with and meet the requirements of the Medical Device Regulation, which was implemented on May 26, 2021. Devices that conform to these requirements can be affixed with a CE marking and commercialized throughout the European Economic Area ("EEA") and in Switzerland. Prior to affixing a CE marking, manufacturers must demonstrate that their products comply with minimum standards of performance, safety, and quality, through a conformity assessment procedure that depends on the product's classification. The classification of a medical device is determined by its intended purpose. Devices are classified from lowest to highest, as either Class I, IIa, IIb, or III. Classification is dependent on a variety of factors, including duration of use, whether the device is invasive or non-invasive, and whether the device is considered "active." The competent authorities of the EU countries are responsible for regulating clinical investigations of medical devices and post-market surveillance of devices once they are placed on the market.

Pharmaceutical Products
Our pharmaceutical products are regulated by the European Medicines Agency ("EMA"), or the national competent authorities of the EU/EEA countries where our products are marketed. The EMA, acting through the Committee for Medicinal Products for Human Use ("CHMP"), is responsible for the scientific evaluation of pharmaceutical products developed by pharmaceutical companies for use in the EU and submitted for assessment through the EU centralized procedure. If the CHMP concludes that all requirements for quality, safety, and efficacy are met, it issues a positive opinion that the EMA forwards to the European Commission, which takes the final decision on the granting of a marketing authorization.

CHINA.

We must comply with medical device and pharmaceutical product laws and regulations and standards governing the design, development, testing, manufacturing, packaging, labeling, distribution, import/export, sale, servicing, and advertising and promotion of our products in China. The chief pharmaceutical product and medical device regulator is the National Medical Products Administration ("NMPA"), which enforces these laws and has the power to issue fines, seize products, withdraw or suspend an approval or a registration for serious non-compliances, and refer cases for criminal prosecution. These national laws and regulations are also supplemented by provincial and other local-level rules and enforcement policies.

Devices
Medical devices are strictly regulated by the NMPA and various provincial, city, and county regulators and are classified into three risk-based classes from lowest to highest, Class I, II, and III. Approved products are subject to post-market requirements for reporting adverse events and recalls, as well as regular risk assessments of devices and potentially re-evaluation reports of the safety and effectiveness of the device based on more significant safety signals.

In addition to product licenses, manufacturing and distribution facilities that handle Class II and III devices require licenses or notifications and must comply with cGMP requirements and good supply practices. The NMPA regularly conducts inspections of manufacturing facilities in China (as part of a pre-market submission review, routine or for-cause inspections, or unannounced inspections) as well as periodic inspections of overseas manufacturers for compliance with China medical device cGMP requirements. The NMPA inspects distributors and user facilities and conducts annual national and provincial sampling inspections and testing to ensure compliance with labeling, licensing, mandatory standards, and other related requirements. In addition, the NMPA conducts regular and for-cause good clinical practice audits of clinical sites that provide data and clinical trial reports for product registration.

Pharmaceutical Products
Our pharmaceutical products are strictly regulated by the NMPA and various provincial, city, and county regulators. Significant changes were recently made to the China Drug Administration Law with more to follow regarding new regulatory requirements and technical guidelines. All our pharmaceutical products require pre-market approval from the NMPA before they can be marketed in China, and those marketing applications must be supported by clinical data, which typically comes from a multi-phase study in China or by relying on clinical data generated abroad that meets the NMPA's requirements.

DATA PRIVACY LAWS.

Due to our extensive global footprint and handling of personal data as both a data controller (on our own behalf) and data processor (on behalf of third parties, primarily customers), we are also subject to an extensive collection of global laws and regulations protecting the privacy, security and integrity of the personal data, sensitive personal data, and patient health information that we create, receive, use, and maintain as a business.

Among the most relevant and material to our business, based on the volume and sensitivity of the data at issue, are: the U.S. Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information and Technology for Economic and Clinical Health Act (collectively "HIPAA"); the EU General Data Protection Regulation (Regulation (EU) 2016/679) ("GDPR"), similar U.K. legislation resulting from the European Union (Withdrawal) Act of 2018 ("U.K. GDPR"), and other EU country-level laws; the Lei Geral de Proteção de Dados Pessoias ("Brazil LGPD"); and the various laws and accompanying regulations in China governing data privacy and cybersecurity (e.g., the Cybersecurity Law of the People's Republic of China, Personal Information Protection Law ("China PIPL")). In addition, there are also various U.S. state-level laws (e.g., the California Consumer Privacy Act), country regional laws, and proposed legislation that we monitor for applicability and impact to our business. These laws present a continuing challenge to businesses to structure their data collection, storage, use, and cross-border transmission in a compliant manner.

Many of these laws impose a significant compliance burden on organizations within their scope, and failure to comply can result in a variety of sanctions, including administrative fines for the most serious compliance failures up to 4-5% of a company's total annual revenue of the preceding fiscal year (e.g., GDPR, U.K. GDPR, China PIPL). While there have been some recent enforcement actions by EU country-level data protection authorities resulting in substantial fines pursuant to GDPR, there remains uncertainty as to how data protection authorities throughout the rest of the globe will choose to interpret and enforce violations of applicable privacy and cybersecurity laws and regulations (e.g., Brazil LGPD, China PIPL). Furthermore, these laws and regulations are continuously evolving, and further clarification in the form of implementing rules, guidelines, and related guidance from the data protection authorities is necessary to paint a full picture of the compliance obligations imposed on businesses within their scope.

REGULATION ON ADVERTISING, MARKETING, AND PROMOTION.

The advertising, marketing, and promotion of our products must be truthful and non-misleading, consistent with our regulatory clearances and approvals, and supported by adequate and reasonable scientific data. We may not promote or advertise our products for uses not within the scope of our intended use statement in our regulatory clearances or approvals or make unsupported safety and effectiveness claims. With limited exceptions, we may not market, promote, or sell regulated products prior to health authority clearance or approval. For our pharmaceutical products, health authorities regulate labeling and advertising. For our device products, health authorities regulate the labeling and, for certain devices, advertising in coordination with other enforcement agencies. A failure to comply with these regulations could expose the Company to legal liability, such as enforcement actions, investigations by a governmental authority, civil fines or criminal actions, lawsuits brought by competitors or company whistleblowers, or other actions. We must also comply with advertising, marketing, and promotion rules in all countries in which we market our products.

GLOBAL HEALTHCARE COMPLIANCE.

The marketing, promotion, and sale of medical devices, drugs, and services are regulated by the U.S. Department of Health and Human Services and comparable U.S. state and non-U.S. agencies responsible for reimbursement and regulation of the delivery of healthcare items and services, representing government's interest in regulating the quality and cost of healthcare. Similar regulations are imposed in many global markets in which we do business. Industry trade associations (such as Advanced Medical Technology Association ("AdvaMed") and MedTech) increasingly provide guidance on, and compliance with, applicable laws and regulations.

U.S. federal healthcare laws apply when we or our customers submit claims for items or services that are reimbursed under Medicare, Medicaid, or other federally funded healthcare programs, including laws related to kickbacks, false claims, self-referrals, and healthcare fraud and abuse. Similar state false claims, anti-kickback, anti-self-referral, and insurance laws also apply to state-funded Medicaid and other healthcare programs and private third-party payers. Any failure to comply with these laws and regulations could subject us or our officers and colleagues to criminal and civil financial penalties and expose us to civil liability and risk of further enforcement action under the U.S. Anti-Kickback Statute ("AKS"), the False Claims Act ("FCA"), or other healthcare fraud and abuse laws. In addition, as a manufacturer of U.S. FDA-cleared and -approved devices and drugs reimbursable by federal healthcare programs, we are subject to the U.S. federal Physician Payments Sunshine Act (the "Sunshine Act"), which requires us to annually track and report to the federal government certain payments and other transfers of value we make to U.S.-licensed physicians and other healthcare professionals or U.S. teaching hospitals.

The U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act of 2010, and similar anti-corruption and anti-bribery laws in other jurisdictions generally prohibit companies from making corrupt payments to or otherwise engaging in bribery of government officials. These laws apply to many of our customer interactions, as healthcare professionals in other countries are often considered government officials, and in some cases lay out requirements of how to operationalize compliance with the legal requirements. Failure to comply with these laws may expose us to criminal and civil enforcement actions, monetary fines and penalties, and reputational harm.

INFORMATION ABOUT OUR EXECUTIVE OFFICERS

The following table presents the names, ages, and positions of our executive officers as of the date of this Annual Report.

Name	Age	Position
Peter J. Arduini	59	President, Chief Executive Officer, and Director
James K. Saccaro	51	Vice President and Chief Financial Officer
Frank R. Jimenez	59	General Counsel and Corporate Secretary
Taha Kass-Hout	52	Chief Science and Technology Officer
Betty D. Larson	48	Chief People Officer
Jan Makela	55	CEO, Imaging
Kevin M. O'Neill	55	CEO, Pharmaceutical Diagnostics
Roland Rott	52	CEO, Ultrasound
Kenneth Stacherski	53	Chief Global Supply Chain and Service Officer
Thomas J. Westrick	55	CEO, Patient Care Solutions

The following are brief biographies describing the backgrounds of our executive officers.

Peter J. Arduini. Mr. Arduini was appointed as our President and Chief Executive Officer in connection with our Spin-Off from GE. He served as the President and Chief Executive Officer of GE's healthcare business from January 2022 until the Spin-Off. Previously, Mr. Arduini was the President and Chief Executive Officer of Integra LifeSciences ("Integra"), a global medical technologies and solutions company, from January 2012 to December 2021. During his tenure as CEO, the Integra portfolio evolved significantly to a faster growing and more profitable company through multiple acquisitions and a sustainable research and development pipeline. Prior to Integra, Mr. Arduini worked at Baxter Healthcare as President of its Medication Delivery division. Before Baxter Healthcare, he spent 15 years at GE's healthcare business in a variety of leadership roles in the United States and globally, including leading the Computed Tomography and Molecular Imaging business, Healthcare Services and U.S. sales. Mr. Arduini serves on the boards of the Bristol-Myers Squibb Company (NYSE: BMY), where he serves on the compensation and management development committee and the science and technology committee; AdvaMed, where he serves as Chairman of the board; and the National Italian American Foundation.

James K. Saccaro. Mr. Saccaro has served as our Vice President and Chief Financial Officer since June 2023. Previously, Mr. Saccaro served as the Chief Financial Officer of Baxter International Inc. (NYSE: BAX) ("Baxter"), a multinational healthcare company, starting in 2015. He held a variety of positions of increasing responsibility at Baxter from 2002 through 2013, including Vice President of Financial Planning and Analysis; Vice President of Finance for Baxter's operations in Europe, the Middle East, and Africa; Vice President of Strategy; and Corporate Vice President and Treasurer. Mr. Saccaro served as Senior Vice President and Chief Financial Officer of Hill-Rom Holdings, Inc. from 2013 to 2014 prior to rejoining Baxter as Special Assistant to the CEO in 2014. Prior to Baxter, he held strategy and business development positions at Clear Channel Communications and The Walt Disney Company.

Frank R. Jimenez. Mr. Jimenez has served as our General Counsel and Corporate Secretary since our Spin-Off from GE. He served as the General Counsel of GE's healthcare business from February 2022 until the Spin-Off. Previously, Mr. Jimenez served as Vice President, General Counsel and Corporate Secretary of Raytheon Company (and, following Raytheon's April 2020 merger with United Technologies Corporation, Executive Vice President and General Counsel of Raytheon Technologies Corporation), an aerospace and defense company, from January 2015 to December 2021, as well as Special Advisor to the Chairman and CEO of Raytheon Technologies Corporation from December 2021 to February 2022. In prior corporate positions, Mr. Jimenez served as General Counsel of Bunge Limited, ITT Corporation, and ITT spin-off Xylem Inc. In prior public service positions, Mr. Jimenez served as General Counsel of the Navy, Deputy General Counsel of the U.S. Department of Defense, Principal Deputy General Counsel of the Navy, Chief of Staff at the U.S. Department of Housing and Urban Development, and Deputy Chief of Staff and Acting General Counsel for former Florida Governor Jeb Bush. He was previously a litigation partner at Steel Hector & Davis LLP (now Squire Patton Boggs LLP). Mr. Jimenez serves on the boards of Huntington Ingalls Industries (NYSE: HII) (where he serves on the compensation committee and the governance and policy committee), Equal Justice Works, and the Yale Law School Fund, and on the advisory boards of the Columbia University Mailman School of Public Health, the Yale Law School Center for the Study of Corporate Law, the Yale Law School Tsai Leadership Program, and the National Security Institute of the Antonin Scalia Law School at George Mason University, as well as serving on the University of Miami President's Council.

Taha Kass-Hout. Dr. Kass-Hout, MD, MS has served as GE HealthCare's Chief Science and Technology Officer since January 2023, where he leads the Company's Science and Technology organization, as well as efforts to drive growth through clinical research and the advancement of digital and machine learning capabilities. Prior to his role with GE HealthCare, Dr. Kass-Hout served as Vice President of Machine Learning, Distinguished Engineer and Chief Medical Officer at Amazon from May 2017 to January 2023, where he led the company's cloud health AI strategy, products, and services, and was a key contributor to Amazon health initiatives, including pharmacy and diagnostics. In 2020, he led teams at Amazon responsible for developing the science, technology, and scale for Amazon's COVID-19 lab, including Amazon's first FDA authorization for testing its associates globally – later offered to the public for at-home testing. Dr. Kass-Hout also served as the FDA's first Chief Health Informatics Officer from 2013 to 2016, leading the U.S. President's precision medicine initiative, precisionFDA.

Betty D. Larson. Ms. Larson has served as the Chief People Officer of GE HealthCare since the Spin-Off. She served as the Chief People Officer of GE's healthcare business from February 2022 until the Spin-Off. Previously, she was EVP and Chief Human Resources Officer at Becton, Dickinson and Company ("BD"), a global medical technology company, responsible for HR, Communications and Social Investing from June 2018 to February 2022. Prior to that role, Ms. Larson served starting in September 2014 as Chief Human Resources Officer for C.R. Bard, Inc., a leading medical technology company in the fields of vascular, urology, and surgical specialty products, which was acquired by BD in 2017. She started her career at Baxter International, where she held a variety of leadership roles during her 16-year tenure. Ms. Larson currently serves on the Board of Directors of Fortrea Holdings Inc. (where she serves on the nominating, corporate governance and compliance committee and the management development and compensation committee) and Baxter Credit Union. She previously served on the Board of Directors of the Overlook Hospital Foundation, Summit Speech School, and the United Way of Lake County.

Jan Makela. Mr. Makela has served as our Chief Executive Officer, Imaging since the Spin-Off. He served as Chief Executive Officer, Imaging of GE's healthcare business from February 2020 until the Spin-Off. Mr. Makela previously served as President and CEO, Global Services of GE's healthcare business from December 2017 to February 2020, where he oversaw the global development and execution of service solutions and operations. From 2013 to 2017, Mr. Makela worked in the Life Sciences division of GE's healthcare business as the General Manager, initially as General Manager of the Core Imaging business, now called PDx, and from 2015 as General Manager of the BioProcess business. From 2010 to 2013, he served as Chief Operations Officer for the European region. Mr. Makela joined GE Corporate in 2000 and moved to GE's healthcare business in 2007 to lead the Diagnostic Imaging Services division across Northern Europe. Mr. Makela began his career in engineering and production management with M&M/Mars Inc., followed by leadership roles at A.T. Kearney management consultants before joining GE.

Kevin M. O'Neill. Mr. O'Neill has served as our Chief Executive Officer, Pharmaceutical Diagnostics since the Spin-Off. He served as as Chief Executive Officer, Pharmaceutical Diagnostics of GE's healthcare business from July 2017 until the Spin-Off. Mr. O'Neill has also served as President and CEO, GE Ireland and U.K., since 2018. Prior to that, he was the Chief Financial Officer of the Life Sciences division of GE's healthcare business starting in August 2013. Mr. O'Neill has over 20 years of experience with GE, beginning in the Energy services business in the U.K. and U.S. This was followed by a series of CFO roles in GE's healthcare business, including in the Life Sciences, Supply Chain, Western Europe, and the PDx business. Prior to joining GE, Mr. O'Neill was Financial Controller for Eurostar, the European high-speed train operator.

Roland Rott. Mr. Rott has served as our Chief Executive Officer, Ultrasound since the Spin-Off. He served as Chief Executive Officer, Ultrasound of GE's healthcare business from April 2021 until the Spin-Off. Mr. Rott joined GE's healthcare business in 2011 and has held several leadership roles including in the global Women's Health Ultrasound and Ultrasound IT segments as well as Maternal Infant Care. Before joining GE, Mr. Rott was Managing Director, Europe, the Middle East, and Africa and Asia Pacific, and Executive Board Member of the then Euronext listed ERP Software group Exact Holding, Netherlands. In his early career, he had an entrepreneurial start, founding and successfully exiting two software companies in Austria.

Kenneth Stacherski. Mr. Stacherski has served as the Chief Global Supply Chain and Service Officer of GE HealthCare since the Spin-Off. He served as the Chief Global Supply Chain and Service Officer of GE's healthcare business from October 2022 until the Spin-Off. Previously, from July 2021 to October 2022 he served as the Chief Operations Officer of Array Technologies, a solar tracking company, where he led the company's global integrated supply chain strategy including procurement, manufacturing, operations, logistics, planning, quality and business systems. Before joining Array Technologies, Mr. Stacherski served for over ten years in various leadership roles with Honeywell, a diversified technology and manufacturing company, including Vice President of Integrated Supply Chain from October 2019 to June 2021; Vice President of Enterprise Digital Transformation from November 2018 to October 2019; Vice President of Portfolio Transformation from October 2017 to October 2018; Vice President and General Manager of Honeywell UOP from April 2016 to October 2017; Vice President of Procurement, Logistics, and Trade Compliance from May 2013 to April 2016; and Global Director of Integrated Supply Chain from June 2011 to May 2013. Prior to Honeywell, he acted as President and Chief Operating Officer of Composite Technologies Corporation and spent 13 years at Ford Motor Company.

Thomas J. Westrick. Mr. Westrick has served as our Chief Executive Officer, Patient Care Solutions since the Spin-Off. He served as Chief Executive Officer, Patient Care Solutions of GE's healthcare business from September 2020 until the Spin-Off. Previously, he led the Global Quality, Medical, Regulatory Affairs and Global Research organization for GE's healthcare business from January 2016 to September 2020. Mr. Westrick joined GE's healthcare business in 2003 as Global Controller and Chief Accounting Officer. He was also named Chief Risk Officer in 2010 and was responsible for leading a comprehensive enterprise risk management program. Prior to joining GE's healthcare business, Mr. Westrick spent 13 years in public accounting with Arthur Andersen LLP and Deloitte & Touche LLP in the audit and consulting practice serving a variety of complex global companies. He currently serves on the Dean's Advisory Board for the Wisconsin School of Business.

ETHICS AND GOVERNANCE

We have adopted The Spirit & The Letter (GE HealthCare's code of conduct), which qualifies as a code of ethics under Item 406 of Regulation S-K. The code applies to all of our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions.

Our code of ethics is available free of charge on our website, gehealthcare.com, and will be provided free of charge to any shareholder submitting a written request to: Corporate Secretary, GE HealthCare Technologies Inc., 500 W. Monroe Street, Chicago, IL 60661. We will disclose any waiver we grant to an executive officer or director under our code of ethics, or certain amendments to the code of ethics, on our website.

In addition, we have adopted Governance Principles and charters for each of the three standing committees of our Board of Directors (the "Board"). All of these materials are available on our web site, gehealthcare.com, and will be provided free of charge to any shareholder requesting a copy by writing to: Corporate Secretary, GE HealthCare Technologies Inc., 500 W. Monroe Street, Chicago, IL 60661.

ADDITIONAL INFORMATION ABOUT GE HEALTHCARE

GE HealthCare's Internet address is gehealthcare.com, and our Investor Relations website is investor.gehealthcare.com. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), are available, without charge, on our website, as soon as reasonably practicable after they are filed electronically with the SEC. Reports filed with the SEC may be viewed at sec.gov. The information on our website is not, and shall not be deemed to be, a part of this Annual Report on Form 10-K or incorporated into any other filings we make with the SEC.

ITEM 1A. RISK FACTORS

SUMMARY OF RISK FACTORS.

An investment in our company is subject to a number of risks. These risks relate to our business, the healthcare industry, data privacy, laws and regulations, financing and capital markets activities, our Spin-Off from GE, our common stock, and the securities market. Any of these risks and other risks could materially and adversely affect our business, results of operations, cash flows, and financial condition and the actual outcome of matters as to which forward-looking statements are made in this Annual Report on Form 10-K. Some of the more significant challenges and risks we face include the following:

- We operate in highly competitive markets, competition may increase in the future, and our industry may be disrupted, requiring us to lower prices or resulting in a loss of market share.
- Our business dealings involve third-party partners in various markets, and the actions or inactions of these third parties could adversely affect our business.
- Our inability to successfully complete strategic transactions could adversely affect our business.
- Our inability to manage our supply chain or obtain supplies of components or raw materials has restricted, and could continue to restrict, the manufacturing of products, cause delays in delivery, or significantly increase our costs.
- Any interruption in the operations of our manufacturing facilities, or our suppliers' or customers' facilities, may impair our ability to deliver products or provide services.
- We rely on third parties to help perform logistics, transportation, shipping, warehousing, and services functions on our behalf, and disruptions at these third-party providers could adversely affect our business.
- We have significant postretirement benefit liabilities, including pension, healthcare, and life insurance benefits obligations, and the actual costs and related cash flows of these obligations are uncertain and could exceed current estimates.
- If we are unable to attract or retain key personnel and qualified employees or maintain relations with our employees, unions, and other employee representatives it could adversely affect our business.
- Public health crises, epidemics, and pandemics, such as the COVID-19 pandemic, have had and in the future may have a material adverse impact on our business, as well as on the operations and financial performance of some of the customers and suppliers in industries that we serve.
- Our research and development efforts may not succeed in developing commercially successful products and technologies, which could adversely affect our business.
- We may be unable to obtain, maintain, protect, or effectively enforce our IP rights.

4L

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* See Attachment A ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 03236	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) See Attachment A ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: ImmunoGen, Inc.

Physical Address: 830 Winter Street

City: Waltham State: MA Zip: 02451

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

City: _____ State: _____ Zip: _____

Telephone: 781-895-0600 Website: www.immunogen.com

Name of Designated Representative (DR): Michael T. Bock

Licensing Company Email: michael.bock@immunogen.com DR Email: michael.bock@immunogen.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☑ Pharmacies	☑ Dangerous Drugs	☑ Manufacturer (Virtual)
☑ Practitioners	☐ Controlled Substances	☐ Repacker
☑ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☑ Others: distributors, pharmaceutical companies and clinics.		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

24JUL2024
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attachment B

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Massachusetts

Parent Company (if any): Athene Subsidiary LLC (wholly-owned by AbbVie Inc., a publicly traded company)

Corporation Name: ImmunoGen, Inc.

Mailing Address: 830 Winter Street

City: Waltham State: NJ Zip: 02451

Telephone: 781-895-0600 Email: michael.bock@immunogen.com

Contact Person Name: Michael T. Bock

Date of SEC Registration: 12-19-2012 | SEC Registration Number: 333 | Stock Exchange Symbol: ABBV

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: N/A		✔
1. Copy of Certification N/A 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. N/A		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration See Attachment B N/A - ultimate parent company is publicly held. 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment C	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** See Attachment E	✓			
• **List of all corporation shareholders and their percent ownership.** N/A		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment D	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) See Attachment E	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment C	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment F	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

ImmunoGen, Inc.

Facility Name

Michael T. Bock

Print Name of Authorized Person Submitting Application

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

24 JUL 2024

Date

Board Use Only	Date Received: 9/18/24	Amount: $1000 - ck 4000503383

Attachment A

Regarding the Ownership Change

Effective February 12, 2024, ImmunoGen, Inc. underwent a change in ownership. The company was previously publicly held and is now owned by Athene Subsidiary LLC. Provided is documentation of the ownership change. Note that the ultimate parent company is AbbVie Inc., a publicly traded company.

ASSISTANT SECRETARY CERTIFICATE

I, Michelle Bratzke, do hereby certify that:

1. I am a duly appointed and qualified Assistant Secretary of AbbVie Inc. and acting as such; that AbbVie Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal office at 1 N. Waukegan Road, North Chicago, Illinois, USA and its registered address at 1521 Concord Pike, Suite 201, Wilmington Delaware USA;

2. I am a keeper of its books and records;

3. ImmunoGen, Inc. is a corporation organized and existing under the laws of the State of Massachusetts with its principal office at 830 Winter Street, Waltham Massachusetts 02451 USA and its registered address at 84 State Street, Boston, Massachusetts 02109 USA;

4. ImmunoGen, Inc. is an indirectly wholly-owned *subsidiary* of AbbVie Inc.

IN WITNESS WHEROF, I have subscribed my name as Assistant Secretary of said corporation this 19th day of April 2024.

Michelle Bratzke
Assistant Secretary

Attachment B

Nature of Business and FDA Registration

ImmunoGen, Inc. "ImmunoGen" is a virtual prescription drug manufacturer. ImmunoGen's product is for the treatment of ovarian cancer. ImmunoGen uses contract manufacturers to produce its product and a third party logistics provider to ship. No product is handled at ImmunoGen's business office. Provided below is the contact information for the contract manufacturers and third party logistics provider. In addition, enclosed is documentation of ImmunoGen's FDA labeler code registration.

Contract Manufacturers:

BSP Pharmaceuticals S.R.L.
via Appia Kim 65,561
04013 Latina Scalo (LT) Italy
FDA registration #: 3007255826

Anderson Brecon dba PCI Pharma Services
1635 New Milford School Road
Rockford, IL 61109
FDA registration #: 3003015528

Third Party Logistics Provider:

Cardinal Health 105, LLC
15 Ingram Boulevard
La Vergne, TN 37086

National Drug Code Directory

Current through March 20, 2024

You have searched Finished drug products

Search Results: *'72903'*

Back to Search Page () | **Search Again ()**

CSV Excel

Display 50 **records per page**

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class
ELAHERE	72903-853-01	100 mg/20mL	INJECTION, SOLUTION	INTRAVENOUS	BLA761310	ImmunoGen, Inc.	72903-853	mirvetuximab soravtansine	MIRVETUXIMAB SORAVTANSINE	HUMAN PRESCRIPTION DRUG	11/14/2022	N/A	BLA	1 VIAL, SINGLE-USE in 1 CARTON (72903-853-01) / 20 mL in 1 VIAL, SINGLE-USE	N/A

Showing 1 to 1 of 1 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Attachment C

Corporate Officer, Director and Employee Information

ImmunoGen, Inc.
830 Winter Street
Waltham, MA 02451

Corporate Officers

Scott T. Reents
President and Sole Director

Lindsey Bristow
Vice President

Stefan Geldmeyer
Treasurer

Wayne Klintworth
Assistant Treasurer

Emily A. Weith
Secretary

Please see the following pages that include a list of the Board of Director and employees at the Waltham office.

The Commonwealth of Massachusetts

Secretary of the Commonwealth

State House, Boston, Massachusetts 02133

William Francis Galvin
Secretary of the
Commonwealth

Date: July 24, 2024

To Whom It May Concern :

I hereby certify that according to the records of this office,

IMMUNOGEN, INC.

is a domestic corporation organized on **March 27, 1981** , under the General Laws of the Commonwealth of Massachusetts. I further certify that there are no proceedings presently pending under the Massachusetts General Laws Chapter 156D section 14.21 for said corporation's dissolution; that articles of dissolution have not been filed by said corporation; that, said corporation has filed all annual reports, and paid all fees with respect to such reports, and so far as appears of record said corporation has legal existence and is in good standing with this office.

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

William Francis Galvin

Secretary of the Commonwealth

Certificate Number: 24070333840

Verify this Certificate at: http://corp.sec.state.ma.us/CorpWeb/Certificates/Verify.aspx

Processed by: hng

THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration to:

IMMUNOGEN, INC.
830 WINTER STREET
WALTHAM, MA 02451

Robert Goldstein, MD, PhD
Commissioner - Department of Public Health

Registration Number: MA0000656

Type: Virtual Manufacturer

Issue Date: 04/15/2024

Expiration Date: 05/26/2025

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH

Commonwealth of Massachusetts
Department of Revenue
Geoffrey E. Snyder, Commissioner

mass.gov/dor

Letter ID: L1903224480
Notice Date: July 19, 2024
Case ID: 0-002-466-867

CERTIFICATE OF GOOD STANDING AND/OR TAX COMPLIANCE

IMMUNOGEN INC
830 WINTER ST STE 6
WALTHAM MA 02451-1477

Why did I receive this notice?

The Commissioner of Revenue certifies that, as of the date of this certificate, IMMUNOGEN INC is in compliance with its tax obligations under Chapter 62C of the Massachusetts General Laws.

This certificate doesn't certify that the taxpayer is compliant in taxes such as unemployment insurance administered by agencies other than the Department of Revenue, or taxes under any other provisions of law.

This is not a waiver of lien issued under Chapter 62C, section 52 of the Massachusetts General Laws.

What if I have questions?

If you have questions, call us at (617) 887-6400, Monday through Friday, 9:00 a.m. to 4:00 p.m.

Visit us online!

Visit mass.gov/dor to learn more about Massachusetts tax laws and DOR policies and procedures, including your Taxpayer Bill of Rights, and MassTaxConnect for easy access to your account:

- Review or update your account
- Contact us using e-message
- Sign up for e-billing to save paper
- Make payments or set up autopay

Edward W. Coyle, Jr., Chief
Collections Bureau

Attachment E

SEC Report and Top Shareholders

Parent Company:

Athene Subsidiary LLC
Ownership: 100%

Ultimate Parent Company:

AbbVie Inc. (a publicly traded company)

Top Shareholders of AbbVie Inc. (latest available):

Shareholder's Name	Percent Ownership
Vanguard Group Inc.	9.06%
Blackrock Inc.	8.06%
State Street Corporation	4.42%
JP Morgan Chase & Co.	2.93%

Enclosed are the first 15 pages from AbbVie Inc.'s latest SEC 10-K report.

Last Name	First Name	Job Title	Division	Location Type
		ImmunoGen, Inc.		
Ab	Olga	Sr Dir, Research Drug Discovery	Research, Development, & Medical Affairs	Headquarters (US)
Abrar	Faiz	Sr Pharmacovigilance Specialist	Research, Development, & Medical Affairs	Headquarters (US)
Adler	Shelly	Sr Dir, Benefits	General Administration	Headquarters (US)
Ahmed	Yasmin	Sr Engineer II, Data Analytics	Technical Operations	Headquarters (US)
Balaji	Sri	Dir, Translational Medicine	Research, Development, & Medical Affairs	Headquarters (US)
Bedse	Gaurav	Assoc Dir, Clinical Pharmacology	Research, Development, & Medical Affairs	Headquarters (US)
Bhattacharya	Tuhina	Sr Mgr, Regulatory CMC	Research, Development, & Medical Affairs	Headquarters (US)
Bleichfeld	Howard	Dir, Clinical Contracts Attorney	General Administration	Headquarters (US)
Bock	Michael	Exec Dir, External Manufacturing	Technical Operations	Headquarters (US)
Bour	Chumnith	Sr Mgr, Pharmacovigilance	Research, Development, & Medical Affairs	Headquarters (US)
Brodeur	Jason	Assoc Dir, External Manufacturing	Technical Operations	Headquarters (US)
Brousseau	Anna	Mgr, Analytical Development	Technical Operations	Headquarters (US)
Brown	Eric	Principal Process Engineer, Manufacturing Sciences	Technical Operations	Headquarters (US)
Burek	Terrence	Exec Dir, Lead Healthcare Counsel	General Administration	Headquarters (US)
Burkey	Cecelia	Project Manager - CMC	Technical Operations	Headquarters (US)
Ciccarelli	Lorna	Sr Executive Assistant	Commercial	Headquarters (US)
Clouden	Clevon	End User Experience Specialist	General Administration	Headquarters (US)
Colon	Mari	Sr Quality Assurance Operations Specialist	Research, Development, & Medical Affairs	Headquarters (US)
Connelly	Nicole	Dir, Medical Affairs	Research, Development, & Medical Affairs	Headquarters (US)
Connolly	Sarah	Ocular Medical Director	Research, Development, & Medical Affairs	Headquarters (US)
Croce	Maurisa	VP, Marketing	Commercial	Headquarters (US)
DaSilva	Adam	Dir, Clinical Outsourcing & Contracts	Research, Development, & Medical Affairs	Headquarters (US)
Dempsey	Patrick	Assoc Dir, EH&S/Facilities	General Administration	Headquarters (US)
Deutschman	Emily	Scientist III	Research, Development, & Medical Affairs	Headquarters (US)
Dey	Arup	Sr Mgr, Lab Operations	General Administration	Headquarters (US)
Dionne	Benjamin	Dir, Biologics Process Development	Technical Operations	Headquarters (US)
Donahue	Bradley	Assoc Dir, FP&A	General Administration	Headquarters (US)
Donahue	Kelly	Sr Translational Sciences Operations Specialist	Research, Development, & Medical Affairs	Headquarters (US)
Donovan	Luna	Sr Development Associate, Analytical Development	Technical Operations	Headquarters (US)

Doyle	Leslie	Sr Dir, Manufacturing Sciences	Technical Operations	Headquarters (US)
Dushime	Junia	Assoc Dir, Analytical Development	Technical Operations	Headquarters (US)
Erion	Thanh	Sr Dir, IP	General Administration	Headquarters (US)
Esposito	Eric	Sr Mgr, Facilities	General Administration	Headquarters (US)
Fang	Christina	Dir, Regulatory Affairs Global Lead	Research, Development, & Medical Affairs	Headquarters (US)
Fitzgerald	Kristen	Sr Administrative Assistant	General Administration	Headquarters (US)
Flaherty	Mark	Principal Supply Chain Planning and Analytics Associate	Technical Operations	Headquarters (US)
Fudeman	Mary	Dir, Program Management	General Administration	Headquarters (US)
Gabriel	Richshelle	Documentation Specialist III	Research, Development, & Medical Affairs	Headquarters (US)
Gallo	Stephen	Development Associate III, Process Development	Technical Operations	Headquarters (US)
Germeys	Philip	Dir, IT	General Administration	Headquarters (US)
Gill	Brandy	Assoc Dir, Product Disposition	Research, Development, & Medical Affairs	Headquarters (US)
Gimenez	Julia	Sr Quality Assurance Specialist	Research, Development, & Medical Affairs	Headquarters (US)
Giordani	James	VP, Corporate Planning & Program Management	General Administration	Headquarters (US)
Griffin	Celina	Sr Dir, Pharmacovigilance Science	Research, Development, & Medical Affairs	Headquarters (US)
Hague	Andrew	Sr Principal Scientist, Process Development	Technical Operations	Headquarters (US)
Herbst	Robert	VP, Technical Operations	Technical Operations	Headquarters (US)
Issa	Sandy	Sr Mgr, Purchasing	General Administration	Headquarters (US)
Jaffe	Geula	VP, Product Team Lead	Research, Development, & Medical Affairs	Headquarters (US)
Johnson	Kendra	Sr Dir, CMC & Operations Management	Technical Operations	Headquarters (US)
Joyce	Maureen	Principal IP Specialist	General Administration	Headquarters (US)
Kavouris	John	Scientist II, Process Development	Technical Operations	Headquarters (US)
Kim	Jenna	Dir, Regulatory CMC	Research, Development, & Medical Affairs	Headquarters (US)
Kitchener	Seth	Sr Dir, Process Development	Technical Operations	Headquarters (US)
Krolewicz	Barbara	Assoc Dir, Supply Chain	Technical Operations	Headquarters (US)
Lauziere	Kevin	Dir, Manufacturing Sciences	Technical Operations	Headquarters (US)
Leander	Michael	Mgr, End User Experience	General Administration	Headquarters (US)
LeDoux	Juli	Dir, Patient Marketing	Commercial	Headquarters (US)
Lemos Ribeir	Francisco	VP, Chief Compliance Officer	General Administration	Headquarters (US)
Leuci	Jacqueline	Development Associate II	Technical Operations	Headquarters (US)
Lytle	Grace	Executive Ocular Medical Director	Research, Development, & Medical Affairs	Headquarters (US)
Lyu	Weijia	Principal SAS Programmer	Research, Development, & Medical Affairs	Headquarters (US)

Makarova	Alexandra	Dir, Commercial Analytics and Insights	Commercial	Headquarters (US)
Malcolm	Kara	Sr Dir, Clinical Research	Research, Development, & Medical Affairs	Headquarters (US)
Maldonado Br	Anthony	Principal Product Testing Specialist	Research, Development, & Medical Affairs	Headquarters (US)
Mastrullo	Jeanine	Sr Mgr, Regulatory Operations	Research, Development, & Medical Affairs	Headquarters (US)
Mathe	Jeffrey	Sr Documentation Specialist	Research, Development, & Medical Affairs	Headquarters (US)
Milano	Daniel	Sr Dir, Process Development	Technical Operations	Headquarters (US)
Morneault	Ashley	Sr Mgr, Initiative Management	Research, Development, & Medical Affairs	Headquarters (US)
Morse	Jennifer	Sr Mgr, Analytical Development	Technical Operations	Headquarters (US)
Mosgofian	Paula	Assoc Dir, Quality Systems	Research, Development, & Medical Affairs	Headquarters (US)
Nagle	Steven	Assoc Dir, Finance	General Administration	Headquarters (US)
Narsimhan	Karthik	Sr Development Engineer III, Process Development	Technical Operations	Headquarters (US)
Neenan	Allison	Sr Project Manager - CMC	Technical Operations	Headquarters (US)
O'Neil	Kevin	Dir, FP&A	General Administration	Headquarters (US)
Paniagua	Juana	Exec Dir, Quality Assurance	Research, Development, & Medical Affairs	Headquarters (US)
Parrott	Timothy	Dir, Pharmacovigilance Quality and Compliance	Research, Development, & Medical Affairs	Headquarters (US)
Patel	Hardikkumar	Sr Quality Assurance Specialist	Research, Development, & Medical Affairs	Headquarters (US)
Pepe	Michael	Sr Mgr, Analytical Development	Technical Operations	Headquarters (US)
Pessia	Mary Beth	Sr Executive Assistant	Research, Development, & Medical Affairs	Headquarters (US)
Pieroni	Steven	Principal Process Engineer, Manufacturing Sciences	Technical Operations	Headquarters (US)
Plesac	Colleen	Assoc Dir, Competitive Intelligence	General Administration	Headquarters (US)
Polanco	Gloria	Sr Quality Product Manager	Research, Development, & Medical Affairs	Headquarters (US)
Poole	Tracey	Sr Dir, Commercial and Medical IT	General Administration	Headquarters (US)
Poudel	Ishwari	Sr Mgr, E-Systems Validation and Compliance	Research, Development, & Medical Affairs	Headquarters (US)
Powers	William	Assoc Dir, Global Logistics	Technical Operations	Headquarters (US)
Radesca	Lilian	Sr Dir, External Manufacturing	Technical Operations	Headquarters (US)
Rajaratnam	Priyadharshin	Dir, Clinical Operations	Research, Development, & Medical Affairs	Headquarters (US)
Reid	Emily	Sr Scientist, Research Chemistry	Technical Operations	Headquarters (US)
Richard	Anna	Sr Executive Assistant	Research, Development, & Medical Affairs	Headquarters (US)
Robins	Barry	Dir, Product Quality	Research, Development, & Medical Affairs	Headquarters (US)
Rodriguez Be	Jose	Assoc Dir, Product Testing	Research, Development, & Medical Affairs	Headquarters (US)
Rogers	Meredith	Sr Process Engineer III, Manufacturing Sciences	Technical Operations	Headquarters (US)
Romero	Oswald	Mgr, IT Infrastructure and Operations	General Administration	Headquarters (US)

Sachdev	Shwetank	Dir, Data Analyst and Architect	General Administration	Headquarters (US)
Schenk	Nicole	Principal Clinical Data Manager	Research, Development, & Medical Affairs	Headquarters (US)
Sen	Jayita	Assoc Dir, Clinical Research	Research, Development, & Medical Affairs	Headquarters (US)
Sevigny	Chelsea	Dir, Competitive Intelligence	General Administration	Headquarters (US)
Sharpe	Meredith	Associate Project Manager, External Manufacturing	Technical Operations	Headquarters (US)
Silva	Frances	Principal Clinical Data Manager	Research, Development, & Medical Affairs	Headquarters (US)
Som	Brenda	Assoc Dir, Total Rewards	General Administration	Headquarters (US)
Spunt	Sheri	Sr Medical Director	Research, Development, & Medical Affairs	Headquarters (US)
Stanzione	Marcello	Scientist III, Early Pipeline Research and Development	Research, Development, & Medical Affairs	Headquarters (US)
Sun	Yingchuan	Dir, Clinical Research	Research, Development, & Medical Affairs	Headquarters (US)
Szeto	Victor	Sr Mgr, Regulatory CMC	Research, Development, & Medical Affairs	Headquarters (US)
Themeles	Marian	Assoc Dir, IHC Lab	Research, Development, & Medical Affairs	Headquarters (US)
Trudeau	Alexander	Assoc Dir, Manufacturing	Technical Operations	Headquarters (US)
Vakil	Shweta	Principal GMP Audit and Compliance Specialist	Research, Development, & Medical Affairs	Headquarters (US)
Wang	Peng	Principal SAS Programmer	Research, Development, & Medical Affairs	Headquarters (US)
Wang	Yuemei	Sr Dir, Biostatistics	Research, Development, & Medical Affairs	Headquarters (US)
Wildt	Adrienne	Sr Dir, Analytical Development	Technical Operations	Headquarters (US)
Williamson	Michaelle	Dir, Regulatory CMC	Research, Development, & Medical Affairs	Headquarters (US)
Zhao	John	Principal Scientist, Analytical Development	Technical Operations	Headquarters (US)
Zhou	Xinhua	Exec Dir, Clinical Programming	Research, Development, & Medical Affairs	Headquarters (US)
Zhu	Fengying	Dir, Bioanalysis	Research, Development, & Medical Affairs	Headquarters (US)
Zulick	Alan	Dir, Program Management	General Administration	Headquarters (US)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D. C. 20549

FORM 10-K

(MARK ONE)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 001-35565

abbvie

AbbVie Inc.

(Exact name of registrant as specified in its charter)

Delaware	32-0375147
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer identification number)

1 North Waukegan Road
North Chicago, Illinois 60064-6400
(847) 932-7900
(Address, including zip code, and telephone number of principal executive offices)

Securities Registered Pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value $0.01 per share	ABBV	New York Stock Exchange
		Chicago Stock Exchange
1.375% Senior Notes due 2024	ABBV24	New York Stock Exchange
1.250% Senior Notes due 2024	ABBV24B	New York Stock Exchange
0.750% Senior Notes due 2027	ABBV27	New York Stock Exchange
2.125% Senior Notes due 2028	ABBV28	New York Stock Exchange
2.625% Senior Notes due 2028	ABBV28B	New York Stock Exchange
2.125% Senior Notes due 2029	ABBV29	New York Stock Exchange
1.250% Senior Notes due 2031	ABBV31	New York Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer ☒ Accelerated Filer ☐
Non-Accelerated Filer ☐ Smaller reporting company ☐
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by checkmark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes ☐ No ☒

The aggregate market value of the 1,748,902,939 shares of voting stock held by non-affiliates of the registrant, computed by reference to the closing price as reported on the New York Stock Exchange, as of the last business day of AbbVie Inc.'s most recently completed second fiscal quarter (June 30, 2023), was $235,629,692,915. AbbVie has no non-voting common equity.

Number of common shares outstanding as of January 31, 2024: 1,766,473,359

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the 2024 AbbVie Inc. Proxy Statement are incorporated by reference into Part III. The Definitive Proxy Statement will be filed on or about March 18, 2024.

ABBVIE INC.
FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2023
TABLE OF CONTENTS

		Page No.
PART I		
Item 1.	BUSINESS	1
Item 1A.	RISK FACTORS	14
Item 1B.	UNRESOLVED STAFF COMMENTS	25
Item 1C	CYBERSECURITY	25
Item 2.	PROPERTIES	27
Item 3.	LEGAL PROCEEDINGS	27
Item 4.	MINE SAFETY DISCLOSURES	27
	INFORMATION ABOUT OUR EXECUTIVE OFFICERS	28
PART II		
Item 5.	MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	30
Item 6.	[RESERVED]	32
Item 7.	MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	33
Item 7A.	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	49
Item 8.	FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	50
Item 9.	CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	99
Item 9A.	CONTROLS AND PROCEDURES	99
Item 9B.	OTHER INFORMATION	101
Item 9C.	DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS	101
PART III		
Item 10.	DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	102
Item 11.	EXECUTIVE COMPENSATION	102
Item 12.	SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	103
Item 13.	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	103
Item 14.	PRINCIPAL ACCOUNTING FEES AND SERVICES	103
PART IV		
Item 15.	EXHIBITS, FINANCIAL STATEMENT SCHEDULES	104
Item 16.	FORM 10-K SUMMARY	108
	SIGNATURES	109

PART I

ITEM 1. BUSINESS

Overview

AbbVie or "the company" refer to AbbVie Inc., or AbbVie Inc. and its consolidated subsidiaries, as the context requires. AbbVie is a global, diversified research-based biopharmaceutical company positioned for success with a comprehensive product portfolio that has leadership positions across immunology, oncology, aesthetics, neuroscience and eye care. AbbVie uses its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. AbbVie was incorporated in Delaware on April 10, 2012. On January 1, 2013, AbbVie became an independent, publicly-traded company as a result of the distribution by Abbott Laboratories (Abbott) of 100% of the outstanding common stock of AbbVie to Abbott's shareholders.

Segments

AbbVie operates as a single global business segment dedicated to the research and development, manufacturing, commercialization and sale of innovative medicines and therapies. This operating structure enables the Chief Executive Officer, as chief operating decision maker (CODM), to allocate resources and assess business performance on a global basis in order to achieve established long-term strategic goals. Consistent with this structure, a global research and development and supply chain organization is responsible for the discovery, development, manufacturing and supply of products. Commercial efforts that coordinate the marketing, sales and distribution of these products are organized by geographic region or therapeutic area. All of these activities are supported by a global corporate administrative staff. The determination of a single business segment is consistent with the consolidated financial information regularly reviewed by the CODM for purposes of assessing performance, allocating resources and planning and forecasting future periods. See Note 16, "Segment and Geographic Area Information" to the Consolidated Financial Statements included under Item 8, "Financial Statements and Supplementary Data" and the sales information related to AbbVie's key products and geographies included under Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Products

AbbVie's portfolio of products includes a broad line of therapies that address some of the world's most complex and serious diseases.

Immunology products. AbbVie maintains an extensive immunology portfolio across rheumatology, dermatology and gastroenterology. AbbVie's immunology products address unmet needs for patients with autoimmune diseases. These products are:

Humira. Humira (adalimumab) is a biologic therapy administered as a subcutaneous injection. It is approved to treat the following autoimmune diseases in the United States, Canada and Mexico (collectively, North America) and in the European Union:

Condition	Principal Markets
Rheumatoid arthritis (moderate to severe)	North America, European Union
Psoriatic arthritis	North America, European Union
Ankylosing spondylitis	North America, European Union
Adult Crohn's disease (moderate to severe)	North America, European Union
Plaque psoriasis (moderate to severe chronic)	North America, European Union
Juvenile idiopathic arthritis (moderate to severe polyarticular)	North America, European Union
Ulcerative colitis (moderate to severe)	North America, European Union
Axial spondyloarthropathy	European Union
Pediatric Crohn's disease (moderate to severe)	North America, European Union
Hidradenitis suppurativa (moderate to severe)	North America, European Union
Pediatric enthesitis-related arthritis	European Union
Non-infectious intermediate, posterior and panuveitis	North America, European Union
Pediatric ulcerative colitis (moderate to severe)	U.S., Canada, European Union
Pediatric uveitis	North America, European Union

Humira is also approved in Japan for the treatment of intestinal Behçet's disease and pyoderma gangrenosum.

Humira is sold in numerous other markets worldwide, including Japan, China, Brazil and Australia, and accounted for approximately 27% of AbbVie's total net revenues in 2023.

Skyrizi. Skyrizi (risankizumab) is an interleukin-23 (IL-23) inhibitor that selectively blocks IL-23 by binding to its p19 subunit. It is a biologic therapy approved to treat the following autoimmune diseases in North America, the European Union and Japan:

Condition	Principal Markets
Plaque psoriasis (moderate to severe)	North America, European Union, Japan
Psoriatic arthritis	U.S., European Union
Crohn's disease (moderate to severe)	U.S., Canada, European Union

Skyrizi is also approved in Japan for the treatment of plaque psoriasis, psoriatic arthritis, erythrodermic psoriasis in patients who have an inadequate response to conventional therapies, and for induction and maintenance in moderately to severely active Crohn's disease.

Skyrizi is approved in multiple countries globally, including the United States, Canada and the European Union, for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. In psoriatic disease (psoriasis or psoriatic arthritis) Skyrizi is administered as a quarterly subcutaneous injection following two induction doses. When administered for Crohn's disease, Skyrizi is given in three induction doses via IV infusion, followed by subcutaneous injection via an on-body injector every eight weeks.

Rinvoq. Rinvoq (upadacitinib) is an oral, once-daily selective and reversible JAK inhibitor that is approved to treat the following inflammatory diseases in North America, the European Union and Japan:

Condition	Principal Markets
Rheumatoid arthritis (moderate to severe)	North America, European Union, Japan
Psoriatic arthritis	U.S., Canada, European Union, Japan
Ankylosing spondylitis	U.S., European Union
Atopic dermatitis (moderate to severe)	U.S., Canada, European Union, Japan
Axial spondyloarthropathy	U.S., European Union
Ulcerative colitis (moderate to severe)	U.S., European Union
Crohn's disease (moderate to severe)	U.S., European Union

In the United States, Rinvoq is indicated for both the treatment of moderate to severe active rheumatoid arthritis, for active psoriatic arthritis, for moderate to severe active ulcerative colitis, for active ankylosing spondylitis and for active non-radiographic axial spondyloarthritis in adult patients who have an inadequate response or intolerance to one or more TNF blockers. It is also indicated for the treatment of Crohn's disease in adult patients who have an inadequate response or intolerance to one or more TNF blockers and for moderate to severe atopic dermatitis in adults and children 12 years of age and older whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable.

In the European Union, Rinvoq is indicated for the treatment of moderate to severe rheumatoid arthritis in adults, for active psoriatic arthritis in adults who have an inadequate response or intolerance to disease-modifying anti-rheumatic medicines (DMARDs), and for active axial spondyloarthritis in adults. It is also indicated for the treatment of Crohn's disease in adult patients who have an inadequate response or intolerance to one or more TNF blockers and for moderate to severe atopic dermatitis in adults and children 12 years of age and older, and for moderately to severely active ulcerative colitis in adults.

Oncology products. AbbVie's oncology products target some of the most complex and difficult-to-treat cancers. These products are:

Imbruvica. Imbruvica (ibrutinib) is an oral, once-daily therapy that inhibits a protein called Bruton's tyrosine kinase. Imbruvica was one of the first medicines to receive a United States Food and Drug Administration (FDA) approval after being granted a Breakthrough Therapy Designation and is one of the few therapies to receive four separate designations. Imbruvica currently is approved for the treatment of adult patients with blood cancers such as chronic lymphocytic leukemia (CLL), as well as certain forms of non-Hodgkin lymphoma. Imbruvica is approved in adult and pediatric patients one year and older with chronic graft versus host disease after failure of one or more lines of systemic therapy.

Venclexta/Venclyxto. Venclexta (venetoclax) is a B-cell lymphoma 2 (BCL-2) inhibitor used to treat blood cancers. Venclexta is approved by the FDA for adults with CLL or small lymphocytic lymphoma. In addition, Venclexta is approved in combination with azacitidine, or decitabine, or low-dose cytarabine to treat adults with newly-diagnosed acute myeloid leukemia who are 75 years of age or older or have other medical conditions that prevent the use of standard chemotherapy.

Epkinly. Epkinly (epcoritimab) is a product used to treat adults with certain types of diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma that has recurred or that does not respond to previous treatment after receiving two or more treatments. Epkinly is administered as a subcutaneous injection.

Elahere. Elahere (mirvetuximab soravtansine-gynx) is an antibody-drug conjugate (ADC) used to treat certain types of cancer. On November 14, 2022, the FDA granted accelerated approval for the treatment of adult patients with FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Aesthetics products. AbbVie's Aesthetics portfolio consists of facial injectables, plastics and regenerative medicine, body contouring and skincare products, which hold market-leading positions in the U.S. and in key markets around the world. These products are:

Botox Cosmetic. Botox Cosmetic is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for treatment in three areas: temporary improvement in the appearance of moderate to severe glabellar lines (frown lines between the eyebrows), moderate to severe crow's feet and moderate to severe forehead lines in adults. Having received its initial FDA approval in 2002, Botox Cosmetic is now approved for use in all major markets around the world.

The Juvederm Collection of Fillers. The Juvederm Collection of Fillers is a portfolio of hyaluronic acid-based dermal fillers with a variety of approved indications in the U.S. and in other major markets around the world to augment or treat volume loss in the cheeks, chin, lips and lower face.

Other aesthetics. Other aesthetics products include, but are not limited to, Alloderm regenerative dermal tissue, CoolSculpting body contouring technology, Natrelle breast implants, the SkinMedica skincare line, Latisse eyelash solution and DiamondGlow dermabrasion technology.

Neuroscience products. AbbVie's neuroscience products address some of the most difficult-to-treat neurologic diseases. These products are:

Botox Therapeutic. Botox Therapeutic (onabotulinumtoxinA injection) is an acetylcholine release inhibitor and a neuromuscular blocking agent that is injected into muscle tissue. In the United States, it is approved to treat numerous indications, including chronic migraine, overactive bladder in adults who have an inadequate response to an anticholinergic medication, and urinary incontinence due to detrusor overactivity associated with a neurologic condition in adults who have an inadequate response to an anticholinergic medication. In addition, Botox Therapeutic is approved to treat spasticity in patients two years of age and older, cervical dystonia in adults, as well as other conditions. Botox is marketed in other countries around the world and licenses will vary. Botox Therapeutic is marketed by GSK in Japan.

Vraylar. Vraylar (cariprazine) is a dopamine D3-preferring D3/D2 receptor partial agonist and a 5-HT1A receptor partial agonist. Vraylar is indicated for acute and maintenance treatment of schizophrenia in adults, acute treatment of manic or mixed episodes associated with bipolar disorder in adults, acute treatment of depressive episodes associated with bipolar I disorder in adults and as an adjunctive treatment in major depressive disorder.

Duopa and Duodopa (carbidopa and levodopa). AbbVie's levodopa-carbidopa intestinal gel for the treatment of advanced Parkinson's disease is marketed as Duopa in the United States and as Duodopa outside of the United States.

Ubrelvy. Ubrelvy (ubrogepant) is a calcitonin gene-related peptide receptor antagonist indicated for the acute treatment of migraine with or without aura in adults. Ubrelvy is commercialized in the United States, Israel, Saudi Arabia, United Arab Emirates and Canada.

Qulipta. Qulipta (atogepant) is a calcitonin gene-related peptide receptor antagonist indicated for the preventive treatment of episodic and chronic migraine in adults. Qulipta is commercialized in the United States and Canada and is approved in the European Union under the brand name Aquipta.

Eye care products. AbbVie's eye care products address unmet needs and new approaches to help preserve and protect patients' vision. These products are:

Ozurdex. Ozurdex (dexamethasone intravitreal implant) is a corticosteroid implant that slowly releases medication over time. Injected directly into the back of the eye, it dissolves naturally and does not need to be removed. Ozurdex is indicated for the treatment of adult patients with visual impairment due to diabetic macular oedema (DME), adult patients with macular oedema following either Branch Retinal Vein Occlusion (BRVO) or Central Retinal Vein Occlusion (CRVO) and patients with inflammation of the posterior segment of the eye presenting as non-infectious uveitis. Ozurdex® is commercially available in the United States and numerous markets around the world.

Lumigan/Ganfort. Lumigan (bimatoprost ophthalmic solution) 0.01% is a once daily, topical prostaglandin analog indicated for the reduction of elevated intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT). Ganfort is a once daily topical fixed combination of bimatoprost 0.03% and timolol 0.5% for the reduction of IOP in adult patients with OAG or OHT. Lumigan is sold in the United States and numerous markets around the world, while Ganfort is approved in the European Union and some markets in South America, the Middle East and Asia.

Alphagan/Combigan. Alphagan (brimonidine tartrate ophthalmic solution) is an alpha-adrenergic receptor agonist indicated for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension. Combigan (brimonidine tartrate/timolol maleate ophthalmic solution) is approved for reducing elevated IOP in patients with glaucoma who require additional or adjunctive IOP-lowering therapy. Both Alphagan and Combigan are available for sale in the United States and numerous markets around the world.

Restasis. Restasis is a calcineurin inhibitor immunosuppressant indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Restasis is approved in the United States and a number of other markets in South America, the Middle East and Asia.

Other eye care. Other eye care products include Refresh/Optive, Xen and Durysta.

Other key products. AbbVie's other key products include, among other things, treatments for patients with hepatitis C virus (HCV), metabolic and hormone products that target a number of conditions, including exocrine pancreatic insufficiency and hypothyroidism, as well as endocrinology products for the palliative treatment of advanced prostate cancer, treatment of endometriosis and central precocious puberty and for the preoperative treatment of patients with anemia caused by uterine fibroids. These products are:

Mavyret/Maviret. Mavyret (glecaprevir/pibrentasvir) is approved in the United States and European Union (Maviret) for the treatment of adult and pediatric patients (12 years and older or weighing at least 45 kilograms) with chronic HCV genotype 1-6 infection without cirrhosis and with compensated cirrhosis (Child-Pugh A). It is also indicated for the treatment of adult and pediatric patients (12 years and older or weighing at least 45 kilograms) with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.

Creon. Creon (pancrelipase) is a pancreatic enzyme therapy for exocrine pancreatic insufficiency, a condition that occurs in patients with cystic fibrosis, chronic pancreatitis and several other conditions.

Lupron. Lupron (leuprolide acetate), which is also marketed as Lucrin and Lupron Depot, is a product for the palliative treatment of advanced prostate cancer, treatment of endometriosis and central precocious puberty and for the preoperative treatment of patients with anemia caused by uterine fibroids. Lupron is approved for daily subcutaneous injection and one-month, three-month, four-month and six-month intramuscular injection.

Linzess/Constella. Linzess (linaclotide) is a once-daily guanylate cyclase-C agonist used in adults to treat irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation. The product is marketed as Linzess in the United States and as Constella outside of the United States.

Synthroid. Synthroid (levothyroxine sodium tablets, USP) is used in the treatment of hypothyroidism.

AbbVie has the rights to sell Creon and Synthroid only in the United States.

Marketing, Sales and Distribution Capabilities

AbbVie utilizes a combination of dedicated commercial resources, regional commercial resources and distributorships to market, sell and distribute its products worldwide. AbbVie directs its primary marketing efforts toward securing the prescription, or recommendation, of its brand of products by physicians, external experts and other health care providers. Managed care providers (for example, health maintenance organizations and pharmacy benefit managers), hospitals and state and federal government agencies (for example, State Medicaid programs, the United States Department of Veterans Affairs and the United States Department of Defense) are also important customers. AbbVie also markets directly to consumers themselves, although in the United States many of the company's products must be sold pursuant to a prescription. Outside of the United States, AbbVie focuses its promotional and market access efforts on external experts, payers, physicians and health systems. AbbVie also provides patient support programs closely related to its products.

AbbVie's products are generally sold worldwide directly to wholesalers, distributors, government agencies, health care facilities, specialty pharmacies and independent retailers from AbbVie-owned distribution centers and public warehouses. Certain products (including aesthetic products and devices) are also sold directly to physicians and other licensed healthcare providers. Although AbbVie's business does not have significant seasonality, AbbVie's product revenues may be affected by end customer and retail buying patterns, fluctuations in wholesaler inventory levels and other factors.

In the United States, AbbVie distributes pharmaceutical products principally through independent wholesale distributors, with some sales directly to retailers, pharmacies, patients or other customers. In 2023, three wholesale distributors (McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen Corporation) accounted for substantially all of AbbVie's pharmaceutical product sales in the United States. No individual wholesaler accounted for greater than 39% of AbbVie's 2023 gross revenues in the United States. Outside the United States, AbbVie sells products primarily to wholesalers or through distributors, and depending on the market works through largely centralized national payers systems to agree on reimbursement terms.

Certain products are co-marketed or co-promoted with other companies. AbbVie has no single customer that, if the customer were lost, would have a material adverse effect on the company's business. No material portion of AbbVie's business is subject to renegotiation of profits or termination of contracts at the election of the government. Orders are generally filled on a current basis and order backlog is not material to AbbVie's business.

Competition

The markets for AbbVie's products are highly competitive. AbbVie competes with other research-based pharmaceuticals and biotechnology companies that discover, manufacture, market and sell proprietary pharmaceutical products, therapies and biologics. For example, AbbVie's immunology products compete with anti-TNF products, JAK inhibitors and other competitive products intended to treat a number of disease states, and AbbVie's oncology products compete with BTK inhibitors and other competitive products intended to treat certain cancers. In addition, in the past few years, a number of other companies have started to develop, have successfully developed and/or are currently marketing products that are being positioned as competitors to Botox. The search for technological innovations in pharmaceutical products is a significant aspect of competition. The introduction of new products by competitors and changes in medical practices and procedures can result in product obsolescence. Price is also a competitive factor. In addition, the substitution of generic and biosimilar pharmaceutical products for branded pharmaceutical products creates competitive pressures on AbbVie's products that do not have patent protection. New products or treatments brought to market by AbbVie's competitors could cause revenues for AbbVie's products to decrease due to price reductions and sales volume decreases.

Biosimilars. Competition for AbbVie's biologic products is affected by the approval of follow-on biologics, also known as "biosimilars." Biologics have added major therapeutic options for the treatment of many diseases, including some for which therapies were unavailable or inadequate. The cost of developing and producing biologic therapies is typically dramatically higher than for small molecule medications, and many biologic medications are used for ongoing treatment of chronic diseases, such as rheumatoid arthritis or inflammatory bowel disease, or for the treatment of previously untreatable cancer. Significant investments in biologics infrastructure and manufacturing are necessary to produce biologic products.

Humira is facing direct biosimilar competition globally, and AbbVie will continue to face competitive pressure from these biologics and from orally administered products.

In the United States, the FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act (the FFDCA), the Public Health Service Act (PHSA) and the regulations implementing these statutes. The enactment of federal health care reform legislation in March 2010 provided a pathway for approval of biosimilars under the PHSA, but the approval process for, and science behind, biosimilars is complex. Approval by the FDA is dependent upon many factors, including a showing that the biosimilar is "highly similar" to the original product and has no clinically meaningful differences from the original product in

terms of safety, purity and potency. The types of data that could ordinarily be required in an application to show similarity may include analytical data, bioequivalence studies and studies to demonstrate chemical similarity, animal studies (including toxicity studies) and clinical studies.

Furthermore, the law provides that only a biosimilar product that is determined to be "interchangeable" will be considered by the FDA as substitutable for the original biologic product without the intervention of the health care provider who prescribed the original biologic product. To prove that a biosimilar product is interchangeable, the applicant must demonstrate that the product can be expected to produce the same clinical results as the original biologic product in any given patient, and if the product is administered more than once in a patient, that safety risks and potential for diminished efficacy of alternating or switching between the use of the interchangeable biosimilar biologic product and the original biologic product is no greater than the risk of using the original biologic product without switching. The law continues to be interpreted and implemented by the FDA. As a result, its full ultimate impact, implementation and meaning remains subject to uncertainty.

Intellectual Property Protection and Regulatory Exclusivity

Generally, upon approval, products may be entitled to certain kinds of exclusivity under applicable intellectual property and regulatory regimes. AbbVie's intellectual property is materially valuable to the company, and AbbVie seeks patent protection, where available, in all significant markets and/or countries for each product in development. In the United States, the expiration date for patents is 20 years after the filing date. Given that patents relating to pharmaceutical products are often obtained early in the development process and given the amount of time needed to complete clinical trials and other development activities required for regulatory approval, the length of time between product launch and patent expiration is significantly less than 20 years. The Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act) permits a patent holder to seek a patent extension, commonly called a "patent term restoration," for patents on products (or processes for making the product) regulated by the FFDCA. The length of the patent extension is roughly based on 50 percent of the period of time from the filing of an Investigational New Drug Application (NDA) for a compound to the submission of the NDA for such compound, plus 100 percent of the time period from NDA submission to regulatory approval. The extension, however, cannot exceed five years and the patent term remaining after regulatory approval cannot exceed 14 years. Biological products licensed under the PHSA are similarly eligible for terms of patent restoration.

Pharmaceutical products may be entitled to other forms of legal or regulatory exclusivity upon approval. The scope, length and requirements for each of these exclusivities vary both in the United States and in other jurisdictions. In the United States, if the FDA approves a conventional drug product that contains an active ingredient not previously approved, the product is typically entitled to five years of non-patent regulatory exclusivity. Specific conditions of use approved for individual products may also be entitled to three years of exclusivity if approval was based on the FDA's reliance on new clinical studies essential to approval submitted by the NDA applicant. If the NDA applicant studies the product for use by children, the FDA may grant pediatric exclusivity, which extends by 180 days all existing exclusivities (patent and regulatory) related to the product. For products that are either used to treat conditions that afflict a relatively small population or for which there is not a reasonable expectation that the research and development costs will be recovered, the FDA may designate the pharmaceutical as an orphan drug and grant it seven years of exclusivity. Other types of regulatory exclusivity may also be available, such as Generating New Antibiotic Incentives Now (GAIN) exclusivity, which can provide new antibiotic or new antifungal drugs an additional five years of exclusivity to be added to certain exclusivities already provided for by law.

Applicable laws and regulations dictate the scope of any exclusivity to which a product or particular characteristics of a product is entitled upon approval in any particular country. In certain instances, regulatory exclusivity may offer protection where patent protection is no longer available or for a period of time in excess of patent protection. It is not possible to estimate for each product in development the total period and scope of exclusivity to which it may become entitled until regulatory approval is obtained or sometimes even later. However, given the length of time required to complete clinical development of a pharmaceutical product, the periods of exclusivity that might be achieved in any individual case would not generally be expected to exceed a minimum of three years and a maximum of 14 years. These estimates do not consider other factors, such as the difficulty of recreating the manufacturing process for a particular product or other proprietary knowledge that may delay the introduction of a generic or other follow-on product after the expiration of applicable patent and other regulatory exclusivity periods.

Biologics may be entitled to exclusivity under the Biologics Price Competition and Innovation Act, which was passed on March 23, 2010 as Title VII to the Patient Protection and Affordable Care Act. The law provides a pathway for approval of biosimilars following the expiration of 12 years of regulatory exclusivity for the innovator biologic and a potential additional 180 day-extension term for conducting pediatric studies. Biologics are also eligible for orphan drug exclusivity, as discussed above. The law also includes an extensive process for the innovator biologic and biosimilar manufacturer to litigate patent

infringement, validity and enforceability. The European Union has also created a pathway for approval of biosimilars and has published guidelines for approval of certain biosimilar products. The more complex nature of biologics and biosimilar products has led to close regulatory scrutiny over follow-on biosimilar products, which can reduce the effect of biosimilars on sales of the innovator biologic as compared to the sales erosion caused by generic versions of small molecule pharmaceutical products.

AbbVie owns or has licensed rights to a substantial number of patents and patent applications. AbbVie licenses or owns a patent portfolio of thousands of patent families, each of which includes United States patent applications and/or issued patents and may also contain the non-United States counterparts to these patents and applications.

These patents and applications, including various patents that expire during the period 2024 to the mid 2040s, in aggregate are believed to be of material importance in the operation of AbbVie's business. However, AbbVie believes that no single patent, license, trademark (or related group of patents, licenses, or trademarks), are material in relation to the company's business as a whole.

In addition, the following patents, licenses and trademarks are significant: those related to ibrutinib (which is sold under the trademark Imbruvica), those related to risankizumab (which is sold under the trademark Skyrizi) and those related to upadacitinib (which is sold under the trademark Rinvoq). The United States composition of matter patent covering ibrutinib is expected to expire in 2027, with pediatric regulatory exclusivity then extending until May 2028. However, no generic entry for any ibrutinib product is expected prior to March 30, 2032. The United States composition of matter patent covering risankizumab is expected to expire in 2033. And the United States composition of matter patent covering upadacitinib is expected to expire in 2033.

AbbVie may rely, in some circumstances, on trade secrets to protect its technology. AbbVie seeks to protect its technology and product candidates, in part, by confidentiality agreements with its employees, consultants, advisors, contractors and collaborators. These agreements may be breached and AbbVie may not have adequate remedies for any breach. In addition, AbbVie's trade secrets may otherwise become known or be independently discovered by competitors. To the extent that AbbVie's employees, consultants, advisors, contractors and collaborators use intellectual property owned by others in their work for the company, disputes may arise as to the rights in related or resulting know-how and inventions.

Licensing, Acquisitions and Other Arrangements

In addition to its independent efforts to develop and market products, AbbVie enters into arrangements such as acquisitions, option-to-acquire agreements, licensing arrangements, option-to-license arrangements, strategic alliances, co-promotion arrangements, co-development and co-marketing agreements and joint ventures. The acquisitions and option-to-acquire agreements typically include, among other terms and conditions, non-refundable purchase price payments or option fees, option exercise payments, milestones or earn-outs and other customary terms and obligations. The licensing and other arrangements typically include, among other terms and conditions, non-refundable upfront license fees, option fees and option exercise payments, milestone payments and royalty and/or profit sharing obligations. See Note 5, "Licensing, Acquisitions and Other Arrangements—Other Licensing & Acquisitions Activity," to the Consolidated Financial Statements included under Item 8, "Financial Statements and Supplementary Data."

Third Party Agreements

AbbVie has agreements with third parties for process development, product distribution, analytical services and manufacturing of certain products. AbbVie procures certain products and services from a limited number of suppliers and, in some cases, a single supply source. In addition, AbbVie has agreements with third parties for active pharmaceutical ingredient and product manufacturing, formulation and development services, fill, finish and packaging services, transportation and distribution and logistics services for certain products. AbbVie does not believe that these manufacturing-related agreements are material because AbbVie's business is not substantially dependent on any individual agreement. In most cases, AbbVie maintains alternate supply relationships that it can utilize without undue disruption of its manufacturing processes if a third party fails to perform its contractual obligations. AbbVie seeks to maintain sufficient inventory of product to minimize the impact of any supply disruption.

AbbVie is also party to certain collaborations and other arrangements, as discussed in Note 5, "Licensing, Acquisitions and Other Arrangements—Other Licensing & Acquisitions Activity," to the Consolidated Financial Statements included under Item 8, "Financial Statements and Supplementary Data."

Sources and Availability of Raw Materials

AbbVie purchases, in the ordinary course of business, raw materials and supplies essential to its operations from numerous suppliers around the world. In addition, certain medical devices and components necessary for the manufacture of

AbbVie products are provided by unaffiliated third party suppliers. AbbVie has robust business continuity and supplier monitoring programs.

Research and Development Activities

AbbVie makes a significant investment in research and development and has numerous compounds (and complementary devices) in clinical development, including potential treatments for complex, life-threatening diseases. AbbVie's ability to discover and develop new compounds is enhanced by the company's use of integrated discovery and development project teams, which include chemists, biologists, physicians and pharmacologists who work on the same compounds as a team. AbbVie also partners with third parties, such as biotechnology companies, other pharmaceutical companies and academic institutions to identify and prioritize promising new treatments that complement and enhance AbbVie's existing portfolio. AbbVie also supplements its research and development efforts with acquisitions.

The research and development process generally begins with discovery research which focuses on the identification of a molecule that has a desired effect against a given disease. If preclinical testing of an identified compound proves successful, the compound moves into clinical development which generally includes the following phases:

- Phase 1— involves the first human tests in a small number of healthy volunteers or patients to assess safety, tolerability and doses for later phases.
- Phase 2— tests different doses of the drug in a disease state in order to assess efficacy.
- Phase 3— tests a drug that demonstrates favorable results in the earlier phases in a significantly larger patient population to further demonstrate efficacy and safety in order to meet requirements to enable global approval.

Preclinical data and clinical trials from all of the development phases provide the data required to prepare and submit an NDA, a Biological License Application (BLA) or other submission for regulatory approval to the FDA or similar government agencies outside the United States. The specific requirements (e.g., scope of clinical trials) for obtaining regulatory approval vary across different countries and geographic regions.

The research and development process from discovery through a new drug launch typically takes 8 to 12 years and can be even longer. The research and development of new pharmaceutical products has a significant amount of inherent uncertainty. There is no guarantee when, or if, a molecule will receive the regulatory approval required to launch a new drug or indication.

In addition to the development of new products, delivery devices and new formulations, research and development projects also may include Phase 4 trials, sometimes called post-marketing studies. For such projects, clinical trials are designed and conducted to collect additional data regarding, among other parameters, the benefits and risks of an approved drug.

Regulation—Discovery and Clinical Development

United States. Securing approval to market a new pharmaceutical product in the United States requires substantial effort and financial resources and takes several years to complete. The applicant must complete preclinical tests and submit protocols to the FDA before commencing clinical trials. Clinical trials are intended to establish the safety and efficacy of the pharmaceutical product and typically are conducted in sequential phases, although the phases may overlap or be combined. If the required clinical testing is successful, the results are submitted to the FDA in the form of an NDA or BLA requesting approval to market the product for one or more indications. The FDA reviews an NDA or BLA to determine whether a product is safe and effective for its intended use and whether its manufacturing is compliant with current Good Manufacturing Practices (cGMP).

Compliance with regulatory requirements is assured through periodic, announced or unannounced inspections by the FDA and other regulatory authorities, and these inspections associated with clinical development may include the sponsor, investigator sites, laboratories, hospitals and manufacturing facilities of AbbVie's subcontractors or other third-party manufacturers. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, including rejection of an NDA or BLA.

Even if an NDA or a BLA receives approval, the applicant must comply with post-approval requirements. For example, holders of an approval must report adverse reactions, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional materials and activities. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and certain changes to the manufacturing procedures and finished product must be submitted and approved by the FDA prior to implementation. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural and record keeping requirements. In addition, as a condition of approval, the FDA may require post-marketing testing and surveillance to further

assess and monitor the product's safety or efficacy after commercialization, which may require additional clinical trials, patient registries, observational data or additional work on chemistry, manufacturing and controls. Any post-approval regulatory obligations, and the cost of complying with such obligations, could expand in the future. Further, the FDA continues to regulate product labeling, and prohibits the promotion of products for unapproved or "off-label" uses along with other labeling restrictions.

Outside the United States. AbbVie is subject to similar regulatory requirements outside the United States for approval and marketing of pharmaceutical products. AbbVie must obtain approval of a clinical trial application or product from applicable supervising regulatory authorities before it can commence clinical trials or marketing of the product in target markets. The approval requirements and process for each country can vary, and the time required to obtain approval may be longer or shorter than that required for FDA approval in the United States. For example, AbbVie may submit marketing authorizations in the European Union under either a centralized or decentralized procedure. The centralized procedure is mandatory for the approval of biotechnology products and many pharmaceutical products and provides for a single marketing authorization that is valid for all European Union member states. Under the centralized procedure, a single marketing authorization application is submitted to the European Medicines Agency. After the agency evaluates the application, it makes a recommendation to the European Commission, which then makes the final determination on whether to approve the application. The decentralized procedure provides for mutual recognition of individual national approval decisions and is available for products that are not subject to the centralized procedure.

In Japan, applications for approval of a new product are made through the Pharmaceutical and Medical Devices Agency (PMDA). Japan-specific trials and/or bridging studies to demonstrate that the non-Japanese clinical data applies to Japanese patients are usually required. After completing a comprehensive review, the PMDA reports to the Ministry of Health, Labour and Welfare, which then approves or denies the application.

Similarly, applications for a new product in China are submitted to the Center for Drug Evaluation of the National Medical Products Administration for technical review and approval of a product for marketing in China. Clinical data in Chinese subjects are usually required to support approval in China, requiring the inclusion of China in global pivotal studies, or a separate China/Asian clinical trial.

The regulatory process in many emerging markets continues to evolve. Many emerging markets, including those in Asia, generally require regulatory approval to have been obtained in a large developed market (such as the United States or Europe) before the country will begin or complete its regulatory review process. Similar to the requirements in Japan and China, certain countries (notably South Korea, Taiwan, India and Russia) also generally require that clinical studies that include data from patients in those countries be conducted in order to support local regulatory approval.

The requirements governing the conduct of clinical trials and product licensing also vary. In addition, post-approval regulatory obligations such as adverse event reporting and cGMP compliance generally apply and may vary by country. For example, after a marketing authorization has been granted in the European Union, periodic safety reports must be submitted and other pharmacovigilance measures may be required (such as Risk Management Plans).

Regulation—Commercialization, Distribution and Manufacturing

The manufacturing, marketing, sale, promotion and distribution of AbbVie's products are subject to comprehensive government regulation. Government regulation by various national, regional, federal, state and local agencies, both in the United States and other countries, addresses (among other matters) inspection of, and controls over, research and laboratory procedures, clinical investigations, product approvals and manufacturing, labeling, packaging, marketing and promotion, pricing and reimbursement, sampling, distribution, quality control, post-marketing surveillance, record keeping, storage and disposal practices. AbbVie's operations are also affected by trade regulations in many countries that limit the import of raw materials and finished products and by laws and regulations that seek to prevent corruption and bribery in the marketplace (including the United States Foreign Corrupt Practices Act and the United Kingdom Bribery Act, which provide guidance on corporate interactions with government officials) and require safeguards for the protection of personal data. In addition, AbbVie is subject to laws and regulations pertaining to health care fraud and abuse, including state and federal anti-kickback and false claims laws in the United States. Prescription drug manufacturers such as AbbVie are also subject to taxes, as well as application, product, user and other fees.

Compliance with these laws and regulations is costly and materially affects AbbVie's business. Among other effects, health care regulations substantially increase the time, difficulty and costs incurred in obtaining and maintaining approval to market newly developed and existing products. AbbVie expects compliance with these regulations to continue to require significant technical expertise and capital investment to ensure compliance. Failure to comply can delay the release of a new product or result in regulatory and enforcement actions, the seizure or recall of a product, the suspension or revocation of the authority necessary for a product's production and sale and other civil or criminal sanctions, including fines and penalties.

In addition to regulatory initiatives, AbbVie's business can be affected by ongoing studies of the utilization, safety, efficacy and outcomes of health care products and their components that are regularly conducted by industry participants, government agencies and others. These studies can lead to updates to the data regarding utilization, safety and efficacy of previously marketed products. In some cases, these studies have resulted, and may in the future result, in the discontinuance of, or limitations on, marketing of such products domestically or worldwide, and may give rise to claims for damages from persons who believe they have been injured as a result of their use.

Access to human health care products continues to be a subject of oversight, investigation and action by governmental agencies, legislative bodies and private organizations in the United States and other countries. A major focus is cost containment. Efforts to reduce health care costs are also being made in the private sector, notably by health care payers and providers, which have instituted various cost reduction and containment measures. AbbVie expects insurers and providers to continue attempts to reduce the cost of health care products. Outside the United States, many countries control the price of health care products directly or indirectly, through reimbursement, payment, pricing, coverage limitations, or compulsory licensing. Political and budgetary pressures in the United States and in other countries may also heighten the scope and severity of pricing pressures on AbbVie's products for the foreseeable future.

United States. Specifically, U.S. federal laws require pharmaceutical manufacturers to pay certain statutorily-prescribed rebates to state Medicaid programs on prescription drugs reimbursed under state Medicaid plans, and the efforts by states to seek additional rebates may affect AbbVie's business. Similarly, the Veterans Health Care Act of 1992, as a prerequisite to participation in Medicaid and other federal health care programs, requires that manufacturers extend additional discounts on pharmaceutical products to various federal agencies, including the United States Department of Veterans Affairs, Department of Defense and Public Health Service entities and institutions. In addition, recent legislative changes would require similarly discounted prices to be offered to TRICARE program beneficiaries. The Veterans Health Care Act of 1992 also established the 340B drug discount program, which requires pharmaceutical manufacturers to provide products at reduced prices to various designated health care entities and facilities.

In the United States, most states also have generic substitution legislation requiring or permitting a dispensing pharmacist to substitute a different manufacturer's generic version of a pharmaceutical product for the one prescribed. In addition, the federal government follows a diagnosis-related group (DRG) payment system for certain institutional services provided under Medicare or Medicaid and has implemented a prospective payment system (PPS) for services delivered in hospital outpatient, nursing home and home health settings. DRG and PPS entitle a health care facility to a fixed reimbursement based on the diagnosis and/or procedure rather than actual costs incurred in patient treatment, thereby increasing the incentive for the facility to limit or control expenditures for many health care products. Medicare reimburses Part B drugs based on average sales price plus a certain percentage to account for physician administration costs, which have been reduced in the hospital outpatient setting. Medicare enters into contracts with private plans to negotiate prices for most patient-administered medicine delivered under Part D.

Under the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (together, the Affordable Care Act), AbbVie pays a fee related to its pharmaceuticals sales to government programs. In addition, AbbVie provides a discount of 70% for branded prescription drugs sold to patients who fall into the Medicare Part D coverage gap, or "donut hole."

The Affordable Care Act also includes provisions known as the Physician Payments Sunshine Act, which require manufacturers of drugs and biologics covered under Medicare and Medicaid to record any transfers of value to physicians and teaching hospitals and to report this data to the Centers for Medicare and Medicaid Services for subsequent public disclosure. Similar reporting requirements have also been enacted on the state level in the United States, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring disclosure of interactions with health care professionals. Failure to report appropriate data may result in civil or criminal fines and/or penalties.

The Inflation Reduction Act of 2022 (the IRA) requires: (i) the government to set prices for select high expenditure Medicare Part D drugs (prices effective beginning in 2026) and Part B drugs (prices effective beginning in 2028) that are more than nine years (for small-molecule drugs) or 13 years (for biological products) from their FDA approval, (ii) manufacturers to pay a rebate for Medicare Part B and Part D drugs when prices for those drugs increase faster than inflation beginning in 2022 for Part D and 2023 for Part B, and (iii) a Medicare Part D redesign replacing the current coverage gap provisions and establishing a $2,000 cap for out-of-pocket costs for Medicare beneficiaries beginning in 2025, with manufacturers being responsible for 10% of costs up to the $2,000 cap and 20% after that cap is reached. In August 2023, the U.S. Department of Health and Human Services, through the Centers for Medicare & Medicaid Services (the CMS), selected Imbruvica as one of the first 10 medicines subject to government-set prices beginning in 2026. The price-setting process will conclude by August 1, 2024, and on September 1, 2024, the CMS will publish prices that will be applicable to the 10 drugs in the Medicare program beginning January 1, 2026. It is possible that more of our products, including products that generate substantial revenues,

could be selected in future years, which could, among other things, accelerate revenue erosion prior to expiration of intellectual property protections. The effect of reducing prices and reimbursement would significantly impact revenues for certain of our products.

European Union. The European Union has adopted directives and other legislation governing labeling, advertising, distribution, supply, pharmacovigilance and marketing of pharmaceutical products. Such legislation provides mandatory standards throughout the European Union and permits member states to supplement these standards with additional regulations. European governments also regulate pharmaceutical product prices through their control of national health care systems that fund a large part of the cost of such products to consumers. As a result, patients are unlikely to use a pharmaceutical product that is not reimbursed by the government. In many European countries, the government either regulates the pricing of a new product at launch or subsequent launch through direct price controls or reference pricing. In recent years, many countries have also imposed new or additional cost containment measures on pharmaceutical products. Differences between national pricing regimes create price differentials within the European Union that can lead to significant parallel trade in pharmaceutical products.

Most governments also promote generic substitution by mandating or permitting a pharmacist to substitute a different manufacturer's generic version of a pharmaceutical product for the one prescribed and by permitting or mandating that health care professionals prescribe generic versions in certain circumstances. Many governments are also following a similar path for biosimilar therapies. In addition, governments use reimbursement lists to limit the pharmaceutical products that are eligible for reimbursement by national health care systems.

Japan. In Japan, the National Health Insurance system maintains a Drug Price List specifying which pharmaceutical products are eligible for reimbursement, and the Ministry of Health, Labour and Welfare sets the prices of the products on this list. The government generally introduces price cut rounds every other year and also mandates price decreases for specific products. New products judged innovative or useful, that are indicated for pediatric use, or that target orphan or small population diseases, however, may be eligible for a pricing premium. The government has also promoted the use of generics, where available.

Emerging Markets. Many emerging markets take steps to reduce pharmaceutical product prices, in some cases through direct price controls and in others through the promotion of generic/biosimilar alternatives to branded pharmaceuticals.

Since AbbVie markets its products worldwide, certain products of a local nature and variations of product lines must also meet other local regulatory requirements. Certain additional risks are inherent in conducting business outside the United States, including price and currency exchange controls, changes in currency exchange rates, limitations on participation in local enterprises, expropriation, nationalization and other governmental action.

Regulation – Medical Devices

Medical devices are subject to regulation by the FDA, state agencies and foreign government health authorities. FDA regulations, as well as various U.S. federal and state laws, govern the development, clinical testing, manufacturing, labeling, record keeping and marketing of medical device products agencies in the United States. AbbVie's medical device product candidates, including AbbVie's breast implants, must undergo rigorous clinical testing and an extensive government regulatory clearance or approval process prior to sale in the United States and other countries. The lengthy process of clinical development and submissions for clearance or approval, and the continuing need for compliance with applicable laws and regulations, require the expenditure of substantial resources. Regulatory clearance or approval, when and if obtained, may be limited in scope, and may significantly limit the indicated uses for which a product may be marketed. Cleared or approved products and their manufacturers are subject to ongoing review, and discovery of previously unknown problems with products may result in restrictions on their manufacture, sale and/or use or require their withdrawal from the market.

United States. AbbVie's medical device products are subject to extensive regulation by the FDA in the United States. Unless an exemption applies, each medical device AbbVie markets in the United States must have a 510(k) clearance or a Premarket Approval Application (PMA) in accordance with the FFDCA and its implementing regulations. The FDA classifies medical devices into one of three classes, depending on the degree of risk associated with each medical device and the extent of controls that are needed to ensure safety and effectiveness. Devices deemed to pose a lower risk are placed in either Class I or Class II, and devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or a device deemed to be not substantially equivalent to a previously cleared 510(k) device, are placed in Class III. In general, a Class III device cannot be marketed in the United States unless the FDA approves the device after submission of a PMA, and any changes to the device subsequent to initial FDA approval must also be reviewed and approved by the FDA. The majority of AbbVie's medical device products, including AbbVie's breast implants, are regulated as Class III medical devices. A Class III device may have significant additional obligations imposed in its conditions of approval, and the time in which it takes

to obtain approval can be long. Compliance with regulatory requirements is assured through periodic, unannounced facility inspections by the FDA and other regulatory authorities, and these inspections may include the manufacturing facilities of AbbVie's subcontractors or other third-party manufacturers. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions: warning letters or untitled letters; fines, injunctions and civil penalties; recall or seizure of AbbVie' products; operating restrictions, partial suspension or total shutdown of production; refusing AbbVie' request for 510(k) clearance or PMA approval of new products; withdrawing 510(k) clearance or PMA approvals that are already granted; and criminal prosecution.

A clinical trial is almost always required to support a PMA application and is sometimes required for a 510(k) premarket notification. Clinical trials generally require submission of an application for an investigational device exemption (IDE), which must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. A study sponsor must obtain approval for its IDE from the FDA, and it must also obtain approval of its study from the institutional Review Board overseeing the trial. The results of clinical testing may not be sufficient to obtain approval of the investigational device.

Once a device is approved, the manufacture and distribution of the device remains subject to continuing regulation by the FDA, including Quality System Regulation requirements, which involve design, testing, control, documentation and other quality assurance procedures during the manufacturing process. Medical device manufacturers and their subcontractors are required to register their establishments and list their manufactured devices with the FDA and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with regulatory requirements. Manufacturers must also report to the FDA if their devices may have caused or contributed to a death or serious injury or malfunctioned in a way that could likely cause or contribute to a death or serious injury, or if the manufacturer conducts a field correction or product recall or removal to reduce a risk to health posed by a device or to remedy a violation of the FFDCA that may present a health risk. Further, the FDA continues to regulate device labeling, and prohibits the promotion of products for unapproved or "off-label" uses along with other labeling restrictions.

European Union. Medical device products that are marketed in the European Union must comply with the requirements of the Medical Device Regulation (the MDR), which came into effect in May 2021. The MDR provides for regulatory oversight with respect to the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices to ensure that medical devices marketed in the European Union are safe and effective for their intended uses. Medical devices that comply with the MDR are entitled to bear a Conformité Européenne marking evidencing such compliance and may be marketed in the European Union. Failure to comply with these domestic and international regulatory requirements could affect AbbVie's ability to market and sell AbbVie's products in these countries.

Environmental Matters

AbbVie believes that its operations comply in all material respects with applicable laws and regulations concerning environmental protection. Regulations under federal and state environmental laws impose stringent limitations on emissions and discharges to the environment from various manufacturing operations. AbbVie's capital expenditures for pollution control in 2023 were approximately $16 million and operating expenditures were approximately $43 million. In 2024, capital expenditures for pollution control are estimated to be approximately $22 million and operating expenditures are estimated to be approximately $45 million.

Abbott was identified as one of many potentially responsible parties in investigations and/or remediations at several locations in the United States, including Puerto Rico, under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund. Some of these locations were transferred to AbbVie in connection with the separation and distribution, and AbbVie has become a party to these investigations and remediations. Abbott was also engaged in remediation at several other sites, some of which have been transferred to AbbVie in connection with the separation and distribution, in cooperation with the Environmental Protection Agency or similar agencies. While it is not feasible to predict with certainty the final costs related to those investigations and remediation activities, AbbVie believes that such costs, together with other expenditures to maintain compliance with applicable laws and regulations concerning environmental protection, should not have a material adverse effect on the company's financial position, cash flows, or results of operations.

Employees

AbbVie employed approximately 50,000 employees in over 70 countries as of January 31, 2024. Outside the United States, some of AbbVie's employees are represented by unions or works councils. AbbVie believes that it has good relations with its employees.

Human Capital Management

Attracting, retaining and providing meaningful growth and development opportunities to AbbVie's employees is critical to the company's success in making a remarkable impact on people's lives around the world. AbbVie leverages numerous resources to identify and enhance strategic and leadership capability, foster employee engagement and create a culture where talent is productive and engaged. AbbVie invests in its employees through competitive compensation, benefits and employee support programs and offers best-in-class development and leadership opportunities. AbbVie has developed a deep talent base through ongoing investment in functional and leadership training and by sourcing world-class external talent, ensuring a sustainable talent pipeline. AbbVie continuously cultivates and enhances its working culture and embraces equality, diversity and inclusion as fundamental to the company's mission.

Attracting and Developing Talent. Attracting and developing high-performing talent is essential to AbbVie's continued success. AbbVie implements detailed talent attraction strategies, with an emphasis on STEM skill sets, a diverse talent base and other critical skillsets, including drug discovery, clinical development, market access and business development. AbbVie also invests in competitive compensation and benefits programs. In addition to offering a comprehensive suite of benefits ranging from medical and dental coverage to retirement, disability and life insurance programs, AbbVie also provides health promotion programs, mental health awareness campaigns and employee assistance programs in several countries, financial wellness support, on-site health screenings and immunizations in several countries and on-site fitness and rehabilitation centers. AbbVie has on-site health care clinics at certain locations, offering convenient and affordable access to quality healthcare, flu shots and vaccines. In addition, the AbbVie Employee Assistance Fund (a part of the AbbVie Foundation) supports two programs for global employees: the AbbVie Possibilities Scholarship for children of employees, which is an annual merit-based scholarship for use at accredited colleges, universities or vocational-technical schools; and the Employee Relief Program, which is financial assistance to support short term needs of employees when faced with large-scale disasters (e.g. a hurricane), individual disasters (e.g. a home fire) or financial hardship (e.g. the death of a spouse). Finally, AbbVie empowers managers and their teams with tools, tips and guidelines on effectively managing workloads, managing teams from a distance and supporting flexible work practices, including "Where We Work", AbbVie's hybrid work model, offering eligible employees predictable flexibility.

New AbbVie employees are given a tailored onboarding experience for faster integration and to support performance. One of AbbVie's mentorship programs allows employees to self-nominate as mentors or mentees and facilitates meaningful relationships supporting employees' career and development goals.

AbbVie also provides structured, broad-based development opportunities, focusing on high-performance skills and leadership training. AbbVie's talent philosophy holds leaders accountable for building a high-performing organization, and the company provides development opportunities for all levels of leadership. AbbVie's Learn, Develop, Perform program offers year-long, self-directed leadership education, supplemented with tools and resources, and leverages leaders as role models and teachers. In addition, a foundational success factor to AbbVie's leadership pipeline is the company's Professional Development Programs, which attract graduates, postgraduates and post-doctoral talent to participate in formal development programs lasting up to three years, with the objective of strengthening functional and leadership capabilities.

Culture. AbbVie's shared principles of transforming lives, acting with integrity, driving innovation, embracing diversity and inclusion and serving the community form the core of the company's culture. AbbVie articulates the behaviors associated with these values in the Ways We Work, a core set of working behaviors that emphasize how the company achieves results is equally as important as achieving them. The Ways We Work are designed to ensure that every AbbVie employee is aware of the company's cultural expectations. AbbVie integrates the Ways We Work into all talent processes, forming the basis for assessing performance, prioritizing development and ultimately rewarding employees. AbbVie believes its culture creates strong engagement, which is measured regularly through a confidential, third-party all-employee survey, and this engagement supports AbbVie's mission of making a remarkable impact on people's lives.

Equity, Equality, Diversity & Inclusion (EED&I). A cornerstone of AbbVie's human capital management approach is to prioritize fostering an inclusive and diverse workforce. AbbVie's Equity, Equality, Diversity & Inclusion roadmap defines key global focus areas, objectives and associated initiatives, and includes implementation plans organized by business function and geography. AbbVie's senior leaders have adopted formal goals aligned with executing this strategy. Through December 2023, women represented 52 percent of management positions globally and in the United States, 37 percent of AbbVie's workforce was comprised of members of historically underrepresented populations, consistent with 2022. Further, AbbVie is committed to pay equity and conducts pay equity analyses annually. A critical component of AbbVie's strategy is to instill an inclusive mindset in all AbbVie leaders and employees, so the company continues to realize the full value of its workforce from recruitment through retirement. AbbVie's Employee Resource Groups also help the company nurture an inclusive culture by building community and creating connections. Additional information about AbbVie's Equity, Equality, Diversity and

Inclusion efforts can be found on the company's website at: https://www.abbvie.com/who-we-are/equity-equality-inclusion-diversity.html.

Internet Information

Copies of AbbVie's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge through AbbVie's investor relations website (*investors.abbvie.com*) as soon as reasonably practicable after AbbVie electronically files the material with, or furnishes it to, the Securities and Exchange Commission (SEC).

AbbVie's corporate governance guidelines, outline of directorship qualifications, code of business conduct and the charters of AbbVie's audit committee, compensation committee, nominations and governance committee and public policy committee are all available on AbbVie's investor relations website (*investors.abbvie.com*).

ITEM 1A. RISK FACTORS

You should carefully consider the following risks and other information in this Form 10-K in evaluating AbbVie and AbbVie's common stock. Any of the following risks could materially and adversely affect AbbVie's results of operations, financial condition or cash flows. The risk factors generally have been separated into two groups: risks related to AbbVie's business and risks related to AbbVie's common stock. Based on the information currently known to it, AbbVie believes that the following information identifies the most significant risk factors affecting it in each of these categories of risks. However, the risks and uncertainties AbbVie faces are not limited to those set forth in the risk factors described below and may not be in order of importance or probability of occurrence. Additional risks and uncertainties not presently known to AbbVie or that AbbVie currently believes to be immaterial may also adversely affect its business. In addition, past financial performance may not be a reliable indicator of future performance and historical trends should not be used to anticipate results or trends in future periods.

If any of the following risks and uncertainties develops into actual events, these events could have a material adverse effect on AbbVie's business, results of operations, financial condition or cash flows. In such case, the trading price of AbbVie's common stock could decline.

Risks Related to AbbVie's Business

The expiration or loss of patent protection and licenses, including the loss of exclusivity for Humira and increased competition from biosimilars, may adversely affect AbbVie's revenues and operating earnings.

AbbVie relies on patent, trademark and other intellectual property protection in the discovery, development, manufacturing and sale of its products. In particular, patent protection is, in the aggregate, important in AbbVie's marketing of pharmaceutical products in the United States and most major markets outside of the United States. Patents covering AbbVie products normally provide market exclusivity, which is important for the profitability of many of AbbVie's products.

As patents for certain of its products expire, AbbVie could face competition from lower priced generic or biosimilar products. The expiration or loss of patent protection for a product typically is followed promptly by substitutes that may significantly reduce sales for that product in a short amount of time. If AbbVie's competitive position is compromised because of generics, biosimilars or otherwise, it could have a material adverse effect on AbbVie's business and results of operations. In addition, proposals emerge from time to time for legislation to further encourage the early and rapid approval of generic drugs or biosimilars. Any such proposals that are enacted into law could increase the impact of generic competition.

Large pharmaceutical companies and generics manufacturers of pharmaceutical products continue to expand into the biotechnology field and form partnerships to pursue biosimilars. Companies have developed and are developing biosimilars that compete with AbbVie's biologic products, including Humira. As competitors obtain marketing approval for biosimilars referencing AbbVie's biologic products, AbbVie's products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. Expiration of or successful challenges to AbbVie's applicable patent rights could also trigger competition from other products, assuming any relevant exclusivity period has expired. As a result, AbbVie could face increased litigation and administrative proceedings with respect to the validity and/or scope of patents relating to its biologic products.

For example, Humira accounted for approximately 27% of AbbVie's total net revenues in 2023. Humira is facing competition from biosimilar products in the United States following the loss of exclusivity in 2023, which AbbVie anticipates will continue to cause a significant decline in Humira's revenue and could adversely affect AbbVie's revenues and operating earnings.

AbbVie's principal patents and trademarks are described in greater detail in Item 1, "Business—Intellectual Property Protection and Regulatory Exclusivity" and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations," and litigation regarding these patents is described in Item 3, "Legal Proceedings."

AbbVie's major products could lose patent protection earlier than expected, which could adversely affect AbbVie's revenues and operating earnings.

A significant portion of AbbVie's revenue and operating earnings are derived from several major products. Third parties or government authorities may challenge or seek to invalidate or circumvent AbbVie's patents and patent applications. For example, manufacturers of generic pharmaceutical products file, and may continue to file, Abbreviated New Drug Applications with the FDA seeking to market generic forms of AbbVie's products prior to the expiration of relevant patents owned or licensed by AbbVie by asserting that the patents are invalid, unenforceable and/or not infringed. In addition, petitioners have filed, and may continue to file, challenges to the validity of AbbVie's patents under the 2011 Leahy-Smith America Invents Act, which created *inter partes* review and post grant review procedures for challenging patent validity in administrative proceedings at the United States Patent and Trademark Office.

Although most of the challenges to AbbVie's intellectual property have come from other businesses, governments may also challenge intellectual property rights. For example, court decisions and potential legislation relating to patents, such as legislation regarding biosimilars, and other regulatory initiatives may result in further erosion of intellectual property protection. In addition, certain governments outside the United States have indicated that compulsory licenses to patents may be sought to further their domestic policies or on the basis of national emergencies, such as HIV/AIDS. If triggered, compulsory licenses may diminish or eliminate sales and profits from those jurisdictions and negatively affect AbbVie's results of operations.

AbbVie normally responds to challenges by vigorously defending its patents, including by filing patent infringement lawsuits. Patent litigation, administrative proceedings and other challenges to AbbVie's patents are costly and unpredictable and may deprive AbbVie of market exclusivity for a patented product. To the extent AbbVie's intellectual property is successfully challenged, circumvented or weakened, or to the extent such intellectual property does not allow AbbVie to compete effectively, AbbVie's business will suffer. To the extent that countries do not enforce AbbVie's intellectual property rights or require compulsory licensing of AbbVie's intellectual property, AbbVie's revenues and operating earnings will be reduced.

A third party's intellectual property may prevent AbbVie from selling its products or have a material adverse effect on AbbVie's profitability and financial condition.

Third parties may claim that an AbbVie product infringes upon their intellectual property. In addition, in its pursuit of valid business opportunities, AbbVie may be required to challenge intellectual property rights held by others that it believes were improperly granted. Resolving an intellectual property infringement or other claim can be costly and time consuming and may require AbbVie to enter into license agreements. AbbVie cannot guarantee that it would be able to obtain license agreements on commercially reasonable terms. A successful claim of patent or other intellectual property infringement could subject AbbVie to significant damages or an injunction preventing the manufacture, sale, or use of the affected AbbVie product or products. Any of these events could have a material adverse effect on AbbVie's profitability and financial condition.

AbbVie's research and development efforts may not succeed in developing and marketing commercially successful products and technologies, which may cause its revenues and profitability to decline.

To remain competitive, AbbVie must continue to launch new products and new indications and/or brand extensions for existing products. Such launches must generate revenue sufficient both to cover its substantial research and development costs and to replace revenues of profitable products that are lost to or displaced by competing products or therapies. Failure to do so would have a material adverse effect on AbbVie's revenue and profitability. Accordingly, AbbVie commits substantial effort, funds and other resources to research and development and must make ongoing substantial expenditures without any assurance that its efforts will be commercially successful. A high rate of failure in the biopharmaceutical industry is inherent in the research and development of new products, and failure can occur at any point in the research and development process, including after significant funds have been invested. Products that appear promising in development may fail to reach the market for numerous reasons, including failure to demonstrate effectiveness, safety concerns, superior safety or efficacy of competing therapies, failure to achieve positive clinical or pre-clinical outcomes beyond the current standards of care, inability to obtain necessary regulatory approvals or delays in the approval of new products and new indications, limited scope of approved uses, excessive costs to manufacture or the failure to obtain or maintain intellectual property rights, or infringement of the intellectual property rights of others.

4M

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada ☑ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ☑ Ownership Change* ☑ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 00797	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Auburn Pharmaceutical LLC dba Auburn

Physical Address: 1744 Rochester Industrial Dr.

City: Rochester Hills, State: MI Zip: 48309

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 248-526-3730 Website: auburngenerics.com

Name of Designated Representative (DR): Meridith Leighty

Licensing Company Email: _____ DR Email: compliance@auburnpharm.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☑ Pharmacies	☑ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☑ Controlled Substances	☐ Repacker
☑ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 **. Provide all the following *where applicable*:** See Attached

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below: See Attached

Original Signature (electronic, copies or stamps not accepted)

8/27/24
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: List Attached

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Top Rx Intermediate, LLC

Corporation/Organization Name: Auburn Pharmaceutical, LLC dba Auburn

Mailing Address: 1744 Rochester Industrial Dr.

City: Rochester Hills, State: MI Zip: 48309

Telephone: 248-526-3730 Email: Compliance@auburnpharm.com

Contact Person Name: Merideth Leighty

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Auburn Pharmaceutical, LLC dba Auburn

Facility Name

Amber Versaski

Print Name of Authorized Person Submitting Application

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

8/27/24

Date

Board Use Only	Date Received: 9/5/24	Amount: $1000 ck 228712

AUBURN
PHARMACEUTICAL

Auburn Pharmaceutical Company
Notice of Prior Disciplinary Actions

Prior Actions

1. Oregon
On December 4, 2003, the Oregon Board of Pharmacy issued a Consent Order against Auburn on the grounds that Auburn, located in Troy, Michigan had been distributing drugs into Oregon from approximately 1998 to 2003 without complying with all registration requirements with the Oregon Board. Auburn was unable to locate historic registration materials, and agreed to a Consent Order with Oregon. Auburn's payment of a civil penalty of $1000 resolved the matter.

2. California
On October 22, 2013, the California State Board of Pharmacy issued a Citation and Fine of $2,500 against Auburn involving a pharmacy located in Santa Ana, California (the "Santa Ana Pharmacy") and a second Citation and Fine of $2500, arising out of the same allegation, against the Designated Responsible Party, Mark L. Rumble. On October 22, 2014, the California State Board of Pharmacy issued a Citation and Fine of $5,000 against Auburn involving a pharmacy in Orange, California (the "Orange Pharmacy") and a second Citation and Fine of $2,500, arising out of the same allegation, against the Designated Responsible Party, Mark L. Rumble. The California State Board of Pharmacy alleged that Auburn failed to report an unusual size and frequency of orders placed by the Santa Ana and Orange pharmacies. Auburn objected to and appealed both Citations and Fines because there was no prior substantial deviation or evidence of suspicious orders. Each month during the period examined, Auburn sold monthly dosage units to the Santa Ana and Orange pharmacies (which are located within a group of medical buildings) were substantially and dramatically below average pharmacy sale levels in California and nationally. Notwithstanding its objection and appeal, Auburn discontinued all sales to the Santa Ana and Orange pharmacies. Additionally, for expediency and settlement purposes, Auburn ultimately paid the Fines. All Citations and Fines have been resolved.

3. Kentucky
On March 20, 2014, the Kentucky Board of Pharmacy notified Auburn of its determination that Auburn, although issued a Controlled Substance License 16117 by the Kentucky Cabinet for Health and Family Services, unknowingly failed to apply for a second license from the Kentucky Board of Pharmacy. Pursuant to an Agreed Order dated on or about October 12, 2014, Auburn was fined $5,000 for an "unknowing violation", with a finding by the Kentucky Board of Pharmacy that "there shall be no suspension or revocation of license, probation, or restriction or other disciplinary action against [Auburn] on account of" the unknowing violation. Auburn remitted payment of the fine and the complaint has been resolved.

4. Michigan
On June 27, 2017, the Michigan Department of Licensing and Regulatory Affairs ("LARA") issued an Administrative Complaint charging Auburn with failure to notify LARA "of a complaint filed by another state in which the Applicant is licensed for violations of that state's pharmacy laws, within 30 days of knowledge of the complaint." Specifically, LARA alleged that Auburn failed to provide timely notice of its Citation from the California State Board of Pharmacy (although such notice was thereafter provided) notwithstanding Auburn's appeal of that Citation which was still pending. For expediency and settlement purposes, pursuant to a Consent Order dated on or about December 13, 2017, Auburn voluntarily agreed to pay a fine of $5,000. Auburn has remitted payment of such fine to LARA in accordance with the Consent Order, thereby resolving the Administrative Complaint.

AUBURN
PHARMACEUTICAL

5. Alabama

On April 4, 2018, the Alabama State Board of Pharmacy issued a Consent Order to Auburn arising from a failure to notify the Alabama Board of the prior citations issued by the California Board of Pharmacy on October 22, 2014 and the Kentucky Board of Pharmacy on October 12, 2014. There were no additional or separate conduct violations by Auburn. Auburn has remitted payment of the $1,000 administrative fine to the Alabama Board, thereby resolving the complaint.

Prior Actions

1. Alaska

   On October 2, 2022 a new Facility Manager was appointed for Top Rx, LLC (Alaska License # 191040). The Board received the Change of Facility Manager form on February 6, 2023, 131 days after the change, in violation of 12 AAC 52.635(a). On August 10, 2023, the Alaska Board of Pharmacy issued a Civil Fine to Top Rx, LLC in the amount of $300. Payment of the fine was accepted by the Board, resolving the matter.

IN THE MATTER OF:	)	BEFORE THE ALABAMA STATE
	)	
AUBURN PHARMACEUTICAL COMPANY	)	BOARD OF PHARMACY
	)	
	)	
Wholesaler/Distributor Permit No. 192183	)	**CASE NO: 17-L-0107**
	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Auburn Pharmaceutical Company (hereinafter referred to as "Auburn") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement"), alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement which is attached hereto as **Exhibit "A."**

Pursuant to Code of Alabama (1975) Section 41-22-12(f) the parties through counsel have agreed to informally resolve this matter by the entry of this Consent Order, the terms of which are as follows:

1. The Board finds that Auburn violated the applicable provisions based upon the conduct set out in Count Two of the Statement. Count One shall be dismissed.

2. Auburn shall pay to the Board an administrative fine in the amount of One Thousand dollars ($1,000.00) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of payment to the Board shall not be dischargeable in bankruptcy and Auburn shall not attempt to discharge the same in any bankruptcy proceeding.

3. That Auburn expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama

Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Auburn further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Auburn hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. That Auburn agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

6. That Auburn acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. Auburn acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and had the right to seek advice of counsel before executing this Consent Order.

DONE this the 13th day of March, 2018

Auburn Pharmaceutical Company

By: _____
Its: _____

DONE this the 4th day of April, 2018.

ALABAMA STATE BOARD OF PHARMACY

By: _____
David Darby, R.Ph., President

By: _____
James S. Ward
Its Attorney

WARD & COOPER, LLC.
2100 Southbridge Parkway
Suite 580
Birmingham, Alabama 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
AUBURN PHARMACEUTICAL COMPANY	)	**BOARD OF PHARMACY**
	)	
	)	
Wholesaler/Distributor Permit No. 102183	)	**CASE NO: 17-L-0107**
	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Auburn Pharmaceutical Company
2360 Bellingham
Troy, MI 48083

Pursuant to the provisions of Code of Alabama (1975), § 34-23-32, § 34-23-32.1, § 34-23-34, § 34-23-92(11) and (12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on Dec 13th, 2018 at 1:00 p.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Auburn Pharmaceutical Company (Auburn) as a Wholesaler/Distributor and/or Non-Resident Pharmacy should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted in that it is alleged that Auburn has been guilty of the following, to-wit:

1. Board Rule 680-X-2.23 is entitled Drug Manufacturers, Wholesale Distributors.

2. Board Rule 680-X-2.23(3) provides that the Board of Pharmacy shall consider, at a minimum, certain factors in reviewing the qualifications of those who engage in the wholesale distribution of drugs within Alabama. Those minimum factors

include:

(a) Compliance with licensing requirements under previously granted license, if any.

(b) Compliance with the requirements to maintain records required to be maintained.

(c) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety.

3. Board Rule 680-X-2.23(3)(k)(1) provides that it shall be a violation of this Rule to operate in such a manner as to endanger public health.

4. Board Rule 680-X-2.23(3)(k)(2) provides any violation of this Rule may be grounds for the revocation, suspension, probation or refusal to issue the permit and/or to impose a fine not to exceed the sum of One Thousand and no/100 Dollars ($1,000) for each violation.

5. Board Rule 680-X-2.23(3)(k)(3) provides that must operate in compliance with applicable Federal and State law.

COUNT ONE

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit, and/or your operation is not consistent with the public safety or endangers the public health of the citizens of this state based upon the Citation and Fine entered by the California State Board of Pharmacy on October 22, 2014 attached hereto as Exhibit "A" and/or your failure to report certain suspicious orders for controlled substances required by the law of your domicile and/or federal regulation as more fully set out in the above referenced Citation.

The Board alleges that each failure to report is a separate and distinct violation.

COUNT TWO

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit, and/or your operation is not consistent with the public safety or endangers the public health of the citizens of this state based upon the Agreed Order entered by the Kentucky State Board of Pharmacy in 2014 attached hereto as Exhibit "B" and/or shipping drugs into Kentucky without a permit from at least August 5, 2011 until November 26, 2013 as more fully set out in the referenced Order.

The Board alleges that each shipment without a permit is a separate and distinct violation.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 21st day of December, 2017.

ALABAMA STATE BOARD OF PHARMACY

By: Susan Alverson
Susan Alverson
Secretary

EXHIBIT A

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number: CI 2014 62909
Name, License No: AUBURN PHARMACEUTICAL COMPANY, OSD 3687

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1776; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4161 subd. (h)/Title 21 CFR §1301.74 subd (b)	Nonresident wholesaler; shall at all times maintain a valid, unexpired license to conduct the business of the wholesaler.../The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances	$5,000.00

CONDUCT:

Failure to meet the requirements of a Nonresident Wholesaler: Business and Professions Code (B&PC) section 4161(h) states a nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. As related to Michigan's regulation R 338.493(c)(i) which states a wholesale distributors shall operate in compliance with applicable federal, state, and local laws and regulations and permit representatives of the board and other authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles and audit their records and written operating procedures at reasonable times and in a reasonable manner. As related to CFR section 1301.74(b) states the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. Auburn Pharmaceutical Company located at 2360 Bellingham Troy MI 48083 was not compliant. Auburn Pharmaceutical Company failed to report the unusual size and orders which deviated substantially from normal ordering patterns and frequencies of 2,500 tablets of alprazolam 2mg (5 bottles of 500 tablets), 20,400 tablets of oxycodone 30mg (204 bottles of 100 tablets), 3,400 tablets of hydrocodone/APAP 10mg/325mg (6 bottles of 500 tablets and 1 bottle of 400 tablets), and 28,380ml of promethazine with codeine syrup (60 bottles of 473mls each) from 1/31/13 to 12/3/13 (11 months) by Yorba to the DEA. This is violation of pharmacy law.

CITATION ISSUED ON: October 22, 2014 TOTAL AMOUNT OF FINE(S): [redacted]

PAYMENT OF FINE(S) DUE BY: November 21, 2014

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number: CI 2014/62910

Name, License No: MARK L RUMBLE , EXC 18468

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1776; Bus. & Prof. Code § 4160 subd. (d)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4161 subd. (h)/Title 21 CFR §1301.74 subd (b)	Nonresident wholesaler; shall at all times maintain a valid, unexpired license to conduct the business of the wholesaler.../The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances	$2,500.00

CONDUCT:

Failure to meet the requirements of a Nonresident Wholesaler: Business and Professions Code (B&PC) section 4161(h) states a nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. As related to Michigan's regulation R 338.493(c)(l) which states a wholesale distributors shall operate in compliance with applicable federal, state, and local laws and regulations and permit representatives of the board and other authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles and audit their records and written operating procedures at reasonable times and in a reasonable manner. As related to CFR section 1301.74(b) states the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. Mark Rumble as the DRIC at Auburn Pharmaceutical Company located at 2360 Bellingham Troy MI 48083 was not compliant. Mark Rumble as the DRIC at Auburn Pharmaceutical Company failed to report the unusual size and orders which deviated substantially from normal ordering patterns and frequencies of 2,500 tablets of alprazolam 2mg (5 bottles of 500 tablets), 20,400 tablets of oxycodone 30mg (204 bottles of 100 tablets), 3,400 tablets of hydrocodone/APAP 10mg/325mg (5 bottles of 500 tablets and 1 bottle of 400 tablets), and 28,380ml of promethazine with codeine syrup (60 bottles of 473ml each) from 1/31/13 to 12/3/13 (11 months) by Yorba to the DEA. This is violation of pharmacy law.

CITATION ISSUED ON: October 22, 2014 TOTAL AMOUNT OF FINE(S): $2,500.00

PAYMENT OF FINE(S) DUE BY: November 21, 2014

EXHIBIT B

COMMONWEALTH OF KENTUCKY
KENTUCKY BOARD OF PHARMACY

Case No. 13-0192

IN RE: Permit No. W03282 held by Auburn Pharmaceutical Company

Agreed Order

Come the parties, the Kentucky Board of Pharmacy ("the Board") and Auburn Pharmaceutical Company ("Respondent"), and both having been fully informed regarding the matter set forth herein, state as follows:

(1) Pursuant to Chapter 315 of the Kentucky Revised Statutes, the Board is authorized to regulate and control all matters related to special limited gas pharmacies, manufacturers, and wholesalers.

(2) Respondent was licensed by the Board as set forth above.

(3) (a) On or about November 6, 2013, a Board inspector learned that Respondent had been shipping legend drugs into the Commonwealth of Kentucky since at least August 5, 2011, without a permit. Respondent did not obtain a permit from the Board until November 26, 2013.

(b) The above actions constitute a violation of KRS 315.402(1) and subject the Respondent to discipline pursuant to KRS 315.121(1)(h).

(4) The Board and Respondent have agreed to address this matter by entering into this Agreed Order, in lieu of the filing of a formal Complaint.

WHEREFORE, IT IS HEREBY AGREED AND ORDERED THAT:

(A) In accordance with KRS 315.412(1), for an unknowing violation, the Respondent is fined $5,000.00 payable on or before October 24, 2014. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes St., Frankfort, Kentucky, 40601.

(B) By entering into this Agreed Order, Respondent expressly acknowledges that it was fully and

DEC 0 9 2014

completely informed of its right to due process, that it fully understands those rights, and that it knowingly, voluntarily, and willingly agrees to waive those rights and to enter into this Agreed Order.

(C) Except for the fine set forth above, there shall be no suspension or revocation of license, probation, or restriction or other disciplinary action against the Respondent on account of the violation set forth above in this Agreed Order.

(D) The above information shall be reported to the National Association of Boards of Pharmacy ("NABP"), and is subject to disclosure under the Kentucky Open Records Act.

Cathy Hanna, President
Kentucky Board of Pharmacy

Date

Auburn Pharmaceutical Company
Respondent

10/12/14
Date

DEC 09 2014

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Yorba

CITATION AND FINE

Citation Number	Name, License No
CI 2014 62909	AUBURN PHARMACEUTICAL COMPANY, OSD 3887

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4161 subd. (h)/Title 21 CFR §1301.74 subd (b)	Nonresident wholesaler; shall at all times maintain a valid; unexpired license to conduct the business of the wholesaler.../The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances	$5,000.00

CONDUCT:

Failure to meet the requirements of a Nonresident Wholesaler: Business and Professions Code (B&PC) section 4161(h) states a nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. As related to Michigan's regulation R 338.493(c)(i) which states a wholesale distributors shall operate in compliance with applicable federal, state, and local laws and regulations and permit representatives of the board and other authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles and audit their records and written operating procedures at reasonable times and in a reasonable manner. As related to CFR section 1301.74(b) states the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. Auburn Pharmaceutical Company located at 2360 Bellingham Troy MI 48083 was not compliant. Auburn Pharmaceutical Company failed to report the unusual size and orders which deviated substantially from normal ordering patterns and frequencies of 2,500 tablets of alprazolam 2mg (5 bottles of 500 tablets), 20,400 tablets of oxycodone 30mg (204 bottles of 100 tablets), 3,400 tablets of hydrocodone/APAP 10mg/325mg (6 bottles of 500 tablets and 1 bottle of 400 tablets), and 28,380ml of promethazine with codeine syrup (60 bottles of 473mls each) from 1/31/13 to 12/3/13 (11 months) by Yorba to the DEA. This is violation of pharmacy law.

CITATION ISSUED ON: October 22, 2014 **TOTAL AMOUNT OF FINE(S): $5,000.00**

PAYMENT OF FINE(S) DUE BY: November 21, 2014

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number CI 2014 62910

Name, License No MARK L RUMBLE , EXC 18488

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4160 subd. (d)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4161 subd. (h)/Title 21 CFR §1301.74 subd (b)	**Nonresident wholesaler; shall at all times maintain a valid, unexpired license to conduct the business of the wholesaler.../The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances**	**$2,500.00**

CONDUCT:

Failure to meet the requirements of a Nonresident Wholesaler: Business and Professions Code (B&PC) section 4161(h) states a nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. As related to Michigan's regulation R 338.493(c)(i) which states a wholesale distributors shall operate in compliance with applicable federal, state, and local laws and regulations and permit representatives of the board and other authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles and audit their records and written operating procedures at reasonable times and in a reasonable manner. As related to CFR section 1301.74(b) states the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. Mark Rumble as the DRIC at Auburn Pharmaceutical Company located at 2360 Bellingham Troy MI 48083 was not compliant. Mark Rumble as the DRIC at Auburn Pharmaceutical Company failed to report the unusual size and orders which deviated substantially from normal ordering patterns and frequencies of 2,500 tablets of alprazolam 2mg (5 bottles of 500 tablets), 20,400 tablets of oxycodone 30mg (204 bottles of 100 tablets), 3,400 tablets of hydrocodone/APAP 10mg/325mg (6 bottles of 500 tablets and 1 bottle of 400 tablets), and 28,380ml of promethazine with codeine syrup (60 bottles of 473mls each) from 1/31/13 to 12/3/13 (11 months) by Yorba to the DEA. This is violation of pharmacy law.

CITATION ISSUED ON: October 22, 2014 **TOTAL AMOUNT OF FINE(S): $2,500.00**

PAYMENT OF FINE(S) DUE BY: November 21, 2014

VENDOR NO.: 103955 CHECK NO.: 81864 DATE: 2/22/16
PAYEE: CALIFORNIA STATE BOARD OF RX

INVOICE NUMBER	INVOICE DATE	INVOICE AMOUNT	DISCOUNT TAKEN	AMOUNT OF PAYMENT
CI 2014 62910	2/22/16	2,500.00		2,500.00
CI 2014 62909	2/22/16	5,000.00		5,000.00
			CHECK TOTAL:	****7,500.00

Attn: Frederick Bunby

THIS CHECK IS VOID WITHOUT A WATERMARK - HOLD TO LIGHT TO VIEW - RUB HEAT SENSITIVE CHECKMARK TO SEE COLOR DISAPPEAR AND REAPPEAR

AUBURN PHARMACEUTICAL
DISBURSEMENT ACCOUNT
2354 BELLINGHAM
TROY, MI 48083
(248) 526-3700

CI-2014-62910
CI-2014-62909

Huntington Banks of Michigan
56-1512/441

CHECK 81864

DATE 2/22/16 AMOUNT ****7,500.00

PAY SEVEN THOUSAND FIVE HUNDRED DOLLARS AND NO CENTS

TO THE ORDER OF
CALIFORNIA STATE BOARD OF RX
1625 N MARKET BLVD
#N-219
SACRAMENTO CA 95834-1924

AUTHORIZED SIGNATURE

AUTHORIZED SIGNATURE

SIGNATURE HAS A COLORED BACKGROUND - BORDER CONTAINS MICROPRINTING

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2014 62909	AUBURN PHARMACEUTICAL COMPANY, OSD 3887

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4161 subd. (h)/Title 21 CFR §1301.74 subd (b)	Nonresident wholesaler; shall at all times maintain a valid, unexpired license to conduct the business of the wholesaler.../The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances	$5,000.00

CONDUCT:

Failure to meet the requirements of a Nonresident Wholesaler: Business and Professions Code (B&PC) section 4161(h) states a nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. As related to Michigan's regulation R 338.493(c)(i) which states a wholesale distributors shall operate in compliance with applicable federal, state, and local laws and regulations and permit representatives of the board and other authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles and audit their records and written operating procedures at reasonable times and in a reasonable manner. As related to CFR section 1301.74(b) states the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. Auburn Pharmaceutical Company located at 2360 Bellingham Troy MI 48083 was not compliant. Auburn Pharmaceutical Company failed to report the unusual size and orders which deviated substantially from normal ordering patterns and frequencies of 2,500 tablets of alprazolam 2mg (5 bottles of 500 tablets), 20,400 tablets of oxycodone 30mg (204 bottles of 100 tablets), 3,400 tablets of hydrocodone/APAP 10mg/325mg (6 bottles of 500 tablets and 1 bottle of 400 tablets), and 28,380ml of promethazine with codeine syrup (60 bottles of 473mls each) from 1/31/13 to 12/3/13 (11 months) by Yorba to the DEA. This is violation of pharmacy law.

CITATION ISSUED ON: October 22, 2014 | **TOTAL AMOUNT OF FINE(S): $5,000.00**

PAYMENT OF FINE(S) DUE BY: November 21, 2014

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Citation Issued To: AUBURN PHARMACEUTICAL COMPANY Respondent.	No. CI 2013 58669 OAH No. 2015020938
In the Matter of the Citation Issued To: MARK L. RUMBLE Respondent.	No. CI 2013 58670 OAH No. 2015020940
In the Matter of the Citation Issued To: AUBURN PHARMACEUTICAL COMPANY Respondent.	No. CI 2014 62909 OAH No. 2015020943
In the Matter of the Citation Issued To: MARK L. RUMBLE Respondent.	No. CI 2014 62910 OAH No. 2015020946

DECISION AND ORDER

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective on January 22, 2016.

It is so ORDERED on December 23, 2015.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Citation Issued To: AUBURN PHARMECEUTICAL COMPANY Respondent.	No. CI 2013 58669 OAH No. 2015020938
In the Matter of the Citation Issued To: MARK L. RUMBLE Respondent.	No. CI 2013 58670 OAH No. 2015020940
In the Matter of the Citation Issued To: AUBURN PHARMECEUTICAL COMPANY Respondent.	No. CI 2014 62909 OAH No. 2015020943
In the Matter of the Citation Issued To: MARK L. RUMBLE Respondent.	No. CI 2014 62910 OAH No. 2015020946

PROPOSED DECISION

Alan S. Meth, Administrative Law Judge, Office of Administrative Hearings, State of California, heard these matters that were consolidated for hearing on October 28, 2015, in San Diego, California.

Desiree I. Kellogg, Deputy Attorney General, represented the complainant Virginia Herold.

Tony J. Park and Ivan Petrzelk, Attorneys at Law, represented respondents Auburn Pharmaceutical Company and Mark L. Rumble.

The matter was submitted on October 28, 2015.

FACTUAL FINDINGS

Jurisdiction

1. On October 22, 2013, Virginia Herold, Executive Officer, Board of Pharmacy, Department of Consumer Affairs, State of California filed Citation No. CI 2013 58669 against respondent Auburn Pharmaceutical Company and Citation No. CI 2013 58670 against respondent Mark L. Rumble. Respondents filed timely Notices of Appeal.

On October 22, 2014, complainant filed Citation No. CI 2014 62909 against Auburn and Citation No. CI 2014 62910 against Mr. Rumble. Respondents filed timely Notices of Appeal.

Auburn is an out of state pharmaceutical wholesaler and Mr. Rumble is its designated representative in charge. The four citations allege that Auburn and Mr. Rumble failed to report to the Drug Enforcement Administration suspicious orders of controlled substances placed between August 2012 and November 2013 by a California corporation that owns two pharmacies licensed by the Board. The citations filed against Auburn imposed fines of $2,500 and $5,000. The first citation filed against Mr. Rumble imposed no fine; the second imposed a fine of $2,500.

2. On March 2, 2001, the Board issued Out of State Distributor License No. OSD 3887 to Auburn with an address of record in Troy, Michigan. Its president since August 10, 2000, is Jeffrey Farber. Mr. Rumble was the Designated Representative-in-Charge as of January 26, 2006.

Investigation

3. Christine Acosta is an inspector for the Board and in 2012 and 2013, was assigned to the diversion team. She is also a pharmacist. She began an investigation of Cabrillo Park Pharmacy on January 14, 2013, following an audit performed by another inspector who discovered that Cabrillo had dispensed a large amount of oxycodone 30 mg., a controlled substance, over a short period of time. The Board issued license number PHY 50066 to Cabrillo on September 1, 2009. James Gee is the pharmacist in charge.

Following an extensive investigation, Ms. Acosta determined that Cabrillo had violated numerous provisions of the laws and regulations governing the operation of licensed pharmacies. She found numerous instances of Cabrillo furnishing excessive amounts of controlled substances without a legitimate medical purpose and numerous erroneous and

uncertain prescriptions. She found a troubling pattern of prescriptions for potent pain medications written by Dr. Michael Stream, a pediatrician.

On March 24, 2015, the Board filed a First Amended Accusation against Cabrillo and Mr. Gee alleging eleven causes for discipline. The first amended accusation is currently pending.

4. During the course of the investigation, on April 2, 2013, Ms. Acosta requested of Auburn the records of all sales of oxycodone 30 mg., hydromorphone 4 mg., alprazolam 2 mg., and hydromorphone/APAP 10 mg/325 mg. sold to Cabrillo between January 1, 2012, and April 2, 2013. Auburn provided invoices showing its sales of oxycodone 30 mg. to Cabrillo. The invoices showed that between August 2012 through April 2013, Auburn sold 12 bottles per month of oxycodone 30 mg. to Cabrillo. Each bottle contained 100 tablets. The total was 10,800 tablets.

Ms. Acosta contacted the Orange County office of the DEA and determined that no distributors had reported Cabrillo for excessive purchases of controlled substances.

5. Ms. Acosta determined from her investigation of Cabrillo that Yorba Park Pharmacy was under the same ownership and began an investigation of Yorba. Her investigation revealed that Yorba was a busier pharmacy than Cabrillo. She found numerous similar violations of the pharmacy laws and regulations, and the first amended accusation includes allegations against Yorba as well as Cabrillo.

6. On July 2, 2014, Ms. Acosta requested records of Auburn of its sales of oxycodone 30 mg., alprazolam 2 mg., hydrocodone/APAP 10 mg/325 mg, and promethazine with codeine to Yorba between January 1, 2013, and December 3, 2013. Auburn furnished records to Ms. Acosta that showed that between February and November 2013, it had sold 204 bottles each containing 100 tablets of oxycodone 30 mg (total of 20,400 tablets), 60 bottles of promethazine with codeine manufactured by Actavis each containing 473 mls. (28,380 mls. total)[1], six bottles each containing 500 tablets of Norco 10/325 mg, and four bottles each containing 500 tablets of alprazolam 2 mg. (2,500 tablets total) to Yorba.

Ms. Acosta contacted the Orange County office of the DEA and determined that no distributors had reported Yorba for excessive purchases of controlled substances.

Federal Regulation

7. Title 21, Code of Federal Regulations, section 1301.74 (DEA Regulation), provides in part:

---

[1] Promethazine with codeine manufactured by Actavis is a cough suppressant. It has a sweet grape flavor. It was used by rap musicians as a recreational drug because of it sweet flavor. It is no longer available.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Michigan Regulation

8. Michigan Administrative Code R. 338.493c provides in part:

(i) Wholesale distributors shall operate in compliance with applicable federal, state, and local laws and regulations and permit representatives of the board and other authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles and audit their records and written operating procedures at reasonable times and in a reasonable manner.

Auburn's System

9. Mr. Rumble is Auburn's vice president of operations and among his duties is the oversight of federal and state compliance. He has worked for Auburn for 22 years and was familiar with the DEA regulation requiring a system to disclose suspicious orders of controlled substance and disclosure to the DEA of suspicious orders.

10. Mr. Rumble testified at the hearing as follows:

Since 2006, Auburn has had in place an automated system to monitor orders of controlled substances to determine if a pharmacy is ordering excessive quantities of controlled substances. The system is called Suspicious Ordering Monitoring (SOMS). It is based on the ratio of the average purchases of controlled substances with non-controlled substances purchased. It allows roughly an 80 percent to 20 percent mix of non-controlled substances to controlled substances. To determine the amounts of drugs a pharmacy may purchase and to determine the ratio, Auburn requires each pharmacy to complete a questionnaire. After a questionnaire is received, Mr. Rumble conducts an investigation of the pharmacy. He goes on line and searches the name of the pharmacy to see if there is anything negative about it on file anywhere, whether the pharmacy actually exists, and the area where the pharmacy is located. Auburn does not open an account with a pharmacy unless the pharmacy has been approved by Mr. Rumble. He does not open an account for a pharmacy just to sell controlled substances and he does not base the decision as to the threshold assigned to a pharmacy solely on the basis of volume of purchases. A typical customer of Auburn's is an independent pharmacy or a small chain.

The SOMS system creates four levels based upon the total value of drugs sold and each level provides the pharmacy a maximum amount of controlled substances that it can purchase without triggering an investigation. Both Cabrillo and Yorba were considered Level D pharmacies and that permitted them, for example, to purchase a maximum of 12 bottles (1,200) tablets of oxycodone. The levels are reviewed annually or periodically and may change. In May 2013, the level assigned to Yorba changed from a Level D to a Level C, allowing it to purchase greater quantities of controlled substances.

The system provides that if a pharmacy exceeds its maximum of controlled substances, that is considered unusual and Auburn automatically suspends delivery of the controlled substances until Mr. Rumble or Mr. Farber investigates the orders to determine if they are valid. An investigation typically includes contacting the pharmacy to obtain additional information. Mr. Rumble considers what the average customer would use to determine if orders are unusually frequent or excessively large. If the order is determined to be suspicious, Auburn then cancels the order and contacts DEA and the local board of pharmacy where the pharmacy is located. Auburn has done this numerous times in the past. He noted that the regulation did not require a wholesaler to suspend shipments of orders.

Mr. Rumble has contacted the DEA and asked for guidance in interpreting the regulation but has received none. He has been told that there is no definitive number that makes an order suspicious. He has sought help from the Board and industry trade associations in interpreting the regulation. He has spoken to people in the pharmaceutical industry and learned that other wholesalers also use the dollar level as a starting point for the implementation of an automated system. He did not believe it was possible to individually examine every order received every day.

Neither the DEA nor the Michigan Board of Pharmacy has taken any action against Auburn in the past or in connection with its sales of controlled substances to Cabrillo and Yorba.

Mr. Rumble created a written policy that became effective on October 1, 2006, and has been revised over the years. A revision made on February 18, 2013, provides in relevant part:

> All incoming orders must qualify by meeting the standards of Auburn's DEA control program. All DEA controlled products and non-controlled items that have potential for abuse are part of this control program. If a customer places an order that exceeds the amount of product they are authorized, the order is suspended and must be reviewed by the Operations Manager. If an order is considered to be suspicious by nature of quantity ordered or items being ordered, the order will be canceled and the customer will be reported within 3 business days to the DEA. . . .

Mr. Rumble reviewed the sales figures for Yorba and Cabrillo and concluded they were well within Auburn's limits. When Yorba's sales increased, he conducted a review to determine if it would be permitted to move to the next level, and he permitted Yorba to move to the next level. He did not believe the orders were suspicious. He did not report the orders made by Cabrillo and Yorba to the DEA.

11. Jeffrey Farber is the President and owner of Auburn. He opened the business in 1993 with 12 employees; it now has about 100 employees and is licensed in 48 states. Mr. Farber testified at the hearing as follows:

He has never had any issues with any governmental entity until the Board filed the citations in this matter. He has had excellent relations with the DEA and the Michigan Board of Pharmacy. He believed that the time and expense that would be required in notifying every state of the action taken by the Board in this case, as well as the detrimental effect upon his reputation, required him to contest these citations. He believed that Auburn had a good system to detect suspicious transactions and it has, in fact, reported suspicious orders to the DEA. He admitted it was not a perfect system and it relied upon the honesty of his customers, but it was the best system "out there."

Auburn is active in the community by supporting local and national efforts to combat drug abuse. It has partnered with the Community Anti-Drug Coalitions of America, an organization that supports over 5,000 community anti-drug coalitions across the country. It supports Drug-Free Kids Campaigns and has contributed money to the Partnership for Drug-Free Kids and the Birmingham Bloomfield Community Coalition.

Expert Opinions

12. Ms. Acosta, as a licensed pharmacist and inspector for the Board, testified that in her opinion, the orders of controlled substances placed by Cabrillo and Yorba that Auburn filled were suspicious and should have been reported to the DEA. She pointed out that the oxycodone 30mg. was the highest strength that oxycodone came in and the orders placed by the two pharmacies came shortly after changes in lower-strength forms of the drug made the abuse potential for those strengths disappear. She also pointed out that the many of the prescriptions for controlled substances filled by the two pharmacies were written by a pediatrician who had no business writing these kinds of prescriptions for children. She added that the prescriptions for promethazine with codeine was solely for a form of that drug that was abused because of its taste, and the amount of the orders was suspicious. She stressed that to determine if orders are suspicious, the totality of the circumstances must be examined and a pharmacist had to exercise his or her professional judgment

13. Mr. Rumble testified that in his opinion, the orders placed by Cabrillo and Yorba were not suspicious and did not trigger an investigation based upon the quantities of the drugs orders. He believed SOMS properly detected suspicious orders.

14. Kevin Barnard is a retired police officer. He worked for 28 years for the San Diego Police Department. He served as a narcotics detective for four years and was on the San Diego Regional Pharmaceutical Narcotics Enforcement Team for two years. He worked as a Medicare Fraud investigator after he left the police department and for the last four years, was the regional compliance manager for H.D. Smith Wholesale. H.D. Smith is the fourth largest drug wholesaler in the country and acts as a primary or secondary wholesaler. While he served as the regional compliance manager, he conducted 400 investigations of suspicious orders.

At the request of the Board, Mr. Barnard reviewed the investigation report and Auburn's records. He testified at the hearing that oxycodone 30 mg., alprazolam 2 mg., hydrocodone/APAP 10 mg/325 mg, and promethazine with codeine were controlled substances that had a high potential for abuse, high street value and were frequently diverted.

Mr. Barnard was familiar with the requirement that a wholesaler develop a system to identify suspicious orders of controlled substances and report them to the DEA. He testified that there are different systems used by the various wholesalers but they typically start with the number of controlled substances ordered. He testified that pharmacies have unique circumstances and a wholesaler has to exercise due diligence to learn about its customers, including the type of business the pharmacy does, its community, and its prescribers.

Mr. Barnard examined Auburn's SOMS system and viewed it as a very general one and constituted minimal compliance with the requirement. He described it as a numbers system based on a pharmacy's book of business. He examined Auburn's standard questionnaire and believed it was insufficient, particularly the question asking for the number of controlled substance generic prescriptions filled daily by the pharmacy. He believed a wholesaler had to do a greater investigation.

Mr. Barnard viewed suspicious orders as those that were of high volume, frequent, and departing from normal dispensing patterns. Suspicious orders were those that focused on drugs that were highly abused and unbalanced. By that he meant that within a family of controlled substances such as oxycodone, the orders should include orders for different strengths of the drugs and not just the highest or most abused strength.

In the case of Cabrillo and Yorba, all the orders for oxycodone were for 30 mg. and they were for the same amounts every month. Oxycodone 30 mg. is an abused drug and the orders from the two pharmacies were only for that drug. He believed that was suspicious. He further believed that when Yorba doubled its orders for oxycodone 30 mg., that was suspicious. With respect to Yorba's orders for promethazine with codeine, it was his opinion that the orders were suspicious because they were only for Actavis and that was a drug that was abused. He found the prescriptions for alprazolam 2 mg. and hydrocodone/APAP 10 mg/325 mg. were suspicious because the prescriptions were solely for the highest strengths and the most abused drugs. He noted that alprazolam in combination with any opioid mimicked heroin for addicts.

Based upon the totality of the orders, it was Mr. Barnard's opinion that the orders were suspicious and required Auburn to investigate. He found no evidence in Auburn's files that it had investigated the orders and in fact found no customer files except the pharmacy questionnaires. He testified that the standard of practice in this area was for a drug wholesaler to maintain customer files in order to protect itself. Based upon the orders placed by Cabrillo and Yorba, and the absence of any investigation performed by Auburn, it was Mr. Barnard's opinion that Auburn should have reported the information to DEA and its failure to do so violated the DEA regulation. Indeed, in his view, this was a "no brainer." He stressed that a determination that an order is suspicious is not and should not be based solely upon numbers but rather, the numbers constituted merely a threshold and a wholesaler must look at those controlled substances that are abused and diverted.

Evaluation

15. The question presented by the DEA Regulation is whether the orders for controlled substance made by Cabrillo and Yorba were suspicious. To help determine if they are suspicious, the regulation suggests such matters as unusual size and frequency and deviation from a normal pattern be considered. In analyzing the orders submitted to Auburn by Cabrillo and Yorba, both Ms. Acosta and Mr. Barnard testified the totality of the circumstances must be considered, and they pointed to such factors as the potential for abuse of the drugs, the strength of the medication, and the presence or absence of orders for other controlled substances within the family of medications.

Of the three witnesses who offered expert testimony regarding the applicability of the DEA Regulation, Mr. Barnard was the most credible. He was an independent witness without any connection to the Board or Auburn. He had extensive experience in the enforcement of narcotics laws and worked for a large pharmaceutical wholesaler for years performing the analysis required by the DEA regulation. His testimony was well reasoned, particularly his testimony that a wholesaler cannot simply rely upon a number of tablets or bottles of a controlled substance generated by a dollar ratio. His testimony that a pharmacist must exercise his or her professional judgment in evaluating orders for controlled substances made sense.

Mr. Barnard's testimony that Mr. Rumble failed to properly exercise his professional judgment when he failed to investigate the suspicious orders for controlled substances submitted by Yorba and that Auburn should have reported those orders to the DEA was persuasive. Yorba ordered not only the highest strength of each drug, but ordered four different drugs that had a high potential for abuse. Yorba's orders for oxycodone 30 mg. and promethazine with codeine manufactured by Actavis were particularly suspicious. Then, when Yorba sought to increase the amount of controlled substances that it could order, Mr. Rumble in fact reviewed that request. It was no longer a question of an automated response to an order, but an opportunity for him to exercise his professional judgment. He should have exercised his judgment by concluding that an investigation and a report to the DEA were necessary and not simply permit the increase without question. His failure to report Yorba's suspicious orders of controlled substances to the DEA constituted a violation of the

DEA regulation. The evidence against Auburn and respondent Rumble relating to its sales of controlled substances to Yorba was compelling.

The evidence against Auburn involving Cabrillo's orders of oxycodone 30 mg. was less compelling. While the evidence showed that oxycodone 30 mg., is the most abused drug within the oxycodone family and Cabrillo did not order any other strength of the drug, those considerations in and of themselves did not rise to the level of suspiciousness required by the DEA regulation. The orders were not of unusual size or frequency and did not deviate from the normal pattern. Accordingly, it was not established by a preponderance of the evidence that Auburn and Mr. Rumble violated the DEA regulation with respect to the orders from Cabrillo.

Mr. Barnard's testimony did not establish that Auburn failed to design and operate a system to disclose suspicious orders of controlled substances.

LEGAL CONCLUSIONS

1. Business and Professions Code section 4161 requires that a nonresident wholesaler maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident.

2. In these citation matters, the burden of proof is on complainant to prove the allegations of violations of federal and state law by a preponderance of the evidence. *Owen v. Sands* (2009) 176 Cal. App. 4th 985, 989-93.

3. Cause to affirm Citation Numbers CI 2014 62909 and CI 2014 62910 was established. Business and Professions Code section 4161, subdivision (h) required Auburn as a nonresident wholesaler to comply with the laws of the state in which it is a resident. Michigan Administrative Code R. 338.493c, subdivision (i), required Auburn, as a Michigan resident, to comply with applicable federal laws and regulations. Title 21, Code of Federal Regulations, section 1301.74, subdivision (b), required Auburn to inform the DEA of suspicious orders of controlled substances. Mr. Barnard's testimony established that the orders for controlled substances made by Yorba during the period examined in this matter that were filled by Auburn were suspicious and should have been reported to the DEA. Mr. Rumble, as the Designated Representative-in-Charge of Auburn, was responsible for ensuring that Auburn complied with federal and state pharmacy laws and regulations.

4. Cause to affirm Citation Numbers CI 2013 58669 and CI 2013 58670 was not established. The evidence did not establish that the orders for controlled substances made by Cabrillo during the period examined in this matter that were filled by Auburn were suspicious and should have been reported to the DEA.

5. Respondents argue that section 1301.74, subdivision (b), is vague on its face and its application is arbitrary and capricious. Article III, section 3.5 of the California

Constitution provides that an administrative agency does not have the power to declare a statute unenforceable or to refuse to enforce a statute on the basis of it being unconstitutional. It is reasonable to conclude that an administrative agency likewise does not have the power to declare a federal regulation unenforceable or refuse to enforce it on the basis of it being unconstitutional. Respondents' arguments must therefore be rejected.

ORDER

1. Citation Number CI 2013 58669 issued by the Board against respondent Auburn Pharmaceutical Company is dismissed.

2. Citation Number CI 2013 58670 issued by the Board against respondent Mark L. Rumble is dismissed.

3. Citation Number CI 2014 62909 issued by the Board against respondent Auburn Pharmaceutical Company is affirmed. Respondent Auburn Pharmaceutical Company shall pay the fine of $5,000 to the Board within thirty (30) days of the effective date of this decision.

4. Citation Number CI 2014 62910 issued by the Board against respondent Mark L. Rumble is affirmed. Respondent Rumble shall pay the fine of $2,500 to the Board within thirty (30) days of the effective date of this decision.

DATED: November 20, 2015

DocuSigned by:
Alan S. Meth
E34365E95D56469...

ALAN S. METH
Administrative Law Judge
Office of Administrative Hearings

COMMONWEALTH OF KENTUCKY
KENTUCKY BOARD OF PHARMACY

Case No. 13-0192

IN RE: Permit No. W03282 held by Auburn Pharmaceutical Company

Agreed Order

Come the parties, the Kentucky Board of Pharmacy ("the Board") and Auburn Pharmaceutical Company ("Respondent"), and both having been fully informed regarding the matter set forth herein, state as follows:

(1) Pursuant to Chapter 315 of the Kentucky Revised Statutes, the Board is authorized to regulate and control all matters related to special limited gas pharmacies, manufacturers, and wholesalers.

(2) Respondent was licensed by the Board as set forth above.

(3) (a) On or about November 6, 2013, a Board inspector learned that Respondent had been shipping legend drugs into the Commonwealth of Kentucky since at least August 5, 2011, without a permit. Respondent did not obtain a permit from the Board until November 26, 2013.

(b) The above actions constitute a violation of KRS 315.402(1) and subject the Respondent to discipline pursuant to KRS 315.121(1)(h).

(4) The Board and Respondent have agreed to address this matter by entering into this Agreed Order, in lieu of the filing of a formal Complaint.

WHEREFORE, IT IS HEREBY AGREED AND ORDERED THAT:

(A) In accordance with KRS 315.412(1), for an unknowing violation, the Respondent is fined $5,000.00 payable on or before October 24, 2014. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes St., Frankfort, Kentucky, 40601.

(B) By entering into this Agreed Order, Respondent expressly acknowledges that it was fully and

completely informed of its right to due process, that it fully understands those rights, and that it knowingly, voluntarily, and willingly agrees to waive those rights and to enter into this Agreed Order.

(C) Except for the fine set forth above, there shall be no suspension or revocation of license, probation, or restriction or other disciplinary action against the Respondent on account of the violation set forth above in this Agreed Order.

(D) The above information shall be reported to the National Association of Boards of Pharmacy ("NABP"), and is subject to disclosure under the Kentucky Open Records Act.

Cathy Hanna, President
Kentucky Board of Pharmacy

11-7-14
Date

Auburn Pharmaceutical Company
Respondent

10/12/14
Date

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

AUBURN PHARMACEUTICAL COMPANY
License No. 53-06-001269,
Respondent.

File No. 53-17-145175
CONSENT ORDER AND STIPULATION

CONSENT ORDER

On June 27, 2017, the Department of Licensing and Regulatory Affairs executed an Administrative Complaint charging Respondent with violating the Public Health Code, MCL 333.1101 *et seq.*

Respondent has admitted that the facts alleged in the Complaint are true and constitute violation(s) of MCL 333.17768(1) and (2)(d). The Disciplinary Subcommittee of the Michigan Board of Pharmacy has reviewed this Consent Order and Stipulation and agrees that the public interest is best served by resolution of the outstanding Complaint.

Therefore, IT IS FOUND that the facts alleged in the Complaint are true and constitute violation(s) of MCL 333. 17768(1) and (2)(d).

Accordingly, IT IS ORDERED that for the cited violation(s) of the Public Health Code, Respondent is FINED $5,000.00 to be paid to the State of Michigan within 60 days of the effective date of this Order.

IT IS FURTHER ORDERED that the fine shall be mailed to the **Department of Licensing and Regulatory Affairs, Enforcement Division, Compliance Section, P.O. Box 30189, Lansing, MI 48909**. The fine shall be paid by check or money order, made payable to the State of Michigan, and the check or money order shall clearly display the file number **53-17-145175**.

IT IS FURTHER ORDERED that if Respondent fails to comply with the terms and conditions of this Order, Respondent's license shall be automatically suspended for a minimum of one day. If, within six months of the suspension of the license, Respondent complies with the terms of this Order, the license shall be automatically reinstated.

IT IS FURTHER ORDERED that if Respondent's license remains suspended for more than six months, Respondent must apply for reinstatement of the license. If Respondent applies for reinstatement of the license, application for reinstatement shall be in accordance with sections MCL 333.16245 and 333.16247.

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee, as set forth below.

MICHIGAN BOARD OF PHARMACY

By: _____
Chairperson, Disciplinary Subcommittee

Dated: 2-14-18

STIPULATION

1. The facts alleged in the Complaint are true and constitute violation(s) of MCL 333. 17768(1) and (2)(d).

2. Respondent understands and intends that by signing this Stipulation Respondent is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act, MCL 24.201 *et seq.*, to require the Department to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent is waiving the right to appear with an attorney and such witnesses as Respondent may desire to present a defense to the charges.

3. This matter is a public record required to be published and made available to the public pursuant to the Michigan Freedom of Information Act, MCL 15.231 *et seq.*, and this action will be reported to the National Practitioner Data Bank and any other entity as required by state or federal law, in accordance with 42 USC 11101-11152.

4. Nichole L. Cover, R.Ph., a member of the Board of Pharmacy who supports this proposal, and the Department's representative are free to discuss this matter with the Disciplinary Subcommittee and recommend acceptance of the resolution set forth in this Order.

5. This Order is approved as to form and substance by Respondent and the Department and may be entered as the final order of the Disciplinary Subcommittee in this matter.

6. This proposal is conditioned upon acceptance by the Disciplinary Subcommittee. Respondent and the Department expressly reserve the right to further proceedings without prejudice should this Order be rejected.

AGREED TO BY:

Cheryl Wykoff Pezon, Acting Director
Bureau of Professional Licensing
Department of Licensing and
Regulatory Affairs

Dated: 12/13/17

AGREED TO BY:

Auburn Pharmaceutical Company
Mark Rumble
Vice President, Operations
Respondent

Dated: 12/11/17

Approved as to form by:

Nathan Upfal (P-80764)
Attorney for Respondent

Dated: DECEMBER 11, 2017

se

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the matter of

AUBURN PHARMACEUTICAL COMPANY
License Number: 53-06-001269 File Number: 53-17-145175

ADMINISTRATIVE COMPLAINT

The Michigan Department of Licensing and Regulatory Affairs (Department), by Kim Gaedeke, Director, Bureau of Professional Licensing, files this Complaint against Auburn Pharmaceutical Company (Respondent Pharmacy) as follows:

1. The Michigan Board of Pharmacy (Board) is an administrative agency established by the Public Health Code, MCL 333.1101 et seq. Pursuant to section 17768 of the Public Health Code, supra, the Board's Disciplinary Subcommittee is empowered to discipline licensees for violations of the Public Health Code.

2. Respondent Pharmacy is licensed as a manufacturer/wholesaler pharmacy in the state of Michigan and holds a facility controlled substance license.

3. On October 22, 2014, the California State Board of Pharmacy (California Board) issued a Citation (October 2014 Complaint) against Respondent Pharmacy, alleging that Respondent Pharmacy failed to comply with a California law requiring Respondent Pharmacy to conduct business in compliance with the laws of the state in which it is a resident (i.e., Michigan law). Specifically, through the requirements

set forth under Mich Admin Code, R 338.493c(i), requiring that, in part, a wholesale distributor comply with federal law, the October 2014 Complaint alleged that Respondent Pharmacy failed to comply with a federal regulation requiring Respondent Pharmacy to report suspicious orders of controlled substances to the Drug Enforcement Administration. A copy of the October 2014 Complaint, marked Exhibit A, is attached and incorporated.

4. In resolution of the October 2014 Complaint, on December 23, 2015, the California Board executed a Decision and Order (Order), which ordered Respondent Pharmacy to pay a $5,000.00 fine. A copy of the Order, marked Exhibit B, is attached and incorporated.

5. Respondent Pharmacy failed to notify the Department of the October 22, 2014 Complaint filed by the state of California, in which Respondent Pharmacy is licensed, for violations of California's pharmacy laws, within 30 days of knowledge of the October 2014 Complaint.

COUNT I

The actions, as set forth above, evidence a pharmacy, manufacturer, or wholesale distributor that has had its license or federal registration limited, suspended, or revoked, or been subject to any other criminal, civil, or administrative penalty, in violation of section 17768(2)(d) of the Public Health Code, supra.

COUNT II

Respondent Pharmacy's conduct, as set forth above, evidences a failure to notify the Department of a complaint filed by another state in which the pharmacy is licensed for violations of that state's pharmacy laws, within 30 days of knowledge of the complaint, contrary to section 17748a(5) of the Public Health Code, supra, in violation of section 17768(1) of the Public Health Code, supra.

This Complaint is based upon files and records maintained by the Department and the attached Affidavit of Terri Schrauben.

The Department requests that this Complaint be served upon Respondent Pharmacy and that Respondent Pharmacy be offered an opportunity to show compliance with all lawful requirements for retention of the license. If compliance is not shown, the Department further requests that formal proceedings be commenced pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act, MCL 24.201 et seq.

Pursuant to section 16231(8) of the Public Health Code, supra, Respondent Pharmacy has 30 days from the date of receipt of this Complaint to submit a written response to the allegations contained herein. The written response shall be submitted to Kim Gaedeke, Director, Bureau of Professional Licensing, Department of Licensing and Regulatory Affairs, P.O. Box 30670, Lansing, MI 48909.

Pursuant to section 16231(9) of the Public Health Code, supra, Respondent Pharmacy's failure to submit a written response within 30 days, as noted above, shall be treated as an admission of the allegations contained herein and shall result in transmittal of this complaint directly to the Board's Disciplinary Subcommittee for imposition of an appropriate sanction.

Dated: 6/27/17

Kim Gaedeke, Director
Bureau of Professional Licensing

Attachments

jkp

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF OREGON

In the Matter of	)	Case No. 03-0177
	)	
	)	
AUBURN PHARMACEUTICAL	)	CONSENT ORDER
	)	
Respondent	)	

WHEREAS, the Board of Pharmacy of the State of Oregon has filed a Notice of Proposed Civil Penalty; Answer Required, hereby incorporated by reference, regarding the respondent in the above-captioned matter; and

WHEREAS, the above-noted Notice of Proposed Civil Penalty; Answer Required was duly served on the respondent as required by law; and

WHEREAS, the parties are desirous of resolving and settling those matters contained in the above-noted Notice of Proposed Civil Penalty; Answer Required without further proceedings thereon; and

WHEREAS, the respondent is aware of the right to a hearing with the assistance of counsel and the right to judicial review of the Board's decision, and hereby freely and voluntarily waives those rights; and

WHEREAS, the respondent admits that the facts alleged in the above-noted Notice of Proposed Civil Penalty; Answer Required are true, that the respondent's conduct, as admitted, violated the statutes and rules cited in the Notice, and that legal cause exists pursuant to ORS 689.405 and ORS 689.445 for disciplinary action and imposition of a civil penalty by the Board; and

WHEREAS, the respondent consents to the civil penalty as set forth herein;

The Board finds that the allegations in the notice are true and hereby:

1. The respondent shall pay the Board a civil penalty in the amount of $1,000, said payment to be made within ten days from the date of this Consent Order becomes final.

2. Failure of the respondent to pay the civil penalty as required under this Consent Order may, after notice and hearing, result in further disciplinary action.

I hereby acknowledge that I am the authorized representative of respondent. On behalf of the respondent, I further certify that I have read and understand the Notice of Proposed Civil Penalty and this Consent Order and am aware of the right to a hearing with the assistance of counsel and the right to judicial review of the Boards final order. On behalf of the respondent I agree to the Board entering the Consent Order.

11/24/03
Date

Authorized Representative
Auburn Pharmaceutical
1775 John R. Road
Troy, MI 48083

IT IS SO ORDERED.

DATED this 4 day of December, 2003.

BOARD OF PHARMACY
FOR THE STATE OF OREGON

BY:
Grace Cheung, R.Ph.
Compliance Director

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF OREGON

In the Matter of	)	Case No. 03-0177
	)	
	)	
AUBURN PHARMACEUTICAL	)	NOTICE OF PROPOSED
	)	CIVIL PENALTY;
	)	ANSWER REQUIRED
Respondent	)	
	)	

Under the authority granted under ORS 689.135, 689.145, 689.335, 689.405, 689.445, and 689.832, the Oregon Board of Pharmacy proposes to take disciplinary action against your drug outlet because your employees at Auburn Pharmaceutical in Troy, MI violated the Oregon Pharmacy Act and the Board of Pharmacy rules as set forth below:

Your employees at Auburn Pharmaceutical located at 1775 John R. Road in Troy, Michigan distributed drugs into Oregon from approximately 1998 to 2003 without registering with the Oregon Board of Pharmacy in violation of ORS 689.305, ORS 689.335 and OAR 855-065-0001, which are grounds for discipline and imposition of a civil penalty pursuant to ORS 689.335(1), 689.405(1)(e)(B), 689.832(1) and 689.445.

Based on these alleged violations, the Board proposes to impose a civil penalty in the amount of $1,000.

The corporation is entitled to a hearing as provided by the Administrative Procedures Act (ORS chapter 183). An attorney must represent the corporation. If the corporation wishes to have a hearing, the corporation's attorney must file a written request for hearing with the Board within 21 days from the date this notice was mailed. The corporation's attorney may send or deliver a request for hearing to:

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 425
Portland, OR 97232
Fax: 503-731-4067

Pursuant to OAR 855-001-0010 and OAR 855-001-0015, if you request a hearing you must also provide, within 21 days from the date this contested case notice was served, a written answer to the allegations set forth in this contested case notice. Your written answer must include an admission or denial of each factual matter alleged in the notice and a short and plain statement of each relevant affirmative defense you may have. Except for good cause, factual matters alleged in the notice and not denied in the answer shall be presumed admitted; failure to raise a particular defense in the answer will be considered a waiver of such defense; new matters alleged in the answer (affirmative defenses) shall be presumed to be denied by the agency; and

evidence shall not be taken on any issue not raised in the notice and the answer.

If a request for hearing is not received within this 21-day period, the corporation's right to a hearing shall be considered waived.

If the corporation requests a hearing, the corporation's attorney will be notified of the time and place of the hearing. Before the commencement of the hearing, the corporation will be given information on the procedures, right of representation and other rights of parties relating to the conduct of the hearing.

If the corporation does not request a hearing within 21 days, or if it withdraws a hearing request, notifies the Board or hearing officer that it will not appear, or fails to appear at a scheduled hearing, the Board may issue a final order by default imposing discipline. If the Board issues a final order by default, it designates its file on this matter as the record.

DATED this 12 day of November, 2003.

BOARD OF PHARMACY
FOR THE STATE OF OREGON

BY: _____
Grace Cheung, R.Ph.
Compliance Director

THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Commerce, Community, and Economic Development

DIVISION OF CORPORATIONS, BUSINESS, AND PROFESSIONAL LICENSING
Anchorage Office

550 West Seventh Avenue, Suite 1500
Anchorage, AK 99501-3567
Main: 907.269.8160
Toll free fax: 907.269.8156

CERTIFIED# 7019 0140 0001 0060 8896
RETURN RECEIPT REQUESTED

August 24, 2023

Top Rx, LLC
Attn: John Richardson, Director of Compliance
2950 Brother Blvd
Bartlett, TN 38133

RE: Case No. 2023-000288

Mr. Richardson:

This letter shall serve as formal notice to you that the Alaska Board of Pharmacy, during its August 10, 2023 meeting, adopted the Imposition of Civil Fine, presented to the Board by members of the staff from the Division of Corporations, Business and Professional Licensing. A copy of the Imposition of Civil Fine and Order, as adopted, is enclosed.

Please be advised that you were under official investigation by the Alaska Board and this subsequent disciplinary action is reportable to the necessary entities as required by law. You may be required to report this license action and to disclose it when applying for licensure in other states. Should you have any questions regarding this matter, please do not hesitate to contact me at the address and telephone number listed above.

Sincerely,

DocuSigned by:
Erika Prieksat
34F98CE5F1DF48C

Erika Prieksat,
Chief Investigator

cc: Office of Administrative Hearings
Sylvan Robb, Director CBPL
Glenn Saviers, CBPL Deputy Director
Michael Bowles, Executive Administrator
William "Billy" Homestead, Senior Investigator
Holly Handley, Investigator
Marilyn Zimmerman, Paralegal II
Julienne Kim, Paralegal II
Litigation File 2023-000288 (Original)

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE ALASKA BOARD OF PHARMACY

IMPOSITION OF CIVIL FINE
Case # 2023-000288

I, John Richardson, as an agent for Top Rx, LLC admit and agree the Alaska Board of Pharmacy (Board) has jurisdiction over the subject matter of Out-of-State Wholesale Drug Distributor License No. 191040, and over this Imposition of Civil Fine.

1. On October 02, 2022, we appointed a new Facility Manager in reference to License #191040.
2. On February 06, 2023, the Board received our Change of Facility Manager/ Pharmacist-in-Charge form with the new Facility Manager notification; 131 days after the Facility Manager change occurred.
3. This is a violation of **12 AAC 52.635(a)**.

We admit that as a result of these facts, grounds exist for possible denial of licensure or other disciplinary sanctions of my license pursuant to AS 08.01.75 and 12 AAC 52.635(a). We are agreeing to this Imposition of a Civil Fine of three hundred dollars ($300) in cash, certified check, ~~or money order payable to the "State of Alaska"~~ within ninety (90) days after this Imposition of Civil Fine is accepted by the Board.

We have the right to consult with an attorney, and a right to an administrative hearing on the facts in this case. We understand and agree by voluntarily signing this Imposition of Civil Fine, we are waiving our rights to counsel and to a hearing on this matter.

Agent for Top RX, LLC. (Signature) — Date: 7/26/23

SUBSCRIBED AND SWORN TO before me this 26th day of July, 2023, at BARTLETT, ~~Alaska.~~ TENNESSEE

SEAL

Notary Public in and for ~~Alaska~~ TENNESSEE

BH
BH

NOAH H. GRAY
Notary Printed Name
My commission expires: 12-2-2025

State of Alaska
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

FORM REVISED 5/01/2015

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE ALASKA BOARD OF PHARMACY

In the Matter of:)
)
Top RX, LLC.)
)
Respondent)
Case No. 2023-000288

ORDER

The Alaska Board of Pharmacy (Board), having examined the Imposition of Civil Fine, Case No. 2023-000288, regarding License No. #191040, for failure to timely notify the Board of a Facility Manager change, hereby adopts the Imposition of Civil Fine.

The Board has determined this is a technical violation of professional licensing statutes and regulations, therefore this matter can be resolved with a civil fine.

This Imposition of Civil Fine takes effect immediately upon signature of this Order in accordance with the approval of the Board.

DATED this 10th day of August, 2023, at Anchorage, Alaska.

ALASKA BOARD OF PHARMACY

By: Ashley Schaber
Board Chair

State of Alaska
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

NABP ACCREDITED
DRUG DISTRIBUTOR

Auburn Pharmaceutical Company

located at
1744 Rochester Industrial Drive, Rochester Hills, MI 48309

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

10/13/2021 - 10/12/2024
Period of Accreditation

SAWD Renewed

Accredited Drug Distributors

Find an Accredited Drug Distributor

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.

1 2 Next >>

Name	Address	Accreditation Date
American Pharmaceutical Ingredients, LLC dba American Pharmaceutical Distributors	6650 Highland Road, Unit 302 Waterford, MI 48327	Reaccreditation in process
AmerisourceBergen Drug Corporation	MI	03/01/22
Auburn Pharmaceutical Company	1744 Rochester Industrial Drive Rochester Hills, MI 48309	10/13/24
Bonita Pharmaceuticals LLC dba Bonita Pharmaceuticals	6380 Commerce Drive Westland, MI 48185	10/05/23
Cardinal Health 200, LLC dba Cardinal Health	6000 Rosa Parks Blvd Detroit, MI 48208	05/12/24
Chanvi Pharma Services LLC dba Spectrum Pharmaceutical Distributors	1220 Rankin Dr Troy, MI 48083	01/03/24
Concordance Healthcare Solutions, LLC	3625 Park Circle Dr Kalamazoo, MI 49048	01/25/22
EQ Detroit, Inc dba US Ecology Detroit (South)	1923 Frederick St Detroit, MI 48211	12/12/22
JAB Medical Supply Co Inc	50486 Pontiac Trl Wixom, MI 48393	09/09/24
L. Perrigo Company	900 Industrial Dr Allegan, MI 49010	01/18/23

1 2 Next >>

Copyright © 2023 National Association of Boards of Pharmacy® (NABP®).

Contact

About NABP

Supporting patient and prescription drug safety by working with our members, the state boards of pharmacy, since 1904.

Learn More

What We Do

- Programs
- Members
- Initiatives

Learn More

- Support Center
- Resources
- Newsroom

Stay Connected

- Contact
- Email Sign-up

Copyright © 2024 National Association of Boards of Pharmacy® (NABP®). |

- Terms & Policies
- Privacy Policies
- FCRA Dispute Process

AUBURN
PHARMACEUTICAL

To Whom it May Concern:

Auburn Pharmaceutical LLC, dba Auburn

Officers

- Scott Franklin, CEO
- Amber Versosky, COO
- Elaine McNutt, VP

Ownership

- Top Rx Intermediate, LLC (100% Owning Entity)

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "AUBURN PHARMACEUTICAL, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINETEENTH DAY OF SEPTEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "AUBURN PHARMACEUTICAL, LLC" WAS FORMED ON THE TWENTY-SECOND DAY OF JULY, A.D. 2024.



Jeffrey W. Bullock, Secretary of State

4353102 8300

SR# 20243735709

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204439500

Date: 09-19-24

5306006725APP21

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

AUBURN PHARMACEUTICAL, LLC
DBA - AUBURN
1744 ROCHESTER INDUSTRIAL DR
ROCHESTER HILLS, MI 48309

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

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

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
WHOLESALE DISTRIBUTOR LICENSE

AUBURN PHARMACEUTICAL, LLC
DBA - AUBURN
1744 ROCHESTER INDUSTRIAL DR
ROCHESTER HILLS, MI 48309

LICENSE NO.
5306006725

EXPIRATION DATE
05/07/2025

24295111000

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

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RA0186014	06-30-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	05-23-2024

AUBURN PHARMACEUTICAL
1744 ROCHESTER INDUSTRIAL DR
ROCHESTER HILLS, MI 48309

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RA0186014	06-30-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	05-23-2024

AUBURN PHARMACEUTICAL
1744 ROCHESTER INDUSTRIAL DR
ROCHESTER HILLS, MI 48309

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RA0186014	06-30-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	05-23-2024

AUBURN PHARMACEUTICAL
1744 ROCHESTER INDUSTRIAL DR
ROCHESTER HILLS, MI 48309

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:
   Drug Enforcement Administration
   P.O. Box 2639
   Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

5315223717APP21

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

AUBURN PHARMACEUTICAL, LLC
DBA - AUBURN
1744 ROCHESTER INDUSTRIAL DR
ROCHESTER HILLS, MI 48309

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

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

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
CONTROLLED SUBSTANCE LICENSE

*THIS LICENSE IS ONLY VALID IF PROFESSIONAL LICENSE IS ACTIVE

AUBURN PHARMACEUTICAL, LLC
DBA - AUBURN
1744 ROCHESTER INDUSTRIAL DR
ROCHESTER HILLS, MICHIGAN 48309

LICENSE NO.	EXPIRATION DATE		
5315223717	05/07/2025	24295111018	THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

OLD REPUBLIC SURETY COMPANY
18650 W CORPORATE DRIVE SUITE 10 BROOKFIELD, WI 53045

RENEWAL ADVICE

Bond Number	Effective Date	Expiration Date	Transaction Effective Date	Agency Number
MLI1215310	5/03/2022	5/03/2023	5/03/2022	46-5186

Principal

AUBURN PHARMACEUTICAL CO
2354 BELLINGHAM
TROY, MI 48083

Agency

CONST BONDING SPECIALISTS LLC
29445 BECK RD STE A-209
WIXOM, MI 48393

Obligee

NEVADA STATE BOARD
OF PHARMACY
431 W PLUMB LANE
RENO, NV 89509

Alternate Billing Address

Bond Description	Bond Amount	Current Premium	Commission	Due Company
FINANCIAL GUARANTEE	$100,000	$2,000		

Run Date	Entry Time	Reason	Renewal Premium	Original Date
2/28/2022		RENEWAL	$2,000	5/03/2011

Mkt Rep	Line	Class	SAA Sub	SAA Form	Type Policy	Contract Amount	Cont Type	Tax Location	Fast Bond	Rate Mod	Rate Dep	Co.	Bulk No	Contract Account	Credit File Number
	24	579	4								999	15			

Undr Wrtg	Collateral File	State	Term	Remarks Left	Remarks Right	Canc	Bill Atty	AID	Ren By	LIS	Last Premium Endorsement	Initials	Stat	Deductible Amount	Addn'l Locations	Type Cvg	Ratable Employees
Y		27	1			Y	N	A	1	S		MKO	A				

Special Remarks

LICENSE #WH00797

Standard Remarks NOTICE: Please Respond to any request printed below to avoid further handling & expense

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Auburn Pharmaceutical, LLC dba Auburn

Pharmacy/Wholesaler License # (if applicable): WH00797

Physical Address: 1744 Rochester Industrial Dr

City: Rochester Hills State: MI Zip: 48309

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 248-526-3730 Website: auburngenerics.com

Licensing Company Email: compliance@auburnpharm.com

Section 2: Personal Information

First: Merideth Middle: Katelyn Last: Leighty

Alias(es, nicknames, name changes, etc.): Madien Name: Treusch

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

Mailing Address: 1744 Rochester Industrial Dr

City: Rochester Hills State: MI Zip: 48309

Telephone: 248-526-3730 Email: compliance@auburnpharm.com

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

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

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

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

School Name			From - To (MM/YY – MM/YY)
Lakeview High School			8/99-6/03
Address	**City**	**State**	**Zip**
21100 E Eleven Mile Rd	St Clair Shores	MI	48081
Diploma/Degree obtained, if any			
High School Diploma			

School Name			From - To (MM/YY – MM/YY)
Macomb Community College			8/03-6/04
Address	**City**	**State**	**Zip**
14500 Twelve Mile Rd	Warren	MI	48088
Diploma/Degree obtained, if any			
Did Not Complete Degree			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/20 to Present	[redacted]	Allenton	MI	48002
10/10-12/20		St. Clair Shores	MI	48081
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Auburn Pharmaceutical			From - To (MM/YY – MM/YY): 06/05-06/21 Moved
Business Address: 2360 Bellingham Dr	City: Troy	State: MI	Zip: 48083
Phone: 248-526-3730	Title: Regulatory & Compliance Manager		Number of Employed Hours: 33,280
Description of Duties: Attached			

Business Name: Auburn Pharmaceutical (New Address)			From - To (MM/YY – MM/YY): Moved 06/21-08/22
Business Address: 1744 Rochester Industrial Dr (New Address)	City: Rochester Hills	State: MI	Zip: 48309
Phone: 248-526-3730	Title: Regulatory & Compliance Manager		Number of Employed Hours: 2,400
Description of Duties: Attached			

Business Name: Auburn Pharmaceutical			From - To (MM/YY – MM/YY): Returned 05/23-Present
Business Address: 1744 Rochester Industrial Dr	City: Rochester Hills	State: MI	Zip: 48309
Phone: 248-526-3730	Title: Regulatory & Compliance Manager		Number of Employed Hours: 2,720
Description of Duties: Attached			

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

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

Continue on next page if additional space is needed.

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

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

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/2/2010	10/21/2010	MI	Roseville	Macomb
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
RV04673		Roseville Police Department		
Reason/Charge				
Operating - Impaired				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

In October 2010, I made the poor decision to drive after drinking. I was pulled over and arrested at the time, being charged with Operating While Intoxicated (this charge was dropped and lowered to the charge of Operating While Impaired, a misdemeanor). I was sentenced to Probation, which was completed. Obviously, this was a mistake and something I take very seriously. In the 14 years since, I have had a completely clean record.

Meredith Leighey
Original Signature (electronic, copies or stamps not accepted)

9/24/2024
Date

ICHAT
INTERNET CRIMINAL HISTORY ACCESS TOOL

BROUGHT TO YOU BY

Information Provided

Name : Merideth Katelyn Leighty
Date of Birth :
Gender :
Race :
Reason :
Alias Name 1 :
Amount Paid :
Order Date :
Miscellaneous No :

Based on the information provided, the following is a result of a search of the Michigan State Police criminal history files as of 8/30/2024 2:10:27 PM:

Important: Information Contained in this Record

THE RECORD RESULT PROVIDED IS BASED ON A DATA MATCH AS EXPLAINED ON THE ICHAT HOME PAGE. THE ICHAT SYSTEM HAS LIMITATIONS THAT MAY CAUSE FALSE POSITIVES OR FALSE NEGATIVES. PLEASE REVIEW THE RESULTS CAREFULLY AND DO NOT TAKE ADVERSE ACTION BASED SOLELY ON THIS RECORD. IF YOU CANNOT DETERMINE THESE RESULTS DO NOT BELONG TO THIS INDIVIDUAL, AND THE INDIVIDUAL IS DISPUTING THE RECORD, PLEASE PROVIDE THAT INDIVIDUAL WITH A COPY OF THIS REPORT AND OFFER THAT INDIVIDUAL THE OPPORTUNITY TO PERFORM A RECORD CHALLENGE BY SUBMITTING FINGERPRINTS. THE PROCEDURES ARE EXPLAINED AT THE BOTTOM OF THIS PAGE. SINCE ARREST CONVICTIONS, OR CRIMINAL RECORD DELETIONS MAY OCCUR AT ANY TIME, DO NOT USE THIS INFORMATION FOR FUTURE CLEARANCES.

MICHIGAN CRIMINAL HISTORY RECORD INFORMATION MEETING DISSEMINATION CRITERIA
FOR SID: 4084261M AS OF 08/30/2024

NAM: TREUSCH,MERIDETH KATELYN SID: 4084261M

[redacted]

MNU:

CIZ:

ADDITIONAL IDENTIFIERS AND COMMENTS:

NAM: LEIGHTY,MERIDETH KATELYN

==========

INCIDENT DATE: 10/02/2010

TCN/OCA: H110277010W/RV04673
NAME USED: TREUSCH,MERIDETH KATELYN

==========

ARREST SEGMENT	CHARGE SEGMENT	JUDICIAL SEGMENT
DATE: 10/02/2010	NO DATA RECEIVED	DATE: 10/21/2010
MI5071300		MI500035J
ROSEVILLE POLICE DEPARTMENT		39TH DISTRICT COURT
		CTN: 10 RV04673
OCA: 10-21747		
1 CNT OF 5400		CNT-2 MCL 257.6253-A
ORDINANCE VIOL		ORDINANCE VIOL
TRAFFIC OFFENSE		OPERATING - IMPAIRED
DISP: NOTICE TO APPEAR		DISP: FOUND GUILTY
		SENT/REMARKS:
		PROB-0360D

==========

DISSEMINATION OF CRIMINAL HISTORY RECORD INFORMATION (CHRI) VIA THE INTERNET CRIMINAL HISTORY ACCESS TOOL IS IN COMPLIANCE WITH MICHIGAN COMPILED LAW (MCL) 28.242a, WHICH STATES THAT ALL CHRI THAT IS SUPPORTED BY BIOMETRIC DATA SHALL BE DISSEMINATED IN RESPONSE TO A NAME-BASED SEARCH OF THE CHRI DATABASE, UNLESS THE CHRI IS NONPUBLIC (AS DEFINED BY MCL 769.16a) OR OTHERWISE PROHIBITED BY LAW FROM BEING DISSEMINATED.
PURPOSE CODE USED NOT FORWARDED TO NCIC III
END MSG.
</MESSAGEDATA>

PROCEDURES FOR CORRECTING A RECORD

THE STEPS FOR CORRECTING A MISTAKEN OR INACCURATE RECORD ARE AS FOLLOWS:

1.WRONG PERSON - RECORDS THAT DO NOT BELONG TO THE INDIVIDUAL WHOSE NAME HAS BEEN SEARCHED

- IF THE INDIVIDUAL BELIEVES THAT THE RECORD DOES NOT BELONG TO HIM OR HER, THE INDIVIDUAL SHOULD GO TO THE NEAREST LAW ENFORCEMENT AGENCY AND REQUEST TO BE FINGERPRINTED ON A STATE APPLICANT FINGERPRINT CARD FOR THE PURPOSES OF "RECORD CHALLENGE"; CALL AHEAD TO VERIFY FEES AND/OR SERVICE HOURS. THERE IS NO CHARGE FOR SUCH FINGERPRINTING IF IT IS DONE AT A MICHIGAN STATE POLICE POST.

- THIS CARD SHOULD BE MAILED TO THE CRIMINAL JUSTICE INFORMATION CENTER WITH A COPY OF THIS RECORD AND A LETTER REQUESTING THE CRIMINAL JUSTICE INFORMATION CENTER TO VERIFY THAT THE ENCLOSED CRIMINAL RECORD DOES NOT BELONG TO HIM/HER. THERE IS NO FEE. THE ADDRESS IS:

  MICHIGAN STATE POLICE -- CJIC
  ATTN: RECORD CHALLENGE
  P.O.BOX 30634
  LANSING, MI 48909

2.RIGHT PERSON - INACCURATE, INCOMPLETE, OR OUT-OF-DATE INFORMATION

- SOMETIMES RECORDS CONTAIN REPORTING ERRORS. FOR EXAMPLE, THE NATURE OR DATE OF THE CONVICTION WAS REPORTED INCORRECTLY, OR THE RECORD CONTAINS A CONVICTION THAT SHOULD HAVE BEEN REMOVED FROM THE RECORD.

- IN SUCH CASES THE INDIVIDUAL SHOULD OBTAIN CERTIFIED COPIES OF THE COURT JUDGEMENT OR OTHER DOCUMENTS WHICH SHOW THAT THE INFORMATION CONTAINED ON THE CRIMINAL RECORD IS INCORRECT. IF THE PROOF PROVIDED IS SATISFACTORY, THE MICHIGAN STATE POLICE WILL MODIFY THE RECORD ACCORDINGLY. YOU MAY SEND THE DOCUMENTS TO:

  MICHIGAN STATE POLICE -- CJIC
  ATTN: CRIMINAL HISTORY RECORD CORRECTION
  P.O.BOX 30634
  LANSING, MI 48909

I, Merideth Leighty, **certify that as the designated representative for**

Auburn Pharmaceutical, LLC dba Auburn,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ML I am at least 21 years of age;
3. MV I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MV I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MV I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MV I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MV I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Merideth Leighty

Print Name (First, Last)

Merideth Leighty

Original Signature (electronic, copies or stamps not accepted)

9/24/2024

Date

AUBURN
PHARMACEUTICAL

Designated Representative Duties:

Oversees state and federal compliance. Responsible for ensuring that Auburn fully complies with all applicable statutes and regulations that govern wholesale distribution in all States that we hold licenses and that procedures are adhered to.

Responsible for meeting or exceeding FDA and DEA security requirements, that cameras and recording equipment is in good operating condition. Ensuring the warehouse maintains temperature and humidity levels set forth by the manufacturers packaging requirements.

Responsible for ensuring that damaged, non-returnable, non-saleable product and containers are sent to a licensed pharmaceutical destruction facility.

Responsible for ensuring that all new warehouse employees are trained to follow Auburn Pharmaceutical's rules and policies.

Merideth Leighty

Regulatory and Compliance Manager

NV

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

Merideth Leighty

Print Name (First, Last)

Merideth Leighty

Original Signature (electronic, copies or stamps not accepted)

9/24/2024

Date

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

State of Michigan, ss. County of Oakland

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

Merideth Leighty

Original Signature

9/24/2024

Date

Subscribed and Sworn to before me this 24 day of September, 2024

Tina Howard

Notary Public Signature

Tina Lynn Howard
NOTARY PUBLIC - STATE OF MICHIGAN
COUNTY OF MACOMB
My Commission Expires April 8, 2028
Acting in the County of Oakland

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Auburn Pharmaceutical, LLC dba Auburn

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) WH00797 (current)

Physical Address 1744 Rochester Industrial Dr.

City Rochester Hills State MI Zip 48309

Mailing Address (if different from physical address) same as above

City _____ State _____ Zip _____

Telephone 248-526-3730 Website auburngenerics.com

Licensing Company Email Compliance@auburnpharm.com

Section 2: Personal Information

First Amber Middle Theresa Last Versosky

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

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

Mailing Address 1744 Rochester Industrial Dr

City Rochester Hills State MI Zip 48309

Telephone 248-526-3730 Email aversosky@auburnpharm.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Davenport University		09/2000 – 12/05	
Address	City	State	Zip
27500 Dequindre Rd	Warren	MI	48092
Diploma/Degree obtained, if any			
BBA			

School Name		From - To (MM/YY – MM/YY)	
Clawson High School		09/93	05/97
Address	City	State	Zip
101 John M	Clawson	MI	48017
Diploma/Degree obtained, if any			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2018 – now	[redacted]	West Bloomfield	MI	48323
From - To (MM/YY – MM/YY)		City	State	Zip
05/12 – 11/18		West Bloomfield	MI	48322
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Auburn Pharmaceutical			06/21 - now	
Business Address	**City**		**State**	**Zip**
1744 Rochester Industrial Dr	Rochester Hills		MI	48309
Phone	**Title**			
800-222-5609	President			
Description of Duties	Run company/all departments			

Business Name			From - To (MM/YY – MM/YY)	
Cardinal Health			08/13 - 06/21	
Business Address	**City**		**State**	**Zip**
7000 Cardinal Place	Dublin		OH	43017
Phone	**Title**			
614-757-5000	Director			
Description of Duties	Ran commercial operations for repackaging label			

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

NV

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

Amber Versosky

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/27/24

Date

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

State of Michigan, ss. County of Oakland

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

Original Signature

8.27.24

Date

Subscribed and Sworn to before me this 27 day of August, 2024

Notary Public Signature

Tina Lynn Howard
NOTARY PUBLIC - STATE OF MICHIGAN
COUNTY OF MACOMB
My Commission Expires April 8, 2028
Acting in the County of Oakland

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Auburn Pharmaceutical LLC, DBA Auburn

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WH00797

Physical Address: 1744 Rochester Industrial Dr

City: Rochester Hills State: MI Zip: 48309

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 800-222-5609 Website: www.auburngenerics.com

Licensing Company Email:

Section 2: Personal Information

First: Norma Middle: Elaine Last: McNutt

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

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

Mailing Address: [redacted]

City: Memphis State: TN Zip: 38103

Telephone: [redacted] Email: e.mcnutt@toprx.com

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

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

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

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

School Name			From - To (MM/YY – MM/YY)
University of Phoenix			3/2007 - 10/2008
Address	**City**	**State**	**Zip**
3641 Central Ave	Memphis	TN	38111
Diploma/Degree obtained, if any			
Bachelor of Science, Business Management			

School Name			From - To (MM/YY – MM/YY)
Southwest Tennessee Community College			Jan 1976 - Dec 1978
Address	**City**	**State**	**Zip**
737 Union Ave	Memphis	TN	36103
Diploma/Degree obtained, if any			
Associate of Science Degree, Accounting/Associates of Science Degree, Data Processing Technology			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
-present	[redacted]	Memphis	TN	38103
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
Top Rx, LLC			2005-present
Business Address	**City**	**State**	**Zip**
2950 Brother Blvd	Bartlett	TN	38133
Phone	**Title**		
901-373-9314	VP of Finance		
Description of Duties			
Responsible for all financial, accounting, and payroll operations.			

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

Norma Elaine McNutt

Print Name (First, Last)

Norma Elaine McNutt — 8/20/2024

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

---

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

State of TENNESSEE, ss. County of SHELBY

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

Norma Elaine McNutt — 8/20/2024

Original Signature — **Date**

Subscribed and Sworn to before me this 20TH day of AUGUST.

Noah H Gray

Notary Public Signature

NOAH H. GRAY
STATE OF TENNESSEE NOTARY PUBLIC
SHELBY COUNTY
MY COMMISSION EXPIRES 12-2-2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Auburn Pharmaceutical LLC, DBA Auburn

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WH00797

Physical Address: 1744 Rochester Industrial Dr

City: Rochester Hills State: MI Zip: 48309

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 800-222-5609 Website: www.auburngenerics.com

Licensing Company Email:

Section 2: Personal Information

First: William Middle: Scott Last: Franklin

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

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

Mailing Address: [redacted]

City: Germantown State: TN Zip: 38138

Telephone: [redacted] Email: s.franklin@toprx.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Rhodes College		1990-1994	
Address	**City**	**State**	**Zip**
2000 North Parkway	Memphis	TN	38112
Diploma/Degree obtained, if any			
Bachelor of Arts Biology, Minor in Psychology			

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

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
-present	[redacted]	Germantown	TN	38139
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Top Rx, LLC			1998-present	
Business Address		**City**	**State**	**Zip**
2950 Brother Blvd		Bartlett	TN	38133
Phone	**Title**			
901-441-5059	President			
Description of Duties				
CEO				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

William Scott Franklin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/20/24

Date

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

State of TENNESSEE, ss. County of SHELBY

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

Original Signature

8/20/24

Date

Subscribed and Sworn to before me this 20TH day of AUGUST 2024.

Notary Public Signature

NOAH H. GRAY
STATE OF TENNESSEE NOTARY PUBLIC
SHELBY COUNTY
MY COMMISSION EXPIRES 12-2-2025

(Seal)

First Name	Last Name	Location	Department
Susan	Anderson	Rochester Hills	100
Marcia	Basler	Rochester Hills	100
Delores	Bennett	Rochester Hills	100
Colin	Blatt	Rochester Hills	100
DeShawn	Bogan	Rochester Hills	100
Michelle	Bradley	Rochester Hills	100
Marilyn	Cabigas-Kensora	Rochester Hills	100
Bianca	Caraus	Rochester Hills	100
Ian	Didaleusky	Rochester Hills	100
Sharmaine	Dimayuga	Rochester Hills	100
Lidia	Drasovean	Rochester Hills	100
Cheyenne	Dunlap	Rochester Hills	100
Eric	Ellithorpe	Rochester Hills	100
Hannah	Farris	Rochester Hills	100
Brett	Finlay	Rochester Hills	100
Amanda	Friedlund	Rochester Hills	100
Kenneth	Kukla	Rochester Hills	100
Scott	Lang	Rochester Hills	100
Yang	Lor	Rochester Hills	100
Vanessa	Martinez	Rochester Hills	100
Anna	Marvin	Rochester Hills	100
Bryan	McConner	Rochester Hills	100
Kayla	McLean	Rochester Hills	100
Rade	Mitevski	Rochester Hills	100
Jessica	Moore	Rochester Hills	100
William	Myatt	Rochester Hills	100
Edward	Niedek	Rochester Hills	100
Katherine	Pahal	Rochester Hills	100
Devin	Phillips	Rochester Hills	100
Livia	Popa	Rochester Hills	100
Adriana	Postica	Rochester Hills	100
Deborah	Randall	Rochester Hills	100
Amber	Soldan	Rochester Hills	100
Alexis	Spagnola	Rochester Hills	100
Grace	Stewart	Rochester Hills	100
Lee	Torres	Rochester Hills	100
Michael	Verrelli	Rochester Hills	100
Kyla	Broberg	Salt Lake City	100
Marty	Broberg	Salt Lake City	100
Jonathan	Castillo	Salt Lake City	100
Lourdes	Castro	Salt Lake City	100
Krystal	Criswell	Salt Lake City	100
Jon Paul	Dragos	Salt Lake City	100
Kamryn	Gardner	Salt Lake City	100
Daniel	Hackley	Salt Lake City	100
Lisa	Hall	Salt Lake City	100

Maira	Lopez	Salt Lake City	100
Zackariah	Loveless	Salt Lake City	100
Carmen	Lumbreras	Salt Lake City	100
Madison	Marshall	Salt Lake City	100
Dennis	Moore	Salt Lake City	100
Anna	Musser	Salt Lake City	100
Jaqueline	Perez Loya	Salt Lake City	100
Samantha	Rosas	Salt Lake City	100
Nolvia	Sanchez	Salt Lake City	100
Carol	Schull	Salt Lake City	100
Krista	Sewell	Salt Lake City	100
Tiffany	Warner	Salt Lake City	100
Rebecca	Wayland	Salt Lake City	100
Ashley	Afelt	Salt Lake City	300
Raghad	Batros	Salt Lake City	300
Sherri	Brown	Salt Lake City	300
Robert	Caraway	Rochester Hills	300
Timothy	Casey	Rochester Hills	300
Michael	Clements	Rochester Hills	300
Christine	Clippert	Rochester Hills	300
Rhonda	Doherty	Rochester Hills	300
Dawn Marie	Drehmer	Rochester Hills	300
Mark	Elliott	Rochester Hills	300
Meegen	Elliott	Rochester Hills	300
Karlene	Grifka	Rochester Hills	300
Tahsina	Haque	Rochester Hills	300
James	Hoch	Rochester Hills	300
Tina	Howard	Rochester Hills	300
Merideth	Leighty	Rochester Hills	300
Robert	Meek	Rochester Hills	300
Matthew	Sgriccia	Rochester Hills	300
Andrea	Wolf	Rochester Hills	300
Matthew	Butler	Rochester Hills	400
Lisa	Rossi	Rochester Hills	400
James	Sloat	Rochester Hills	400
Nicole	Wroblewski	Rochester Hills	400
Nacianceno	Danielle	Rochester Hills	400
Javon	Beverly	Rochester Hills	400
Chandra	Britt	Rochester Hills	400
Christopher	Brown	Rochester Hills	400
Bobbie	Bryant	Rochester Hills	400
Lauren	Dimitrievski	Rochester Hills	400
Thomas	Dombrowski	Rochester Hills	400
Kimberly	Fletcher	Rochester Hills	400
Lana	Hanna	Rochester Hills	400
David	Jaramillo	Rochester Hills	400
Karen	King	Rochester Hills	400

Linda	Krcic	Rochester Hills	400
Elizabeth	Nice	Rochester Hills	400
Lindsey	Pacitti	Rochester Hills	400
Nathan	Ray	Rochester Hills	400
Monika	Ribar	Rochester Hills	400
Grant	Roland	Rochester Hills	400
Susan	Ruffino	Rochester Hills	400
Resham	Shah	Rochester Hills	400
Kathy	Spagnola	Rochester Hills	400
Jessica	Walsh	Rochester Hills	400
David	Nacy	Rochester Hills	500
Anthony	Rembao	Rochester Hills	500
Kaja	Clark	Rochester Hills	600
Michael	D'Agostini	Rochester Hills	600
Michael	Larsen	Rochester Hills	600
Christine	Potempa	Rochester Hills	600
Hannah	Quick	Rochester Hills	600
Ronald	Reece	Rochester Hills	600
Amber	Versosky	Rochester Hills	600
Christine	Walker	Rochester Hills	600
Jeffrey	Farber	Rochester Hills	700

Suppliers

Vendor	Address1	Address2	City	State	Zipcode	Phone	Email
ACCORD HEALTHCARE INC	1009 SLATER ROAD	SUITE 210 B	DURHAM	NC	27703	919-941-7878	CSACCORD@INTASPHARMA.COM
ACELLA PHARMACEUTICALS	1800 MCFARLAND PARKWAY		ALPHARETTA	GA	30005	578-325-5188	PURCHASEORDERS@ACELLAPHARMA.COM
ACI PHARMACEUTICAL	10100 W. SAMPLE RD	SUITE 406	CORAL SPRINGS	FL		855-419-0397	AFIFA.ANJUM@ACIHEALTHCAREUSA.COM
ADVAGEN PHARMA LTD	666 PLAINBORO ROAD		PLAINSBORO	NJ	08536		ORDERS@ADVAGENPHARMA.COM
AJANTA PHARMACEUTICALS	P.O. BOX 417863		BOSTON	MA	022417863	866-770-3029	AJANTACS@AJANTAPHARMA.COM
ALEMBIC PHARMACEUTICALS	550 HILLS DRIVE	STE 104B	BEDMINSTER	NJ	07921	908-393-9604	CUSTOMEROPS.ALEMBIC@KNIPPER.COM
ALEOR DERMACEUTICALS	ALEOR DERMACEUTICALS	ALEOR LTD PLOT NO.779/P&790/P	VADODARA		391450		SUBHASISH.PATTANAIK@ALEORDERM.COM
ALEXSO INC. CCD	2317 COTNER AVE		LOS ANGELES	CA	90064	310-282-8086	ORDERS@ALEXSO.COM
ALLISON MEDICAL, INC	8091 SHAFFER PARKWAY		LITTLETON	CO	80127	513-235-8832	ORDERS@ALLISONMEDICAL.COM
ALVOGEN	9 CAMPUS DRIVE	3RD FLOOR	PARSIPPANY	NJ	07054	866-770-3024	CUSTOMERSERVICE-US@ALVOGEN.COM
ALVOGEN C2	UPS SUPPLY CHAIN SOLUTIONS INC	1860 OUTER LOOP	LOUISVILLE	KY	40219		CUSTOMERSERVICE-US@ALVOGEN.COM
ALVOGEN CONTROLS	9 CAMPUS DRIVE	3RD FLOOR	PARSIPPANY	NJ	07054	866-770-3024	CUSTOMERSERVICE-US@ALVOGEN.COM
ALVOGEN DIRECT	9 CAMPUS DRIVE	3RD FLOOR	PARSIPPANY	NJ	07054	866-770-3024	CUSTOMERSERVICE-US@ALVOGEN.COM
AMICI PHARMACEUTICALS	425 BROADHOLLOW ROAD	SUITE 315	MELVILLE	NY	11747		CUSTOMERSERVICE@AMICIPHARMA.COM
AMNEAL C2 (ALL OTHERS)	115 CAROL KNICELY DRIVE		GLASGOW	KY	42141		CUSTOMERRESPONSE@AMNEAL.COM
AMNEAL PHARMACEUTICAL LLC	104 HIPPOCRATES WAY	P.O. BOX 601818	CHARLOTTE	NC	28260	866-525-7270	KAREN.PIERCE@AMNEAL.COM
AMRING PHARMACEUTICALS	1235 WESTLAKES DRIVE		BERWYN	PA	19312	610-285-7196	AMRING@ICSCONNECT.COM
ANI PHARMACEUTICALS	210 MAIN STREET WEST	PO BOX 370	BAUDETTE	MN	56623	800-434-1121	CUSTOMERSERVICE@ANIPHARMACEUTICALS.COM
APOTEX C2	4580 S. MENDENHALL ROAD		MEMPHIS	TN	38141		USCUSTOMERSERVICE@APOTEX.COM
APOTEX CORP	2400 N. COMMERCE PKWY	SUITE #400	WESTON	FL	33326	800-706-5575	USCUSTOMERSERVICE@APOTEX.COM
APOTHECARY HERITAGE	3001 HIGHWAY M-20	P.O BOX 57	NEW ERA	MI	49446	812-797-4507	AMBER.MACLEAN@APOTHECARYHERITAGE.COM
ARCHIS PHARMA	15 CORPORATE PLACE S	SUITE 108	PISCATAWAY	NJ	08854		VMLUKOSE@ARCHISPHARMA.COM
ARMAS PHARMACEUTICAL INC	ARMAS PHARMACEUTICAL INC	303 WEST MAIN STREET	SUITE 300	NJ	07728		CUSTOMERSERVICE@ARMASPHARMA.COM
ASCEND C2 / R&S SOLUTIONS LLC	96 AMERICAN DR STE 100A		JACKSON	TN	383010000		SALES@ASCENDLABORATORIES.COM
ASCEND LABORATORIES	180 SUMMIT AVENUE		MONTVALE	NJ	07645	954-410-8426	SALES@ASCENDLABORATORIES.COM
AUBURN FROM RH TO LOGISTICS	1744 ROCHESTER INDUSTRIAL DR		ROCHESTER HILLS	MI	48309		
AUROBINDO PHARMA	6 WHEELING ROAD		DAYTON	NJ	08810	732-839-9400	CUSTOMERSERVICE@AUROBINDOUSA.COM
AUROBINDO PHARMA C2	6 WHEELING ROAD		DAYTON	NJ	08810		CUSTOMERSERVICE@AUROBINDOUSA.COM
AUROHEALTH LLC	6 WHEELING ROAD		DAYTON	NJ	08810	732-230-8225	CUSTOMERSERVICE@AUROHEALTH.COM
AVET PHARMA / HERITAGE	ONE TOWER CENTER BLVD.	SUITE 1700	EAST BRUNSWICK	NJ	08816	904-278-1008	HERITAGECS@EVERSANA.COM
AVONDALE PHARMACEUTICALS CCD	LOACKBOX 28390	28390 NETWORK PLACE	CHICAGO	IL	60673	800-528-3058	DBOLES@AVONDALEPHARM.COM
BAUSCH & LOMB AMERICAS INC.	400 SOMERSET CORPORATE BLVD.		BRIDGEWATER	NJ	08807		OPHTHAPHARMA@BAUSCH.COM
BAUSCH HEALTH COMPANIES INC.	8500 HIDDEN RIVER PARKWAY		TAMPA	FL	33637	800-323-0000	PHARMRX@BAUSCHHEALTH.COM
BAYSHORE PHARMACEUTICALS	788 MORRIS TURNPIK	SUITE 200	SHORT HILLS	NJ	07071	813-630-0127	CUSTOMERSERVICE@BAYSHOREUS.COM
BIOCON PHARMA	485 ROUTE 1 SOUTH	SUITE B 305	ISELIN	NJ	08830		BIOCONCS@ICSCONNECT.COM
BION PHARMA	600 ALEXANDER ROAD	SUITE 2-4B	PRINCETON	NJ	08540	866-519-3955	SALESOPS@BIONPHARMA.COM
BRECKENRIDGE PHARMACEUTICAL	200 CONNELL DR	SUITE 4200	BERKELEY HEIGHTS	NJ	06037	516-594-9747	CUSTOMERSERVICE@BPIRX.COM
CADISTA PHARMACEUTICALS	207 KILEY DR		SAILSBURY	MD	21801	800-619-9364	KATIE.JONES@CADISTA.COM
CAMBER C2 / R&S NORTHEAST LLC	96 AMERICAN DR SUITE 100A		JACKSON	TN	38301		APREZIOSO@CAMBERPHARMA.COM
CAMBER CONSUMER CARE	1035 CENTENNIAL AVENUE		PISCATAWAY	NJ	08854		CUSTOMERSUPPORT@CAMBERCC.COM
CAMBER PHARMACEUTICALS	200 CENTENNIAL AVE		PISCATAWAY	NJ	08854	866-495-1995	CUSTOMERSERVICE@CAMBERPHARMA.COM
CARLSBAD TECH	5922 FARNSWORTH CT		CARLSBAD	CA	92008	760-431-8284	SERVICE@CARLSBADTECH.COM
CARWIN PHARMACEUTICAL ASSOCCCD	1301 HWY 36 STE 12		HAZLET	NJ	07730	844-700-5011	ORDERS@CARWINPHARMA.COM
CELLTRION	1 EVERTRUST PLAZA	SUITE 1207	JERSEY CITY	NJ	07302		XAVIER.YOON@CELLTRIONHC.COM
CHARTWELL RX, LLC	77 BRENNER DRIVE		CONGERS	NY	10920		CS@CHARTWELLPHARMA.COM
CIPLA USA INC.	10 INDEPENDENCE BLVD	SUITE 300	WARREN	NJ	07059		CIPLACS@UPS.COM
CITRON PHARMA	2 TOWER CENTER BOULEVARD	SUITE 101	EAST BRUNSWICK	NJ	08816		DLUSTGARTEN@RISINGPHARMA.COM
COSETTE PHARMACEUTICALS, INC	P.O BOX 7247 STREET		PHILADELPHIA	PA	19170	800-922-1038	CUSTOMERSERVICE@COSETTEPHARMA.COM
CRANBURY C2	2031 U.S. HIGHWAY 130	SUITE F	MONMOUTH JUNCTION	NJ	08852	732-940-2800	CUSTOMERSERVICE@TRISPHARMA.COM
CRANBURY PHARMACEUTICALS	2031 U.S. HIGHWAY 130	SUITE F	MONOUTH JUNCTION	NJ	08852	732-940-2800	CUSTOMERSERVICE@TRISPHARMA.COM
DASH PHARMACEUTICALS LLC	2 PARK WAY		UPPER SAFFLE RIVER	NJ	07458		DASHPHARM@LSLOG.COM
DPT LABORATORIES LTD CCD	DPT LABORATORIES LTD		ISLINGTON	MI	48332		BUTMAT@AUBURNPHARM.COM

DR REDDY C2	DR REDDY	1860 OUTER LOOP ROAD	LOUISVILLE	KY	40219		CHRISTY.GLOVER@DRREDDYS.COM
DR. REDDY	3600 ARCO CORPORATE DRIVE	SUITE 310	CHARLOTTE	NC	28273		CHRISTY.GLOVER@DRREDDYS.COM
E5 PHARMA LLC	225 NE MIZNER BLVD	SUITE 770	BOCA RATON	FL	33432	561-288-4885	CUSTOMERSERVICE@E5PHARMA.COM
EDENBRIDGE PHARMACEUTICALS	300 INTERPACE PARKWAY	SUITE 360	PARSIPPANY	NJ	07054		SALES@EDENBRIDGEPHARMA.COM
ELITE LABORATORIES C2	165 LUDLOW AVENUE		NORTHVALE	NJ	07647		KKIRKOV@ELITEPHARMA.COM
ELITE LABORATORIES INC	165 LUDLOW AVENUE		NORTHVALE	NJ	07647		KKIRKOV@ELITEPHARMA.COM
ENCUBE ETHICALS, INC.	200 MEREDETH DRIVE	SUITE 101A	DURHAM	NC	27713	919-767-3292	USCS@ENCUBEETHICALS.COM
ENDO USA	1400 ATWATER DR		MALVERN	PA	19355		CUSTOMERORDERS@ENDO.COM
ENDO USA C2	1400 ATWATER DR		MALVERN	PA	19355		CUSTOMERORDERS@ENDO.COM
EPIC PHARMA	227-15 N. CONDUIT AVENUE		LAURELTON	NY	11413	718-276-8607	CS@EPIC-PHARMA.COM
EPIC PHARMA C2	227-15 N. CONDUIT AVENUE		LAURELTON	NY	11413	718-276-8607	CS@EPIC-PHARMA.COM
EUGIA	279 PRINCETON-HIGHTSTOWN ROAD		EAST WINDSOR	NJ	08520		JFARIA@EUGIAUS.COM
EVERSANA LIFE SCIENCE SERVICE	4580 S MENDENHALL ROAD		MEMPHIS	TN	38141	386-673-8376	CUSTOMERSERVICE@SOLCOHEALTHCARE.COM
EYWA C2	501 MASON RD. STE. 200		LAVERGNE	TN	37086		VINCE.SUNEJA@EYWAPHARMA.COM
EYWA PHARMA INC.	2 RESEARCH WAY	FLOOR #3	PRINCETON	NJ	08540	609-751-9600	VINCE.SUNEJA@EYWAPHARMA.COM
FIRST AID RESEARCH	284 CARINA DRIVE		JUPITER	FL	33478	516-783-0274	SMOSLER@FIRSTAIDRESEARCH.COM
FOSUN PHARMA USA	104 CARNEGIE CENTER	SUITE 204	PRINCETON	NJ	08540		FOSUNCS@EVERSANA.COM
FOUGERA PHARMACEUTICALS	PO BOX 2006		MELVILLE	NY	11747	800-645-9833	
FPP	FLORIDA PHARMACEUTICAL PRODUCT	STE 160	BOCA RATON	FL	33487	561-609-3400	SJABR@FLPHARMAPRODUCTS.COM
GERICARE PHARMACEUTICALS CO.	1650 63RD STREET		BROOKLYN	NY	11204	718-234-8800	ORDERS@GERICAREPHARM.COM
GLENMARK PHARMACEUTICALS	750 CORPORATE DRIVE		MAHWAH	NJ	07430		CUSTOMERSERVICE@GLENMARKPHARMA.COM
GRANULES PHARMACEUTICALS C2	3701 CONCORDE PARKWAY		CHANTILLY	VA	20151		GMB-SPS-GRANULES@CORDLOGISTICS.COM
GRANULES PHARMACEUTICALS INC	3701 CONCORDE PARKWAY		CHANTILLY	VA	20151		GMB-SPS-GRANULES@CORDLOGISTICS.COM
GREENSTONE	100 ROUTE 206 NORTH		PEAPACK	NJ	07977	315-571-5662	LORI.LAMATTINA@PFIZER.COM
HEPALINK	HEPALINK/TECHDOW USA	SUITE 200	LANGHORNE	PA	190471885		CUSTOMERSERVICE@TECHDOWUSA.COM
HIKMA C2	1809 WILSON ROAD 08-118		COLUMBUS	OH	43228		CSAC.RDG@BOEHRINGER-INGELHEIM.COM
HIKMA C2 (WEST-WARD)	1809 WILSON ROAD 08-118		COLUMBUS	OH	43228	732-542-1191	CTRICINELLI@WEST-WARD.NET
HIKMA PHARMACEUTICALS	465 INDUSTRIAL WAY WEST		EATONTOWN	NJ	07724	732-542-1191	CUSTOMERSERVICE@HIKMA.COM
I3 PHARMACEUTICALS	200 PARK AVE		WARMINSTER	PA	18974		I3PHARMA@LSLOG.COM
INGENUS PHARMACEUTICALS	4190 MILLENIA BOULEVARD		ORLANDO	FL	32839	866-321-5031	CUSTOMERSERVICE@INGENUS.COM
KEYSOURCE CCD	7820 PALACE DRIVE		CINCINNATI	OH	45249	800-842-5991	JHOPPE@KEYSOURCE.COM
KREMERS URBAN PHARMACEUTICALS	1101 C AVENUE WEST		SEYMOUR	IN	47274	800-477-7877	CUSTOMERSERVICE@LANNETT.COM
KVK TECH INC	110 TERRY DR	SUITE #200	NEWTOWN	PA	18940	267-269-9048	CUSTOMERSERVICE@KVKTECH.COM
KVK TECH INC C2	110 TERRY	SUITE #200	NEWTOWN	PA	18940		CUSTOMERSERVICE@KVKTECH.COM
LANNETT C2	13200 TOWNSEND ROAD		PHILADELPHIA	PA	19154		CUSTOMERSERVICE@LANNETT.COM
LANNETT COMPANY, INC.	9000 STATE ROAD		PHILADELPHIA	PA	19136	800-325-9994	CUSTOMERSERVICE@LANNETT.COM
LAURUS GENERICS, INC.	400 CONNELL DRIVE	SUITE 5200	BERKELEY HEIGHTS	NJ	07922		STEVEN.SMITH@LAURUSGENERICS.COM
LEADING PHARMA	3 G OAK ROAD		FAIRFIELD	NJ	07004	201-746-9152	ORDERS@LEADINGPHARMA.COM
LEADING PHARMA CONTROLS	3 G OAK ROAD		FAIRFIELD	NJ	07004	201-746-9170	ORDERS@LEADINGPHARMA.COM
LIFESTAR PHARMA LLC	1200 MACARTHUR BLVD		MAHWAH	NJ	07430	551-236-5703	CUSTOMERSERVICE@MANKINDPHARMA.COM
LUPIN C2 / UPS SUPPY CHAIN SOL	1860 OUTER LOOP ROAD		LOUISVILLE	KY	40218		CUSTOMERSERVICE-LPI@LUPIN.COM
LUPIN DIRECT	111 SOUTH CALVERT STREET		BALTIMORE	MD	21202	866-587-4617	CUSTOMERSERVICE-LPI@LUPIN.COM
LUPIN PHARMACEUTICALS, INC	111 SOUTH CALVERT STREET		BALTIMORE	MD	21202	866-587-4617	CUSTOMERSERVICE-LPI@LUPIN.COM
MACLEODS	103 COLLEGE ROAD EAST	2ND FLOOR	PRINCETON	NJ	08540	888-441-0911	MACLEODS@LSLOG.COM
MAJOR PHARMACEUTICAL	31778 ENTERPRISE DRIVE		LIVONIA	MI	48150	734-743-6492	MAJOR-ORDERS@MAJOR-PHARM.COM
MAYNE PHARMA	ONE RENAISSANCE CENTRE 3301	BENSON DRIVE, SUITE 401	RALEIGH	NC	27609	800-344-8661	US.CUSTOMERSERVICE@MAYNEPHARMA.COM
MEGALITH PHARMACEUTICALS	PO BOX 21549		NEW YORK	NY	10087	609-356-0210	JOSEPH.DOMBROWSKI@MEGALITHPHARMA.COM
METHOD PHARMACEUTICALS	419 BANK ST.	STE. 100	SOUTHLAKE	TX	76092		ORDERS@METHODPHARM.COM
MICRO LABS USA	220 DAVIDSON AVENUE	SUITE 402	SOMERSET	NJ	08873		CUSTOMERSERVICE@MICROLABS.IN
MODAVAR PHARMACEUTICALS	1016 16TH STREET, NW	SUITE 602	WASHINGTON	DC	20036		MODAVARCS@EVERSANA.COM
MYLAN PHARMACEUTICALS, INC.	781 CHESTNUT RIDGE ROAD	P.O.BOX 4310	MORGANTOWN	WV	26554	800-848-0460	DANIELLE.ANGOTTI@MYLAN.COM
NATCO PHARMA	300 INTERPACE PARKWAY	BUILDING C100	PARSIPPANY	NJ	07054		NATCOPHARMAUSA@LSLOG.COM
NEPHRON PHARMACEUTICAL CORP	4500 12TH STREET EXTENSION		WEST COLUMBIA	SC	29172	803-569-2842	KDEAVER@NEPHRONPHARM.COM

NIVAGEN PHARMACEUTICALS	3050 FITE CIRCLE	SUITE 208	SACRAMENTO	CA	95827		CUSTSERVICE@NIVAGEN.COM
NORDIC PHARMA INC.	1235 WESTLAKES DRIVE		BERWYN	PA	19312	610-285-7196	NORDICPHARMA@ICSCONNECT.COM
NOSTRUM LABORATORIES INC.	190 N MILWAUKEE ST		MILWAUKEE	WI	53202	773-550-9325	NOSTRUMCS@DDNNET.COM
NOVADOZ PHARMACEUTICALS, LLC	P.O. BOX 21758		NEW YORK	NY	10087	848-200-1909	CUSTOMERSERVICE@NOVADOZPHARMA.COM
NOVITIUM PHARMA LLC	PO BOX 24015		NEWARK	NJ	07101	844-735-0711	GMB-SPS-NOVITIUM@CORDLOGISTICS.COM
NOVUGEN	PO BOX 411389		BOSTON	MA	02241		CUSTOMERSERVICE-US@NOVUGEN.COM
OHM LABORATORIES INC	P.O. BOX 7397		NORTH BRUNSWICK	NJ	08902	609-720-5306	OHMORDERSONLY@SUNPHARMA.COM
OMNIVIUM PHARMA	OMNIVIUM PHARMACEUTICALS	2131 FELVER COURT	SUITE A	NJ	07065	732-382-6085	HB@OMNIVIUMPHARMA.COM
ORYZA PHARMACEUTICALS INC	4117 NW 124TH AVENUE		CORAL SPRINGS	FL	33065		ORYZACS@EVERSANA.COM
OXFORD PHARMACEUTICALS	301 LEAF LAKE PARKWAY		BIRMINGHAM	AL	35211		ORDERS@OXFORD-RX.COM
PADAGIS	1251 LINCOLN ROAD		ALLEGAN	MI	49010	800-775-2054	PADAGISRXORDERS@PADAGIS.COM
PAI	201 DELAWARE STREET		GREENVILLE	SC	29605	800-845-8210	PAICUSTSERV@PAIPHARMA.COM
PAI PHARMA	1700 PERIMETER ROAD		GREENVILLE	SC	29605	800-845-8210	PAICUSTSERV@PAIPHARMA.COM
PAR C2	PAR PHARMACEUTICAL	1910 DANIELSIN PLACE	MEMPHIS	TN	38114		CUSTOMERORDERS@PARPHARM.COM
PAR PHARMACEUTICAL	130 VINTAGE DRIVE		HUNTSVILLE	AL	35811		QUALITESTCUSTOMERSERVICE@QUALITESTRX.COM
PAR PHARMACEUTICAL, INC.	ONE RAM RIDGE ROAD		SPRING VALLEY	NY	10977	800-828-9393	CUSTOMERORDERS@PARPHARM.COM
PAR PHARMACEUTICALS	130 VINTAGE DRIVE		HUNTSVILLE	AL	35811	800-444-4011	QUALITESTCUSTOMERSERVICE@QUALITESTRX.COM
PATHEON CCD	123 AUBURN LANE		ROCHESTER	MI	48309		PATHEON@GOONER.COM
PERRIGO DIRECT	725 HIGHWAY 74 SOUTH		PEACHTREE CITY	GA	30269		PERRIGODIRECTORDERS@PERRIGO.COM
PHARMACEUTICAL ASSOC. INC C2	1700 PERIMETER RD	BLDG A	GREENVILLE	SC	29605		SRESCH@AUBURNPHARM.COM
PRASCO LABORATORIES	6125 COMMERCE COURT		MASON	OH	45040	513-618-3362	J.FOGT@PRASCO.COM
PRECISION DOSE	722 PROGRESSIVE LANE		SOUTH BELOIT	IL	61080		CUSTOMERCARE@PRECISIONDOSE.COM
PURETEK CORPORATION CCD	7900 NELSON ROAD	STE A	PANORAMA CITY	CA	91402	818-837-5880	JSMITH@PURETEKCORP.COM
QUAGEN PHARMACEUTICALS LLC	11 PATTON DRIVE		WEST CALDWELL	NJ	07006	973-449-3443	CUSTOMERSERVICE@QUAGENPHARMA.COM
QUINN PHARMACEUTICALS, LLC	6111 BROKEN SOUND PARKWAY NW	SUITE 160	BOCA RATON	FL	33486	954-755-0502	SJABR@QUINNRX.COM
REAL VALUE DRUGS CCD	5100 COMMERCE PARKWAY		SAN ANTONIO	TX	78218	855-681-7201	BOBBY@REALVALUEPRODUCTS.COM
RHODES C2	4701 INTERNATIONAL BLVD. W		WILSON	NC	27893		ERIC.BASIL@PHARMA.COM
RHODES PHARMACEUTICALS	498 WASHINGTON STREET		COVENTRY	RI	02816	888-827-0616	CUSTOMER.SERVICE@PHARMA.COM
RISING CONTROLS	2 TOWER CENTER BLVD	STE. 1401A	EAST BRUNSWICK	NJ	08816		CUSTOMERSERVICE@RISINGPHARMA.COM
RISING PHARMA HOLDINGS	2 TOWER CENTER BLVD	STE. 1401A	EAST BRUNSWICK	NJ	08816		DLUSTGARTEN@RISINGPHARMA.COM
RITEDOSE	1 TECHNOLOGY CIRCLE		COLUMBIA	SC	29203		CUSTOMERSERVICE@RITEDOSE.COM
RUGBY LABORATORIES	1821 RELIABLE PARKWAY		CHICAGO	IL	60686	734-743-6492	MAJOR-ORDERS@MAJOR-PHARM.COM
SANDOZ	2555 W. MIDWAY BLVD	PO BOX 446	BROOMFIELD	CO	800380446	800-525-8747	RUTH.GOLDSTEIN@SANDOZ.COM
SANDOZ C2/ EXEL INC	DBA DHL SUPPLY CHAIN (USA)	260 SALEM CHURCH ROAD	MECHANICSBURG	PA	17050		MDAGOSTINI@AUBURNPHARM.COM
SANDOZ DIRECT	2555 W. MIDWAY BLVD	PO BOX 446	BROOMFIELD	CO	800380446	800-525-8747	RUTH.GOLDSTEIN@SANDOZ.COM
SCIEGEN PHARMACEUTICALS, INC.	7 OSER AVE		HAUPPAUGE	NY	11788	610-940-1066	CUSTOMERSERVICE@SCIEGENPHARM.COM
SIGMAPHARM LABS	3375 PROGRESSIVE DRIVE		BENSALEM	PA	19020	215-352-6655	SIGMAPHARMCS@EVERSANA.COM
SIMPLE DIAGNOSTICS	52-08 GRAND AVE		MASPETH	NY	11378	954-675-1275	ORDERS@SIMPLEDIAGNOSTICS.COM
SOLA PHARACEUTICALS LLC CCD	655 HIGHLANDIA DRIVE	STE B	BATON ROUGE	LA	70810	866-747-7365	ORDERS@SOLAMEDS.US
SOLARIS PHARMA	305 TECH PARK DRIVE	SUITE 113	LAVERGNE	TN	37086		RMATTISON@SOLARIS-PHARMA.COM
SOLCO HEALTHCARE	700 ATRIUM DRIVE	SUITE A	SOMERSET	NJ	08873	386-673-8376	CUSTOMERSERVICE@SOLCOHEALTHCARE.COM
SOMERSET PHARMA LLC	300 FRANKLIN SQUARE DR.		SOMERSET	NJ	08873		CUSTOMERSERVICE@SOMERSETPHARMA.COM
SPEC GX LLC (MALLINCKRODT)	385 MARSHALL AVE		WEBSTER GROVES	MO	63119	651-454-2736	DPHARMA@MNK.COM
SPEC GX LLC C2	172 RAILROAD AVENUE	PO BOX P	HOBART	NY	13788		DPHARMA@COVIDIEN.COM
SPYKA WHOLESALE INC CCD	118 ADAMS STREET	STE 305	FAIRMONT	WV	26554	866-834-2496	SALES@SPYKAWHOLESALE.COM
STRIDES PHARMA	201 SOUTH MAIN STREET	SUITE 3	LAMBERTVILLE	NJ	08530	855-273-0146	STRIDESCUSTOMERSERVICE@STRIDESUSA.COM
SUN C2 / TARO PHARMACEUTICALS	1 COMMERCE DRIVE		CRANBURY	NJ	08512		ORDERS@SUNPHARMAUSA.COM
SUN PHARMACEUTICAL	P.O. BOX 77300		DETROIT	MI	48277	313-871-8400	ALYSON.WEISS@SUNPHARMA.COM
SUNRISE PHARMACEUTICAL	665 E LINCOLN AVE		RAHWAY	NJ	07065	248-308-1105	CUSTOMERSERVICE@WOODWARDPHARMA.COM
SUNRISE PHARMACEUTICAL C2	665 E LINCOLN AVE		RAHWAY	NJ	07065	248-308-1105	CUSTOMERSERVICE@WOODWARDPHARMA.COM
TAGI PHARMA INC	722 PROGESSIVE LANE	ROOM 205	SOUTH BELOIT	IL	61080	301-395-0192	CUSTOMERCARE@TAGIPHARMA.COM
TARO PHARMACEUTICALS U.S.A.	FIVE SKYLINE DRIVE		HAWTHORNE	NY	10532	800-544-1449	NICOLE.CAMELI@TARO.COM
TEVA	1090 HORSHAM ROAD	P.O.BOX 1090	NORTH WALES	PA	19451090	888-838-2872	TEVACS@TEVAPHARM.COM

TEVA C2	1090 HORSHAM ROAD	P.O. BOX 1090	NORTH WALES	PA	19451090		TEVACS@TEVAPHARM.COM
TEVA PHARMA INC C2	605 TRI-STATE PARKWAY		GURNEE	IL	60031		
TEVA PHARMACEUTICAL USA INC C2	111 NEW BRITAIN BLVD		CHALFONT	PA	18914		TEVACS@TEVAPHARM.COM
TIME-CAP LABS, INC.	7 MICHAEL AVENUE		FARMINGDALE	NY	11735	631-753-9090	MDELAROSA@TIMECAPLABS.COM
TOLMAR	701 CENTRE AVE		FORT COLLINS	CO	80526	914-261-8712	TOLMARSMG@TOLMAR.COM
TORRENT PHARMA	150 ALLEN ROAD	SUITE 102	BASKING RIDGE	NJ	07920	269-544-2299	CUSTOMERSERVICE@TORRENTPHARMA.US
TRIGEN LABORATORIES	400 CROSSING BLVD		BRIDGEWATER	NJ	08807	732-721-0070	ORDERS@TRIGENLAB.COM
TRIGEN LABORATORIES C2	400 CROSSING BLVD		BRIDGEWATER	NJ	08807	732-721-0070	ORDERS@TRIGENLAB.COM
TRIS PHARMA	1033 ROUTE 130	SUITE D	MONMOUTH JUNCTION	NJ	08085	732-940-2800	CUSTOMERSERVICE@TRISPHARMA.COM
TRIS PHARMA C2 NEW	RX CROSSROADS 3PL LLC	4200 BINION WAY STE 200	MASON	OH	45036		CUSTOMERSERVICE@TRISPHARMA.COM
TRUPHARMA	190 N MILWAUKEE STREET		MILWAUKEE	WI	53202		TRUPHARMACS@DLSS.COM
TWI PHARMACEUTICALS	1105 EAST NORTHFIELD DRIVE	SUITE 400	BROWNSBURG	IN	46112	949-537-8161	CUSTOMERSERVICE@TWIPHARMAUSA.COM
UNICHEM PHARMACEUTICALS	201 WEST PASSAIC STREET	SUITE 301A	ROCHELLE PARK	NJ	07662	800-510-3401	CUSTOMERSERVICE@UNICHEMUSA.COM
UPSHER-SMITH	6701 EVENSTAD DRIVE		MAPLE GROVE	MN	55369	800-654-2299	CUSTOMERSERVICE@UPSHER-SMITH.COM
UPSHER-SMITH C2	6701 EVENSTAD DR N		MAPLE GROVE	MN	55369		CUSTOMERSERVICE@UPSHER-SMITH.COM
VIONA PHARMACEUTICALS INC.	20 COMMERCE DRIVE		CRANFORD	NJ	07016	888-304-5022	VIONACS@EVERSANA.COM
VIRTUS PHARMACEUTICALS	2050 CABOT BLVD WEST	STE 200	LANGHORNE	PA	19047	813-283-1344	VIRTUSCS@EVERSANA.COM
VISTAPHARM INC	630 CENTRAL AVENUE		NEW PROVIDENCE	NJ	07974	877-530-1633	ORDER@VISTAPHARM.COM
VITRUVIAS THERAPEUTICS, INC.	778 N. DEAN ROAD SUITE 600		AUBURN	AL	36830	334-329-5601	HUNTER@VITRUVIAS.COM
WESTMINSTER PHARMACEUTICALS	3810 NORTHDALE BLVD	SUITE 250	TAMPA	FL	33624	844-202-7585	PURCHASEORDERS@WPRX.COM
WILSHIRE PHARMACEUTICALS, INC	6 CONCOURSE PARKWAY	SUITE 1800	ATLANTA	GA	30328		GMB-SPS-WILSHIRE@CORDLOGISTICS.COM
WINTHROP	55 CORPORATE DRIVE		BRIDGEWATER	NJ	08807		USORDERS@SANOFI.COM
WOCKHARDT	20 WATERVIEW BOULEVARD	THIRD FLOOR	PARSIPPANY	NJ	07054	973-257-5960	USCUSTOMERSERVICE@WOCKHARDT.COM
WOCKHARDT C2	1860 OUTER LOOP DR	DOOR 316	LOUISVILLE	KY	40219		USCUSTOMERSERVICE@WOCKHARDT.COM
WOODWARD PHARMA	47220 CARTIER DR.	SUITE A	WIXOM	MI	48393	248-308-1105	CUSTOMERSERVICE@WOODWARDPHARMA.COM
XIROMED, LLC	PO BOX 21112		NEW YORK	NY	10087	888-255-2878	CUSTOMERSERVICE_USA@XIROMED.COM
XTTRIUM LABORATORIES	1200 E. BUSINESS CENTER DR.		MOUNT PROSPECT	IL	60056	800-587-3721	MGUTIERREZ@XTTRIUM.COM
YARAL PHARMA INC	PO BOX 2571		CAROL STREAM	IL	60132		YARALCS@EVERSANA.COM
ZYDUS C2	4580 S MENDENHALL ROAD		MEMPHIS	TN	38141		CUSTOMERSERVICE@ZYDUSUSA.COM
ZYDUS DIRECT	WWW.ZYDUSUSA.COM		PRINCETON	NJ		877-993-8779	CUSTOMERSERVICE@ZYDUSUSA.COM
ZYDUS PHARMACEUTICALS	WWW.ZYDUSUSA.COM		PRINCETON	NJ		877-993-8779	CUSTOMERSERVICE@ZYDUSUSA.COM

4N

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada ☑ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ☑ Ownership Change* ☑ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 01724	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Auburn Pharmaceutical, LLC dba Auburn

Physical Address: 1979 S 4130 West

City: Salt Lake City State: UT Zip: 84104

Mailing Address (if different from physical address): same as above

City: State: Zip:

Telephone: 248-526-3730 Website: auburngenerics.com

Name of Designated Representative (DR): Daniel Hackley

Licensing Company Email: Compliance@auburnpharm.com DR Email: dhackley@auburnpharm.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☑ Pharmacies	☑ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☑ Controlled Substances	☐ Repacker
☑ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others: OTC	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: List Attached

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Top Rx Intermediate, LLC

Corporation/Organization Name: Auburn Pharmaceutical, LLC dba Auburn

Mailing Address: 1744 Rochester Industrial Dr.

City: Rochester Hills State: MI Zip: 48309

Telephone: 248-526-3730 Email: compliance@auburnpharm.com

Contact Person Name: Merideth Leighty

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
NABP Attached MK **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)**				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Auburn Pharmaceutical LLC, dba Auburn

Facility Name

Amber Versosky

Print Name of Authorized Person Submitting Application

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

9/10/2024

Date

Board Use Only	Date Received: 9/11/24	Amount: $1,000 - CK 228734

Suppliers

Vendor	Address1	Address2	City	State	Zipcode	Phone	Email
ACCORD HEALTHCARE INC	1009 SLATER ROAD	SUITE 210 B	DURHAM	NC	27703	919-941-7878	CSACCORD@INTASPHARMA.COM
ACELLA PHARMACEUTICALS	1800 MCFARLAND PARKWAY		ALPHARETTA	GA	30005	578-325-5188	PURCHASEORDERS@ACELLAPHARMA.COM
ACI PHARMACEUTICAL	10100 W. SAMPLE RD	SUITE 406	CORAL SPRINGS	FL		855-419-0397	AFIFA.ANJUM@ACIHEALTHCAREUSA.COM
ADVAGEN PHARMA LTD	666 PLAINBORO ROAD		PLAINSBORO	NJ	08536		ORDERS@ADVAGENPHARMA.COM
AJANTA PHARMACEUTICALS	P.O. BOX 417863		BOSTON	MA	022417863	866-770-3029	AJANTACS@AJANTAPHARMA.COM
ALEMBIC PHARMACEUTICALS	550 HILLS DRIVE	STE 104B	BEDMINSTER	NJ	07921	908-393-9604	CUSTOMEROPS.ALEMBIC@KNIPPER.COM
ALEOR DERMACEUTICALS	ALEOR DERMACEUTICALS	ALEOR LTD PLOT NO.779/P&790/P	VADODARA		391450		SUBHASISH.PATTANAIK@ALEORDERM.COM
ALEXSO INC. CCD	2317 COTNER AVE		LOS ANGELES	CA	90064	310-282-8086	ORDERS@ALEXSO.COM
ALLISON MEDICAL, INC	8091 SHAFFER PARKWAY		LITTLETON	CO	80127	513-235-8832	ORDERS@ALLISONMEDICAL.COM
ALVOGEN	9 CAMPUS DRIVE	3RD FLOOR	PARSIPPANY	NJ	07054	866-770-3024	CUSTOMERSERVICE-US@ALVOGEN.COM
ALVOGEN C2	UPS SUPPLY CHAIN SOLUTIONS INC	1860 OUTER LOOP	LOUISVILLE	KY	40219		CUSTOMERSERVICE-US@ALVOGEN.COM
ALVOGEN CONTROLS	9 CAMPUS DRIVE	3RD FLOOR	PARSIPPANY	NJ	07054	866-770-3024	CUSTOMERSERVICE-US@ALVOGEN.COM
ALVOGEN DIRECT	9 CAMPUS DRIVE	3RD FLOOR	PARSIPPANY	NJ	07054	866-770-3024	CUSTOMERSERVICE-US@ALVOGEN.COM
AMICI PHARMACEUTICALS	425 BROADHOLLOW ROAD	SUITE 315	MELVILLE	NY	11747		CUSTOMERSERVICE@AMICIPHARMA.COM
AMNEAL C2 (ALL OTHERS)	115 CAROL KNICELY DRIVE		GLASGOW	KY	42141		CUSTOMERRESPONSE@AMNEAL.COM
AMNEAL PHARMACEUTICAL LLC	104 HIPPOCRATES WAY	P.O. BOX 601818	CHARLOTTE	NC	28260	866-525-7270	KAREN.PIERCE@AMNEAL.COM
AMRING PHARMACEUTICALS	1235 WESTLAKES DRIVE		BERWYN	PA	19312	610-285-7196	AMRING@ICSCONNECT.COM
ANI PHARMACEUTICALS	210 MAIN STREET WEST	PO BOX 370	BAUDETTE	MN	56623	800-434-1121	CUSTOMERSERVICE@ANIPHARMACEUTICALS.COM
APOTEX C2	4580 S. MENDENHALL ROAD		MEMPHIS	TN	38141		USCUSTOMERSERVICE@APOTEX.COM
APOTEX CORP	2400 N. COMMERCE PKWY	SUITE #400	WESTON	FL	33326	800-706-5575	USCUSTOMERSERVICE@APOTEX.COM
APOTHECARY HERITAGE	3001 HIGHWAY M-20	P.O BOX 57	NEW ERA	MI	49446	812-797-4507	AMBER.MACLEAN@APOTHECARYHERITAGE.COM
ARCHIS PHARMA	15 CORPORATE PLACE S	SUITE 108	PISCATAWAY	NJ	08854		VMLUKOSE@ARCHISPHARMA.COM
ARMAS PHARMACEUTICAL INC	ARMAS PHARMACEUTICAL INC	303 WEST MAIN STREET	SUITE 300	NJ	07728		CUSTOMERSERVICE@ARMASPHARMA.COM
ASCEND C2 / R&S SOLUTIONS LLC	96 AMERICAN DR STE 100A		JACKSON	TN	383010000		SALES@ASCENDLABORATORIES.COM
ASCEND LABORATORIES	180 SUMMIT AVENUE		MONTVALE	NJ	07645	954-410-8426	SALES@ASCENDLABORATORIES.COM
AUBURN FROM RH TO LOGISTICS	1744 ROCHESTER INDUSTRIAL DR		ROCHESTER HILLS	MI	48309		
AUROBINDO PHARMA	6 WHEELING ROAD		DAYTON	NJ	08810	732-839-9400	CUSTOMERSERVICE@AUROBINDOUSA.COM
AUROBINDO PHARMA C2	6 WHEELING ROAD		DAYTON	NJ	08810		CUSTOMERSERVICE@AUROBINDOUSA.COM
AUROHEALTH LLC	6 WHEELING ROAD		DAYTON	NJ	08810	732-230-8225	CUSTOMERSERVICE@AUROHEALTH.COM
AVET PHARMA / HERITAGE	ONE TOWER CENTER BLVD.	SUITE 1700	EAST BRUNSWICK	NJ	08816	904-278-1008	HERITAGECS@EVERSANA.COM
AVONDALE PHARMACEUTICALS CCD	LOACKBOX 28390	28390 NETWORK PLACE	CHICAGO	IL	60673	800-528-3058	DBOLES@AVONDALEPHARM.COM
BAUSCH & LOMB AMERICAS INC.	400 SOMERSET CORPORATE BLVD.		BRIDGEWATER	NJ	08807		OPHTHAPHARMA@BAUSCH.COM
BAUSCH HEALTH COMPANIES INC.	8500 HIDDEN RIVER PARKWAY		TAMPA	FL	33637	800-323-0000	PHARMRX@BAUSCHHEALTH.COM
BAYSHORE PHARMACEUTICALS	788 MORRIS TURNPIK	SUITE 200	SHORT HILLS	NJ	07071	813-630-0127	CUSTOMERSERVICE@BAYSHOREUS.COM
BIOCON PHARMA	485 ROUTE 1 SOUTH	SUITE B 305	ISELIN	NJ	08830		BIOCONCS@ICSCONNECT.COM
BION PHARMA	600 ALEXANDER ROAD	SUITE 2-4B	PRINCETON	NJ	08540	866-519-3955	SALESOPS@BIONPHARMA.COM
BRECKENRIDGE PHARMACEUTICAL	200 CONNELL DR	SUITE 4200	BERKELEY HEIGHTS	NJ	06037	516-594-9747	CUSTOMERSERVICE@BPIRX.COM
CADISTA PHARMACEUTICALS	207 KILEY DR		SAILSBURY	MD	21801	800-619-9364	KATIE.JONES@CADISTA.COM
CAMBER C2 / R&S NORTHEAST LLC	96 AMERICAN DR SUITE 100A		JACKSON	TN	38301		APREZIOSO@CAMBERPHARMA.COM
CAMBER CONSUMER CARE	1035 CENTENNIAL AVENUE		PISCATAWAY	NJ	08854		CUSTOMERSUPPORT@CAMBERCC.COM
CAMBER PHARMACEUTICALS	200 CENTENNIAL AVE		PISCATAWAY	NJ	08854	866-495-1995	CUSTOMERSERVICE@CAMBERPHARMA.COM
CARLSBAD TECH	5922 FARNSWORTH CT		CARLSBAD	CA	92008	760-431-8284	SERVICE@CARLSBADTECH.COM
CARWIN PHARMACEUTICAL ASSOCCCD	1301 HWY 36 STE 12		HAZLET	NJ	07730	844-700-5011	ORDERS@CARWINPHARMA.COM
CELLTRION	1 EVERTRUST PLAZA	SUITE 1207	JERSEY CITY	NJ	07302		XAVIER.YOON@CELLTRIONHC.COM
CHARTWELL RX, LLC	77 BRENNER DRIVE		CONGERS	NY	10920		CS@CHARTWELLPHARMA.COM
CIPLA USA INC.	10 INDEPENDENCE BLVD	SUITE 300	WARREN	NJ	07059		CIPLACS@UPS.COM
CITRON PHARMA	2 TOWER CENTER BOULEVARD	SUITE 101	EAST BRUNSWICK	NJ	08816		DLUSTGARTEN@RISINGPHARMA.COM
COSETTE PHARMACEUTICALS, INC	P.O BOX 7247 STREET		PHILADELPHIA	PA	19170	800-922-1038	CUSTOMERSERVICE@COSETTEPHARMA.COM
CRANBURY C2	2031 U.S. HIGHWAY 130	SUITE F	MONMOUTH JUNCTION	NJ	08852	732-940-2800	CUSTOMERSERVICE@TRISPHARMA.COM
CRANBURY PHARMACEUTICALS	2031 U.S. HIGHWAY 130	SUITE F	MONOUTH JUNCTION	NJ	08852	732-940-2800	CUSTOMERSERVICE@TRISPHARMA.COM
DASH PHARMACEUTICALS LLC	2 PARK WAY		UPPER SAFFLE RIVER	NJ	07458		DASHPHARM@LSLOG.COM
DPT LABORATORIES LTD CCD	DPT LABORATORIES LTD		ISLINGTON	MI	48332		BUTMAT@AUBURNPHARM.COM

DR REDDY C2	DR REDDY	1860 OUTER LOOP ROAD	LOUISVILLE	KY	40219		CHRISTY.GLOVER@DRREDDYS.COM
DR. REDDY	3600 ARCO CORPORATE DRIVE	SUITE 310	CHARLOTTE	NC	28273		CHRISTY.GLOVER@DRREDDYS.COM
E5 PHARMA LLC	225 NE MIZNER BLVD	SUITE 770	BOCA RATON	FL	33432	561-288-4885	CUSTOMERSERVICE@E5PHARMA.COM
EDENBRIDGE PHARMACEUTICALS	300 INTERPACE PARKWAY	SUITE 360	PARSIPPANY	NJ	07054		SALES@EDENBRIDGEPHARMA.COM
ELITE LABORATORIES C2	165 LUDLOW AVENUE		NORTHVALE	NJ	07647		KKIRKOV@ELITEPHARMA.COM
ELITE LABORATORIES INC	165 LUDLOW AVENUE		NORTHVALE	NJ	07647		KKIRKOV@ELITEPHARMA.COM
ENCUBE ETHICALS, INC.	200 MEREDETH DRIVE	SUITE 101A	DURHAM	NC	27713	919-767-3292	USCS@ENCUBEETHICALS.COM
ENDO USA	1400 ATWATER DR		MALVERN	PA	19355		CUSTOMERORDERS@ENDO.COM
ENDO USA C2	1400 ATWATER DR		MALVERN	PA	19355		CUSTOMERORDERS@ENDO.COM
EPIC PHARMA	227-15 N. CONDUIT AVENUE		LAURELTON	NY	11413	718-276-8607	CS@EPIC-PHARMA.COM
EPIC PHARMA C2	227-15 N. CONDUIT AVENUE		LAURELTON	NY	11413	718-276-8607	CS@EPIC-PHARMA.COM
EUGIA	279 PRINCETON-HIGHTSTOWN ROAD		EAST WINDSOR	NJ	08520		JFARIA@EUGIAUS.COM
EVERSANA LIFE SCIENCE SERVICE	4580 S MENDENHALL ROAD		MEMPHIS	TN	38141	386-673-8376	CUSTOMERSERVICE@SOLCOHEALTHCARE.COM
EYWA C2	501 MASON RD. STE. 200		LAVERGNE	TN	37086		VINCE.SUNEJA@EYWAPHARMA.COM
EYWA PHARMA INC.	2 RESEARCH WAY	FLOOR #3	PRINCETON	NJ	08540	609-751-9600	VINCE.SUNEJA@EYWAPHARMA.COM
FIRST AID RESEARCH	284 CARINA DRIVE		JUPITER	FL	33478	516-783-0274	SMOSLER@FIRSTAIDRESEARCH.COM
FOSUN PHARMA USA	104 CARNEGIE CENTER	SUITE 204	PRINCETON	NJ	08540		FOSUNCS@EVERSANA.COM
FOUGERA PHARMACEUTICALS	PO BOX 2006		MELVILLE	NY	11747	800-645-9833	
FPP	FLORIDA PHARMACEUTICAL PRODUCT	STE 160	BOCA RATON	FL	33487	561-609-3400	SJABR@FLPHARMAPRODUCTS.COM
GERICARE PHARMACEUTICALS CO.	1650 63RD STREET		BROOKLYN	NY	11204	718-234-8800	ORDERS@GERICAREPHARM.COM
GLENMARK PHARMACEUTICALS	750 CORPORATE DRIVE		MAHWAH	NJ	07430		CUSTOMERSERVICE@GLENMARKPHARMA.COM
GRANULES PHARMACEUTICALS C2	3701 CONCORDE PARKWAY		CHANTILLY	VA	20151		GMB-SPS-GRANULES@CORDLOGISTICS.COM
GRANULES PHARMACEUTICALS INC	3701 CONCORDE PARKWAY		CHANTILLY	VA	20151		GMB-SPS-GRANULES@CORDLOGISTICS.COM
GREENSTONE	100 ROUTE 206 NORTH		PEAPACK	NJ	07977	315-571-5662	LORI.LAMATTINA@PFIZER.COM
HEPALINK	HEPALINK/TECHDOW USA	SUITE 200	LANGHORNE	PA	190471885		CUSTOMERSERVICE@TECHDOWUSA.COM
HIKMA C2	1809 WILSON ROAD 08-118		COLUMBUS	OH	43228		CSAC.RDG@BOEHRINGER-INGELHEIM.COM
HIKMA C2 (WEST-WARD)	1809 WILSON ROAD 08-118		COLUMBUS	OH	43228	732-542-1191	CTRICINELLI@WEST-WARD.NET
HIKMA PHARMACEUTICALS	465 INDUSTRIAL WAY WEST		EATONTOWN	NJ	07724	732-542-1191	CUSTOMERSERVICE@HIKMA.COM
I3 PHARMACEUTICALS	200 PARK AVE		WARMINSTER	PA	18974		I3PHARMA@LSLOG.COM
INGENUS PHARMACEUTICALS	4190 MILLENIA BOULEVARD		ORLANDO	FL	32839	866-321-5031	CUSTOMERSERVICE@INGENUS.COM
KEYSOURCE CCD	7820 PALACE DRIVE		CINCINNATI	OH	45249	800-842-5991	JHOPPE@KEYSOURCE.COM
KREMERS URBAN PHARMACEUTICALS	1101 C AVENUE WEST		SEYMOUR	IN	47274	800-477-7877	CUSTOMERSERVICE@LANNETT.COM
KVK TECH INC	110 TERRY DR	SUITE #200	NEWTOWN	PA	18940	267-269-9048	CUSTOMERSERVICE@KVKTECH.COM
KVK TECH INC C2	110 TERRY	SUITE #200	NEWTOWN	PA	18940		CUSTOMERSERVICE@KVKTECH.COM
LANNETT C2	13200 TOWNSEND ROAD		PHILADELPHIA	PA	19154		CUSTOMERSERVICE@LANNETT.COM
LANNETT COMPANY, INC.	9000 STATE ROAD		PHILADELPHIA	PA	19136	800-325-9994	CUSTOMERSERVICE@LANNETT.COM
LAURUS GENERICS, INC.	400 CONNELL DRIVE	SUITE 5200	BERKELEY HEIGHTS	NJ	07922		STEVEN.SMITH@LAURUSGENERICS.COM
LEADING PHARMA	3 G OAK ROAD		FAIRFIELD	NJ	07004	201-746-9152	ORDERS@LEADINGPHARMA.COM
LEADING PHARMA CONTROLS	3 G OAK ROAD		FAIRFIELD	NJ	07004	201-746-9170	ORDERS@LEADINGPHARMA.COM
LIFESTAR PHARMA LLC	1200 MACARTHUR BLVD		MAHWAH	NJ	07430	551-236-5703	CUSTOMERSERVICE@MANKINDPHARMA.COM
LUPIN C2 / UPS SUPPY CHAIN SOL	1860 OUTER LOOP ROAD		LOUISVILLE	KY	40218		CUSTOMERSERVICE-LPI@LUPIN.COM
LUPIN DIRECT	111 SOUTH CALVERT STREET		BALTIMORE	MD	21202	866-587-4617	CUSTOMERSERVICE-LPI@LUPIN.COM
LUPIN PHARMACEUTICALS, INC	111 SOUTH CALVERT STREET		BALTIMORE	MD	21202	866-587-4617	CUSTOMERSERVICE-LPI@LUPIN.COM
MACLEODS	103 COLLEGE ROAD EAST	2ND FLOOR	PRINCETON	NJ	08540	888-441-0911	MACLEODS@LSLOG.COM
MAJOR PHARMACEUTICAL	31778 ENTERPRISE DRIVE		LIVONIA	MI	48150	734-743-6492	MAJOR-ORDERS@MAJOR-PHARM.COM
MAYNE PHARMA	ONE RENAISSANCE CENTRE 3301	BENSON DRIVE, SUITE 401	RALEIGH	NC	27609	800-344-8661	US.CUSTOMERSERVICE@MAYNEPHARMA.COM
MEGALITH PHARMACEUTICALS	PO BOX 21549		NEW YORK	NY	10087	609-356-0210	JOSEPH.DOMBROWSKI@MEGALITHPHARMA.COM
METHOD PHARMACEUTICALS	419 BANK ST.	STE. 100	SOUTHLAKE	TX	76092		ORDERS@METHODPHARM.COM
MICRO LABS USA	220 DAVIDSON AVENUE	SUITE 402	SOMERSET	NJ	08873		CUSTOMERSERVICE@MICROLABS.IN
MODAVAR PHARMACEUTICALS	1016 16TH STREET, NW	SUITE 602	WASHINGTON	DC	20036		MODAVARCS@EVERSANA.COM
MYLAN PHARMACEUTICALS, INC.	781 CHESTNUT RIDGE ROAD	P.O.BOX 4310	MORGANTOWN	WV	26554	800-848-0460	DANIELLE.ANGOTTI@MYLAN.COM
NATCO PHARMA	300 INTERPACE PARKWAY	BUILDING C100	PARSIPPANY	NJ	07054		NATCOPHARMAUSA@LSLOG.COM
NEPHRON PHARMACEUTICAL CORP	4500 12TH STREET EXTENSION		WEST COLUMBIA	SC	29172	803-569-2842	KDEAVER@NEPHRONPHARM.COM

NIVAGEN PHARMACEUTICALS	3050 FITE CIRCLE	SUITE 208	SACRAMENTO	CA	95827		CUSTSERVICE@NIVAGEN.COM
NORDIC PHARMA INC.	1235 WESTLAKES DRIVE		BERWYN	PA	19312	610-285-7196	NORDICPHARMA@ICSCONNECT.COM
NOSTRUM LABORATORIES INC.	190 N MILWAUKEE ST		MILWAUKEE	WI	53202	773-550-9325	NOSTRUMCS@DDNNET.COM
NOVADOZ PHARMACEUTICALS, LLC	P.O. BOX 21758		NEW YORK	NY	10087	848-200-1909	CUSTOMERSERVICE@NOVADOZPHARMA.COM
NOVITIUM PHARMA LLC	PO BOX 24015		NEWARK	NJ	07101	844-735-0711	GMB-SPS-NOVITIUM@CORDLOGISTICS.COM
NOVUGEN	PO BOX 411389		BOSTON	MA	02241		CUSTOMERSERVICE-US@NOVUGEN.COM
OHM LABORATORIES INC	P.O. BOX 7397		NORTH BRUNSWICK	NJ	08902	609-720-5306	OHMORDERSONLY@SUNPHARMA.COM
OMNIVIUM PHARMA	OMNIVIUM PHARMACEUTICALS	2131 FELVER COURT	SUITE A	NJ	07065	732-382-6085	HB@OMNIVIUMPHARMA.COM
ORYZA PHARMACEUTICALS INC	4117 NW 124TH AVENUE		CORAL SPRINGS	FL	33065		ORYZACS@EVERSANA.COM
OXFORD PHARMACEUTICALS	301 LEAF LAKE PARKWAY		BIRMINGHAM	AL	35211		ORDERS@OXFORD-RX.COM
PADAGIS	1251 LINCOLN ROAD		ALLEGAN	MI	49010	800-775-2054	PADAGISRXORDERS@PADAGIS.COM
PAI	201 DELAWARE STREET		GREENVILLE	SC	29605	800-845-8210	PAICUSTSERV@PAIPHARMA.COM
PAI PHARMA	1700 PERIMETER ROAD		GREENVILLE	SC	29605	800-845-8210	PAICUSTSERV@PAIPHARMA.COM
PAR C2	PAR PHARMACEUTICAL	1910 DANIELSIN PLACE	MEMPHIS	TN	38114		CUSTOMERORDERS@PARPHARM.COM
PAR PHARMACEUTICAL	130 VINTAGE DRIVE		HUNTSVILLE	AL	35811		QUALITESTCUSTOMERSERVICE@QUALITESTRX.COM
PAR PHARMACEUTICAL, INC.	ONE RAM RIDGE ROAD		SPRING VALLEY	NY	10977	800-828-9393	CUSTOMERORDERS@PARPHARM.COM
PAR PHARMACEUTICALS	130 VINTAGE DRIVE		HUNTSVILLE	AL	35811	800-444-4011	QUALITESTCUSTOMERSERVICE@QUALITESTRX.COM
PATHEON CCD	123 AUBURN LANE		ROCHESTER	MI	48309		PATHEON@GOONER.COM
PERRIGO DIRECT	725 HIGHWAY 74 SOUTH		PEACHTREE CITY	GA	30269		PERRIGODIRECTORDERS@PERRIGO.COM
PHARMACEUTICAL ASSOC. INC C2	1700 PERIMETER RD	BLDG A	GREENVILLE	SC	29605		SRESCH@AUBURNPHARM.COM
PRASCO LABORATORIES	6125 COMMERCE COURT		MASON	OH	45040	513-618-3362	J.FOGT@PRASCO.COM
PRECISION DOSE	722 PROGRESSIVE LANE		SOUTH BELOIT	IL	61080		CUSTOMERCARE@PRECISIONDOSE.COM
PURETEK CORPORATION CCD	7900 NELSON ROAD	STE A	PANORAMA CITY	CA	91402	818-837-5880	JSMITH@PURETEKCORP.COM
QUAGEN PHARMACEUTICALS LLC	11 PATTON DRIVE		WEST CALDWELL	NJ	07006	973-449-3443	CUSTOMERSERVICE@QUAGENPHARMA.COM
QUINN PHARMACEUTICALS, LLC	6111 BROKEN SOUND PARKWAY NW	SUITE 160	BOCA RATON	FL	33486	954-755-0502	SJABR@QUINNRX.COM
REAL VALUE DRUGS CCD	5100 COMMERCE PARKWAY		SAN ANTONIO	TX	78218	855-681-7201	BOBBY@REALVALUEPRODUCTS.COM
RHODES C2	4701 INTERNATIONAL BLVD. W		WILSON	NC	27893		ERIC.BASIL@PHARMA.COM
RHODES PHARMACEUTICALS	498 WASHINGTON STREET		COVENTRY	RI	02816	888-827-0616	CUSTOMER.SERVICE@PHARMA.COM
RISING CONTROLS	2 TOWER CENTER BLVD	STE. 1401A	EAST BRUNSWICK	NJ	08816		CUSTOMERSERVICE@RISINGPHARMA.COM
RISING PHARMA HOLDINGS	2 TOWER CENTER BLVD	STE. 1401A	EAST BRUNSWICK	NJ	08816		DLUSTGARTEN@RISINGPHARMA.COM
RITEDOSE	1 TECHNOLOGY CIRCLE		COLUMBIA	SC	29203		CUSTOMERSERVICE@RITEDOSE.COM
RUGBY LABORATORIES	1821 RELIABLE PARKWAY		CHICAGO	IL	60686	734-743-6492	MAJOR-ORDERS@MAJOR-PHARM.COM
SANDOZ	2555 W. MIDWAY BLVD	PO BOX 446	BROOMFIELD	CO	800380446	800-525-8747	RUTH.GOLDSTEIN@SANDOZ.COM
SANDOZ C2/ EXEL INC	DBA DHL SUPPLY CHAIN (USA)	260 SALEM CHURCH ROAD	MECHANICSBURG	PA	17050		MDAGOSTINI@AUBURNPHARM.COM
SANDOZ DIRECT	2555 W. MIDWAY BLVD	PO BOX 446	BROOMFIELD	CO	800380446	800-525-8747	RUTH.GOLDSTEIN@SANDOZ.COM
SCIEGEN PHARMACEUTICALS, INC.	7 OSER AVE		HAUPPAUGE	NY	11788	610-940-1066	CUSTOMERSERVICE@SCIEGENPHARM.COM
SIGMAPHARM LABS	3375 PROGRESSIVE DRIVE		BENSALEM	PA	19020	215-352-6655	SIGMAPHARMCS@EVERSANA.COM
SIMPLE DIAGNOSTICS	52-08 GRAND AVE		MASPETH	NY	11378	954-675-1275	ORDERS@SIMPLEDIAGNOSTICS.COM
SOLA PHARACEUTICALS LLC CCD	655 HIGHLANDIA DRIVE	STE B	BATON ROUGE	LA	70810	866-747-7365	ORDERS@SOLAMEDS.US
SOLARIS PHARMA	305 TECH PARK DRIVE	SUITE 113	LAVERGNE	TN	37086		RMATTISON@SOLARIS-PHARMA.COM
SOLCO HEALTHCARE	700 ATRIUM DRIVE	SUITE A	SOMERSET	NJ	08873	386-673-8376	CUSTOMERSERVICE@SOLCOHEALTHCARE.COM
SOMERSET PHARMA LLC	300 FRANKLIN SQUARE DR.		SOMERSET	NJ	08873		CUSTOMERSERVICE@SOMERSETPHARMA.COM
SPEC GX LLC (MALLINCKRODT)	385 MARSHALL AVE		WEBSTER GROVES	MO	63119	651-454-2736	DPHARMA@MNK.COM
SPEC GX LLC C2	172 RAILROAD AVENUE	PO BOX P	HOBART	NY	13788		DPHARMA@COVIDIEN.COM
SPYKA WHOLESALE INC CCD	118 ADAMS STREET	STE 305	FAIRMONT	WV	26554	866-834-2496	SALES@SPYKAWHOLESALE.COM
STRIDES PHARMA	201 SOUTH MAIN STREET	SUITE 3	LAMBERTVILLE	NJ	08530	855-273-0146	STRIDESCUSTOMERSERVICE@STRIDESUSA.COM
SUN C2 / TARO PHARMACEUTICALS	1 COMMERCE DRIVE		CRANBURY	NJ	08512		ORDERS@SUNPHARMAUSA.COM
SUN PHARMACEUTICAL	P.O. BOX 77300		DETROIT	MI	48277	313-871-8400	ALYSON.WEISS@SUNPHARMA.COM
SUNRISE PHARMACEUTICAL	665 E LINCOLN AVE		RAHWAY	NJ	07065	248-308-1105	CUSTOMERSERVICE@WOODWARDPHARMA.COM
SUNRISE PHARMACEUTICAL C2	665 E LINCOLN AVE		RAHWAY	NJ	07065	248-308-1105	CUSTOMERSERVICE@WOODWARDPHARMA.COM
TAGI PHARMA INC	722 PROGESSIVE LANE	ROOM 205	SOUTH BELOIT	IL	61080	301-395-0192	CUSTOMERCARE@TAGIPHARMA.COM
TARO PHARMACEUTICALS U.S.A.	FIVE SKYLINE DRIVE		HAWTHORNE	NY	10532	800-544-1449	NICOLE.CAMELI@TARO.COM
TEVA	1090 HORSHAM ROAD	P.O.BOX 1090	NORTH WALES	PA	19451090	888-838-2872	TEVACS@TEVAPHARM.COM

TEVA C2	1090 HORSHAM ROAD	P.O. BOX 1090	NORTH WALES	PA	19451090		TEVACS@TEVAPHARM.COM
TEVA PHARMA INC C2	605 TRI-STATE PARKWAY		GURNEE	IL	60031		
TEVA PHARMACEUTICAL USA INC C2	111 NEW BRITAIN BLVD		CHALFONT	PA	18914		TEVACS@TEVAPHARM.COM
TIME-CAP LABS, INC.	7 MICHAEL AVENUE		FARMINGDALE	NY	11735	631-753-9090	MDELAROSA@TIMECAPLABS.COM
TOLMAR	701 CENTRE AVE		FORT COLLINS	CO	80526	914-261-8712	TOLMARSMG@TOLMAR.COM
TORRENT PHARMA	150 ALLEN ROAD	SUITE 102	BASKING RIDGE	NJ	07920	269-544-2299	CUSTOMERSERVICE@TORRENTPHARMA.US
TRIGEN LABORATORIES	400 CROSSING BLVD		BRIDGEWATER	NJ	08807	732-721-0070	ORDERS@TRIGENLAB.COM
TRIGEN LABORATORIES C2	400 CROSSING BLVD		BRIDGEWATER	NJ	08807	732-721-0070	ORDERS@TRIGENLAB.COM
TRIS PHARMA	1033 ROUTE 130	SUITE D	MONMOUTH JUNCTION	NJ	08085	732-940-2800	CUSTOMERSERVICE@TRISPHARMA.COM
TRIS PHARMA C2 NEW	RX CROSSROADS 3PL LLC	4200 BINION WAY STE 200	MASON	OH	45036		CUSTOMERSERVICE@TRISPHARMA.COM
TRUPHARMA	190 N MILWAUKEE STREET		MILWAUKEE	WI	53202		TRUPHARMACS@DLSS.COM
TWI PHARMACEUTICALS	1105 EAST NORTHFIELD DRIVE	SUITE 400	BROWNSBURG	IN	46112	949-537-8161	CUSTOMERSERVICE@TWIPHARMAUSA.COM
UNICHEM PHARMACEUTICALS	201 WEST PASSAIC STREET	SUITE 301A	ROCHELLE PARK	NJ	07662	800-510-3401	CUSTOMERSERVICE@UNICHEMUSA.COM
UPSHER-SMITH	6701 EVENSTAD DRIVE		MAPLE GROVE	MN	55369	800-654-2299	CUSTOMERSERVICE@UPSHER-SMITH.COM
UPSHER-SMITH C2	6701 EVENSTAD DR N		MAPLE GROVE	MN	55369		CUSTOMERSERVICE@UPSHER-SMITH.COM
VIONA PHARMACEUTICALS INC.	20 COMMERCE DRIVE		CRANFORD	NJ	07016	888-304-5022	VIONACS@EVERSANA.COM
VIRTUS PHARMACEUTICALS	2050 CABOT BLVD WEST	STE 200	LANGHORNE	PA	19047	813-283-1344	VIRTUSCS@EVERSANA.COM
VISTAPHARM INC	630 CENTRAL AVENUE		NEW PROVIDENCE	NJ	07974	877-530-1633	ORDER@VISTAPHARM.COM
VITRUVIAS THERAPEUTICS, INC.	778 N. DEAN ROAD SUITE 600		AUBURN	AL	36830	334-329-5601	HUNTER@VITRUVIAS.COM
WESTMINSTER PHARMACEUTICALS	3810 NORTHDALE BLVD	SUITE 250	TAMPA	FL	33624	844-202-7585	PURCHASEORDERS@WPRX.COM
WILSHIRE PHARMACEUTICALS, INC	6 CONCOURSE PARKWAY	SUITE 1800	ATLANTA	GA	30328		GMB-SPS-WILSHIRE@CORDLOGISTICS.COM
WINTHROP	55 CORPORATE DRIVE		BRIDGEWATER	NJ	08807		USORDERS@SANOFI.COM
WOCKHARDT	20 WATERVIEW BOULEVARD	THIRD FLOOR	PARSIPPANY	NJ	07054	973-257-5960	USCUSTOMERSERVICE@WOCKHARDT.COM
WOCKHARDT C2	1860 OUTER LOOP DR	DOOR 316	LOUISVILLE	KY	40219		USCUSTOMERSERVICE@WOCKHARDT.COM
WOODWARD PHARMA	47220 CARTIER DR.	SUITE A	WIXOM	MI	48393	248-308-1105	CUSTOMERSERVICE@WOODWARDPHARMA.COM
XIROMED, LLC	PO BOX 21112		NEW YORK	NY	10087	888-255-2878	CUSTOMERSERVICE_USA@XIROMED.COM
XTTRIUM LABORATORIES	1200 E. BUSINESS CENTER DR.		MOUNT PROSPECT	IL	60056	800-587-3721	MGUTIERREZ@XTTRIUM.COM
YARAL PHARMA INC	PO BOX 2571		CAROL STREAM	IL	60132		YARALCS@EVERSANA.COM
ZYDUS C2	4580 S MENDENHALL ROAD		MEMPHIS	TN	38141		CUSTOMERSERVICE@ZYDUSUSA.COM
ZYDUS DIRECT	WWW.ZYDUSUSA.COM		PRINCETON	NJ		877-993-8779	CUSTOMERSERVICE@ZYDUSUSA.COM
ZYDUS PHARMACEUTICALS	WWW.ZYDUSUSA.COM		PRINCETON	NJ		877-993-8779	CUSTOMERSERVICE@ZYDUSUSA.COM

NABP ACCREDITED

DRUG DISTRIBUTOR

Auburn Pharmaceutical Company

located at

1979 South 4130 West, Salt Lake City, UT 84104

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

07/05/2023 - 07/04/2026

Period of Accreditation

0562

AUBURN
PHARMACEUTICAL

To Whom it May Concern:

Auburn Pharmaceutical LLC, dba Auburn

Officers

- Scott Franklin, CEO
- Amber Versosky, COO
- Elaine McNutt, VP

Ownership

- Top Rx Intermediate, LLC (100% Owning Entity)

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "AUBURN PHARMACEUTICAL, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINETEENTH DAY OF SEPTEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "AUBURN PHARMACEUTICAL, LLC" WAS FORMED ON THE TWENTY-SECOND DAY OF JULY, A.D. 2024.



Jeffrey W. Bullock, Secretary of State

4353102 8300

SR# 20243735709

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204439500

Date: 09-19-24

Utah Department of Commerce
Division of Corporations & Commercial Code
160 East 300 South, 2nd Floor, PO Box 146705
Salt Lake City, UT 84114-6705
Service Center: (801) 530-4849
Toll Free: (877) 526-3994 Utah Residents
Fax: (801) 530-6438
Web Site: http://www.commerce.utah.gov

09/10/2024
7832737-016109102024-3585424

CERTIFICATE OF EXISTENCE

Registration Number:	7832737-0161
Business Name:	AUBURN PHARMACEUTICAL, LLC
Registered Date:	November 15, 2010
Entity Type:	LLC - Foreign
Status:	Current

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

Adam Watson

Adam Watson
Director
Division of Corporations and Commercial Code

Power of Attorney

(Name of registrant):	Auburn Pharmaceutical Company
(Address of registrant):	1979 S 4130 W. Salt Lake City, UT 84104
(Utah registration numbers):	7875180-1710 (Wholesaler) 7875180-8913 (Distributor Controlled Substances)

I, Jeffrey Farber, who am authorized to sign on behalf of the above-named registrant under the above-referenced registration numbers, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint, Auburn Pharmaceutical LLC, doing business as Auburn, my true and lawful attorney for me in my name, place, and stead, to utilize the above-referenced registrations and to execute such registrations, renewals, cancellations, assignments, licenses, recording of changes of name and/or address and revisions with respect to the above-referenced registrations. I hereby ratify and confirm all that said attorney must lawfully do or cause to be done by virtue hereof.

Auburn Pharmaceutical Company:

By: _____
Name: Jeffrey Farber
Its: President

Acknowledged by:

I, Amber Versosky, hereby affirm that I am authorized to execute instruments on behalf of Auburn Pharmaceutical LLC, doing business as Auburn, named herein as an attorney-in-fact, and that the signature affixed below is my signature.

Auburn Pharmaceutical LLC:

By: _____
Name: Amber Versosky
Its: President

Signed and dated on September 9, 2024.

STATE OF UTAH
DEPARTMENT OF COMMERCE
ACTIVE LICENSE

Auburn Pharmaceutical Company

EFFECTIVE
03/03/2011

EXPIRATION
09/30/2025

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

7875180-1710	Pharmacy - Class C
7875180-8913 License	Dispensing Controlled Substance
Wholesaler Distributor	

DBA: None Associated

IMPORTANT LICENSURE REMINDERS:

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

AUBURN PHARMACEUTICAL COMPANY
1979 S 4130 W
SALT LAKE CITY UT 84104

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

STATE OF UTAH
DEPARTMENT OF COMMERCE

DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING

ACTIVE LICENSE

EFFECTIVE DATE: **03/03/2011**

EXPIRATION DATE: **09/30/2025**

ISSUED TO: **Auburn Pharmaceutical Company**
1979 S 4130 W
SALT LAKE CITY UT 84104

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

7875180-1710	**Pharmacy - Class C**
7875180-8913	**Dispensing Controlled Substance License**
	Wholesaler Distributor

DBAs: None Associated

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RA0411328	06-30-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	05-23-2024

AUBURN PHARMACEUTICAL COMPANY
DANIEL HACKLEY, WAREHOUSE MANAGER
1979 SOUTH 4130 WEST
SALT LAKE CITY, UT 84104

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RA0411328	06-30-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	05-23-2024

AUBURN PHARMACEUTICAL COMPANY
DANIEL HACKLEY, WAREHOUSE MANAGER
1979 SOUTH 4130 WEST
SALT LAKE CITY, UT 84104

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

OLD REPUBLIC SURETY COMPANY
18650 W CORPORATE DRIVE SUITE 10 BROOKFIELD, WI 53045

RENEWAL ADVICE

Bond Number	Effective Date	Expiration Date	Transaction Effective Date	Agency Number
MLI1215310	5/03/2022	5/03/2023	5/03/2022	46-5186

Principal

AUBURN PHARMACEUTICAL CO
2354 BELLINGHAM
TROY, MI 48083

Agency

CONST BONDING SPECIALISTS LLC
29445 BECK RD STE A-209
WIXOM, MI 48393

Obligee

NEVADA STATE BOARD
OF PHARMACY
431 W PLUMB LANE
RENO, NV 89509

Alternate Billing Address

Bond Description	Bond Amount	Current Premium	Commission	Due Company
FINANCIAL GUARANTEE	$100,000	$2,000		

Run Date	Entry Time	Reason	Renewal Premium	Original Date
2/28/2022		RENEWAL	$2,000	5/03/2011

Mkt Rep	Line	Class	SAA Sub	SAA Form	Type Policy	Contract Amount	Cont Type	Tax Location	Fast Bond	Rate Mod	Rate Dep	Co.	Bulk No.	Contract Account	Credit File Number
	24	579	4								999	15			

Undr Wrtg	Collateral File	State	Term	Remarks Left	Remarks Right	Canc	Bill Atty	A/D	Ren By	L/S	Last Premium Endorsement	Initials	Stat	Deductible Amount	Addnl Locations	Type Cvg	Ratable Employees
Y		27	1			Y	N	A	1	S		MKO	A				

Special Remarks

LICENSE #WH00797

Standard Remarks NOTICE: Please Respond to any request printed below to avoid further handling & expense

ORSC 21075(8/2008)

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Auburn Pharmaceutical

Pharmacy/Wholesaler License # (if applicable): WH01724

Physical Address: 1979 S 4130 W

City: Salt Lake City State: UT Zip: 84104

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 801-886-1522 Website: auburngenerics.com

Licensing Company Email: dhackley@auburnpharm.com

Section 2: Personal Information

First: Daniel Middle: Penrod Last: Hackley

Alias(es, nicknames, name changes, etc.): n/a

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

Mailing Address: 1979 S 4130 W

City: Salt Lake City State: UT Zip: 84104

Telephone: 801-886-1522 Email: dhackley@auburnpharm.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Weber State University		08/87 - 06/90	
Address	City	State	Zip
3848 Harrison Blvd	Ogden	UT	84408
Diploma/Degree obtained, if any			
BA - Criminalistics			

School Name		From - To (MM/YY – MM/YY)	
University of Washington		08/84 - 06/85	
Address	City	State	Zip
1410 NE Campus Parkway	Seattle	WA	98195
Diploma/Degree obtained, if any			
General Studies			

School Name		From - To (MM/YY – MM/YY)	
Sentinel High School		08/80 - 06/84	
Address	City	State	Zip
901 South Avenue West	Missoula	MT	59801
Diploma/Degree obtained, if any			
Diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/10 - Present	[redacted]	Sandy	UT	84070
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Auburn Pharmaceutical			01/11 - Present	
Business Address		City	State	Zip
1979 S 4130 W		Salt Lake City	UT	84104
Phone	Title		Number of Employed Hours	
801-886-1522	Warehouse Manager		28,475	
Description of Duties				
Oversee the day to day operations of a wholesale pharmaceutical distribution facility including the supervision of 21 team members				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

I, Daniel Hackley, **certify that as the designated representative for**

Auburn Pharmaceutical,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. DH I am at least 21 years of age;
3. DH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Daniel Hackley

Print Name (First, Last)

Daniel Hackley

Original Signature (electronic, copies or stamps not accepted)

9/20/2024

Date

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

Daniel Hackley

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/20/2024

Date

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

State of Utah, ss. County of Salt Lake

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

Original Signature

9/20/2024

Date

Subscribed and Sworn to before me this 20th day of September 2024

Notary Public Signature

MARIA L HOFFMANN
NOTARY PUBLIC • STATE OF UTAH
COMMISSION NO. 734200
COMM. EXP. 11/15/2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Auburn Pharmaceutical LLC, DBA Auburn

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WH01724

Physical Address: 1979 South 4130 West

City: Salt Lake City State: UT Zip: 84104

Mailing Address (if different from physical address):

City: State: TN Zip: 38133

Telephone: 800-222-5609 Website: www.auburngenerics.com

Licensing Company Email:

Section 2: Personal Information

First: Norma Middle: Elaine Last: McNutt

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

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

Mailing Address: [redacted]

City: Memphis State: TN Zip: 38103

Telephone: [redacted] Email: e.mcnutt@toprx.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
University of Phoenix		3/2007 - 10/2008	
Address	**City**	**State**	**Zip**
3641 Central Ave	Memphis	TN	38111
Diploma/Degree obtained, if any			
Bachelor of Science, Business Management			

School Name		From - To (MM/YY – MM/YY)	
Southwest Tennessee Community College		Jan 1976 - Dec 1978	
Address	**City**	**State**	**Zip**
737 Union Ave	Memphis	TN	36103
Diploma/Degree obtained, if any			
Associate of Science Degree, Accounting/Associates of Science Degree, Data Processing Technology			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
-present	[redacted]	Memphis	TN	38103
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Top Rx, LLC			2005-present	
Business Address		**City**	**State**	**Zip**
2950 Brother Blvd		Bartlett	TN	38133
Phone	**Title**			
901-373-9314	VP of Finance			
Description of Duties				
Responsible for all financial, accounting, and payroll operations.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

N/A

Norma Elaine McNutt
Original Signature (electronic, copies or stamps not accepted)

9/3/2024
Date

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

Norma Elaine McNutt

Print Name (First, Last)

Norma Elaine McNutt — 9/3/2024

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

---

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

State of TENNESSEE, ss. County of SHELBY

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

Norma Elaine McNutt — 9/3/2024

Original Signature — **Date**

Subscribed and Sworn to before me this 3RD day of SEPTEMBER 2024

Noah H Gray

Notary Public Signature

NOAH H. GRAY
STATE OF TENNESSEE NOTARY PUBLIC
SHELBY COUNTY
MY COMMISSION EXPIRES 12-2-2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Auburn Pharmaceutical LLC, DBA Auburn

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WH01724

Physical Address: 1979 South 4130 West

City: Salt Lake City State: UT Zip: 84104

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 800-222-5609 Website: www.auburngenerics.com

Licensing Company Email:

Section 2: Personal Information

First: William Middle: Scott Last: Franklin

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

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

Mailing Address: [redacted]

City: Germantown State: TN Zip: 38138

Telephone: [redacted] Email: s.franklin@toprx.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Rhodes College		1990-1994	
Address	City	State	Zip
2000 North Parkway	Memphis	TN	38112
Diploma/Degree obtained, if any			
Bachelor of Arts Biology, Minor in Psychology			

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

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
-present	[redacted]	Germantown	TN	38139
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Top Rx, LLC			1998-present	
Business Address		**City**	**State**	**Zip**
2950 Brother Blvd		Bartlett	TN	38133
Phone	**Title**			
901-441-5059	President			
Description of Duties				
CEO				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

9/3/24
Date

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

William Scott Franklin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/3/24

Date

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

State of TENNESSEE, ss. County of SHELBY

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

Original Signature

9/3/24

Date

Subscribed and Sworn to before me this 3RD day of September 2024

Notary Public Signature

NOAH H. GRAY
STATE OF TENNESSEE NOTARY PUBLIC
SHELBY COUNTY
MY COMMISSION EXPIRES 12-2-2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Auburn Pharmaceutical, LLC dba Auburn

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) WHO1724 (current)

Physical Address 1979 S 4130 West

City Salt Lake City State UT Zip 84104

Mailing Address (if different from physical address) same as above

City State Zip

Telephone 248-526-3730 Website auburngenerics.com

Licensing Company Email Compliance@auburnpharm.com

First Amber Middle Theresa Last Versosky

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

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

Mailing Address [redacted]

City Rochester Hills State MI Zip 48309

Telephone 248-526-3730 Email aversosky@auburnpharm.com

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

1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

School Name			From - To (MM/YY – MM/YY)	
Davenport University			09/2000 – 12/05	
Address		City	State	Zip
27500 Dequindre Rd		Warren	MI	48092
Diploma/Degree obtained, if any				
BBA				

School Name			From - To (MM/YY – MM/YY)	
Clawson High School			09/93	05/97
Address		City	State	Zip
101 John M		Clawson	MI	48017
Diploma/Degree obtained, if any				

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

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

School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2018 – now	[redacted]	West Bloomfield	MI	48323
05/12 – 11/18		West Bloomfield	MI	48322
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Business Name			From - To (MM/YY – MM/YY)
Auburn Pharmaceutical			06/21 – now
Business Address	**City**	**State**	**Zip**
1744 Rochester Industrial Dr	Rochester Hills	MI	48309
Phone	**Title**		
800-222-5609	President		
Description of Duties	Run company/all departments		

Business Name			From - To (MM/YY – MM/YY)
Cardinal Health			08/13 – 06/21
Business Address	**City**	**State**	**Zip**
7000 Cardinal Place	Dublin	OH	43017
Phone	**Title**		
614-757-5000	Director		
Description of Duties	Ran commercial operations for repackaging label		

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Auburn Pharmaceutical, LLC dba Auburn

Facility Name

Amber Versaski

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

8/27/24

Date

Board Use Only	Date Received: _____	Amount: _____

NV

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Amber Versosky

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/27/24

Date

Please have this section completed in the presence of a Notary Public.

State of Michigan, ss. County of Oakland

I, Tina Lynn Howard, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8.27.24

Date

Subscribed and Sworn to before me this 27 day of August, 2024

Notary Public Signature

Tina Lynn Howard
NOTARY PUBLIC - STATE OF MICHIGAN
COUNTY OF MACOMB
My Commission Expires April 8, 2028
Acting in the County of Oakland

(Seal)

First Name	Last Name	Location	Department
Susan	Anderson	Rochester Hills	100
Marcia	Basler	Rochester Hills	100
Delores	Bennett	Rochester Hills	100
Colin	Blatt	Rochester Hills	100
DeShawn	Bogan	Rochester Hills	100
Michelle	Bradley	Rochester Hills	100
Marilyn	Cabigas-Kensora	Rochester Hills	100
Bianca	Caraus	Rochester Hills	100
Ian	Didaleusky	Rochester Hills	100
Sharmaine	Dimayuga	Rochester Hills	100
Lidia	Drasovean	Rochester Hills	100
Cheyenne	Dunlap	Rochester Hills	100
Eric	Ellithorpe	Rochester Hills	100
Hannah	Farris	Rochester Hills	100
Brett	Finlay	Rochester Hills	100
Amanda	Friedlund	Rochester Hills	100
Kenneth	Kukla	Rochester Hills	100
Scott	Lang	Rochester Hills	100
Yang	Lor	Rochester Hills	100
Vanessa	Martinez	Rochester Hills	100
Anna	Marvin	Rochester Hills	100
Bryan	McConner	Rochester Hills	100
Kayla	McLean	Rochester Hills	100
Rade	Mitevski	Rochester Hills	100
Jessica	Moore	Rochester Hills	100
William	Myatt	Rochester Hills	100
Edward	Niedek	Rochester Hills	100
Katherine	Pahal	Rochester Hills	100
Devin	Phillips	Rochester Hills	100
Livia	Popa	Rochester Hills	100
Adriana	Postica	Rochester Hills	100
Deborah	Randall	Rochester Hills	100
Amber	Soldan	Rochester Hills	100
Alexis	Spagnola	Rochester Hills	100
Grace	Stewart	Rochester Hills	100
Lee	Torres	Rochester Hills	100
Michael	Verrelli	Rochester Hills	100
Kyla	Broberg	Salt Lake City	100
Marty	Broberg	Salt Lake City	100
Jonathan	Castillo	Salt Lake City	100
Lourdes	Castro	Salt Lake City	100
Krystal	Criswell	Salt Lake City	100
Jon Paul	Dragos	Salt Lake City	100
Kamryn	Gardner	Salt Lake City	100
Daniel	Hackley	Salt Lake City	100
Lisa	Hall	Salt Lake City	100

Maira	Lopez	Salt Lake City	100
Zackariah	Loveless	Salt Lake City	100
Carmen	Lumbreras	Salt Lake City	100
Madison	Marshall	Salt Lake City	100
Dennis	Moore	Salt Lake City	100
Anna	Musser	Salt Lake City	100
Jaqueline	Perez Loya	Salt Lake City	100
Samantha	Rosas	Salt Lake City	100
Nolvia	Sanchez	Salt Lake City	100
Carol	Schull	Salt Lake City	100
Krista	Sewell	Salt Lake City	100
Tiffany	Warner	Salt Lake City	100
Rebecca	Wayland	Salt Lake City	100
Ashley	Afelt	Salt Lake City	300
Raghad	Batros	Salt Lake City	300
Sherri	Brown	Salt Lake City	300
Robert	Caraway	Rochester Hills	300
Timothy	Casey	Rochester Hills	300
Michael	Clements	Rochester Hills	300
Christine	Clippert	Rochester Hills	300
Rhonda	Doherty	Rochester Hills	300
Dawn Marie	Drehmer	Rochester Hills	300
Mark	Elliott	Rochester Hills	300
Meegen	Elliott	Rochester Hills	300
Karlene	Grifka	Rochester Hills	300
Tahsina	Haque	Rochester Hills	300
James	Hoch	Rochester Hills	300
Tina	Howard	Rochester Hills	300
Merideth	Leighty	Rochester Hills	300
Robert	Meek	Rochester Hills	300
Matthew	Sgriccia	Rochester Hills	300
Andrea	Wolf	Rochester Hills	300
Matthew	Butler	Rochester Hills	400
Lisa	Rossi	Rochester Hills	400
James	Sloat	Rochester Hills	400
Nicole	Wroblewski	Rochester Hills	400
Nacianceno	Danielle	Rochester Hills	400
Javon	Beverly	Rochester Hills	400
Chandra	Britt	Rochester Hills	400
Christopher	Brown	Rochester Hills	400
Bobbie	Bryant	Rochester Hills	400
Lauren	Dimitrievski	Rochester Hills	400
Thomas	Dombrowski	Rochester Hills	400
Kimberly	Fletcher	Rochester Hills	400
Lana	Hanna	Rochester Hills	400
David	Jaramillo	Rochester Hills	400
Karen	King	Rochester Hills	400

Linda	Krcic	Rochester Hills	400
Elizabeth	Nice	Rochester Hills	400
Lindsey	Pacitti	Rochester Hills	400
Nathan	Ray	Rochester Hills	400
Monika	Ribar	Rochester Hills	400
Grant	Roland	Rochester Hills	400
Susan	Ruffino	Rochester Hills	400
Resham	Shah	Rochester Hills	400
Kathy	Spagnola	Rochester Hills	400
Jessica	Walsh	Rochester Hills	400
David	Nacy	Rochester Hills	500
Anthony	Rembao	Rochester Hills	500
Kaja	Clark	Rochester Hills	600
Michael	D'Agostini	Rochester Hills	600
Michael	Larsen	Rochester Hills	600
Christine	Potempa	Rochester Hills	600
Hannah	Quick	Rochester Hills	600
Ronald	Reece	Rochester Hills	600
Amber	Versosky	Rochester Hills	600
Christine	Walker	Rochester Hills	600
Jeffrey	Farber	Rochester Hills	700

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Attached

Original Signature (electronic, copies or stamps not accepted)

9/10/24
Date

AUBURN
PHARMACEUTICAL

Auburn Pharmaceutical Company
Notice of Disciplinary Action

1. California

Auburn Pharmaceutical Company ("Auburn") received a Citation and Fine from the Board of Pharmacy of the State of California for the reason that Auburn shipped a "drug or device that by federal or state law can be lawfully dispensed only on prescription" to a licensed pharmacy Pharmacist in California; however, the pharmacy accepted delivery by a pharmacy technician. The pharmacy had acknowledged and agreed in writing that, in accordance with the policy of Auburn, the delivery could only be signed for by a Licensed Pharmacist. Because the pharmacy violated this policy multiple times, Auburn (although not aware of the violations) received the Citation and Fine.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

COPY

CITATION AND FINE

Citation Number	Name, License No
CI 2020 89407	AUBURN PHARMACEUTICAL COMPANY, OSD 5793

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059.5 subd. (a)	Dangerous drugs and devices may only be ordered by... and shall be delivered to licensed premises and signed for and received by a pharmacist...	$1,500.00

CONDUCT:

Who May Order Dangerous Drugs or Devices: Exceptions; Compliance With Laws of All Involved Jurisdictions: Business and Professions Code 4059.5 section (a), states, except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, or in the case of a reverse distributor a designated representative-reverse distributor, that individual shall sign for and receive the delivery. Auburn Pharmaceutical, OSD5793, located at 1979 South 4130 West, Salt Lake City, Utah 84104 was in violation when dangerous drugs were delivered to a licensed premises which were signed for and received by a pharmacy technician at least 16 times out of 30 deliveries between 9/1/2019 to 9/17/2020, instead of a pharmacist, a violation of pharmacy law.

CITATION ISSUED ON: July 21, 2021 | **TOTAL AMOUNT OF FINE(S): $1,500.00**

PAYMENT OF FINE(S) DUE BY: August 20, 2021

VENDOR NO.: 103955 CHECK NO.: 207744 DATE: 8/04/21
PAYEE: BOARD OF PHARMACY

INVOICE NUMBER	INVOICE DATE	INVOICE AMOUNT	DISCOUNT TAKEN	AMOUNT OF PAYMENT
CI 2020 89407	7/21/21	1,500.00		1,500.00
			CHECK TOTAL:	****1,500.00

CA CITATION -

AUBURN PHARMACEUTICAL

DISBURSEMENT ACCOUNT
1744 Rochester Industrial Dr
Rochester Hills, MI 48309
(248) 526-3700

Huntington Banks of Michigan
56-1512/441

CHECK 207744

DATE 8/04/21 AMOUNT ****1,500.00

PAY ONE THOUSAND FIVE HUNDRED DOLLARS AND NO CENTS

TO THE ORDER OF
BOARD OF PHARMACY
CASHIER
2720 GATEWAY OAKS DR-SUITE 100
SACRAMENTO CA 95833

NON-NEGOTIABLE

NON-NEGOTIABLE COPY

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

August 18, 2021

AUBURN PHARMACEUTICAL COMPANY
ATTN: JEFFREY FABER, PRS
1979 SOUTH 4130 WEST
SALT LAKE CITY, UT 84104

RE: CI 2020 89407
AUBURN PHARMACEUTICAL COMPANY
OSD 5793

This is in response to the administrative fine provided to the board for the above referenced citation. The payment has been received and accepted as satisfactorily resolving the matter.

Please be advised that this citation has become a part of the board's records and constitutes a public record for purposes of disclosure.

If you have any questions regarding this matter, please contact the Enforcement Manager, Susan Cappello at (916) 518-3008.

Sincerely

Julia Ansel
Chief of Enforcement
Board of Pharmacy

Prior Actions

1. Alaska

   On October 2, 2022 a new Facility Manager was appointed for Top Rx, LLC (Alaska License # 191040). The Board received the Change of Facility Manager form on February 6, 2023, 131 days after the change, in violation of 12 AAC 52.635(a). On August 10, 2023, the Alaska Board of Pharmacy issued a Civil Fine to Top Rx, LLC in the amount of $300. Payment of the fine was accepted by the Board, resolving the matter.

THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Commerce, Community, and Economic Development

DIVISION OF CORPORATIONS, BUSINESS, AND PROFESSIONAL LICENSING
Anchorage Office

550 West Seventh Avenue, Suite 1500
Anchorage, AK 99501-3567
Main: 907.269.8160
Toll free fax: 907.269.8156

CERTIFIED# 7019 0140 0001 0060 8896
RETURN RECEIPT REQUESTED

August 24, 2023

Top Rx, LLC
Attn: John Richardson, Director of Compliance
2950 Brother Blvd
Bartlett, TN 38133

RE: Case No. 2023-000288

Mr. Richardson:

This letter shall serve as formal notice to you that the Alaska Board of Pharmacy, during its August 10, 2023 meeting, adopted the Imposition of Civil Fine, presented to the Board by members of the staff from the Division of Corporations, Business and Professional Licensing. A copy of the Imposition of Civil Fine and Order, as adopted, is enclosed.

Please be advised that you were under official investigation by the Alaska Board and this subsequent disciplinary action is reportable to the necessary entities as required by law. You may be required to report this license action and to disclose it when applying for licensure in other states. Should you have any questions regarding this matter, please do not hesitate to contact me at the address and telephone number listed above.

Sincerely,

DocuSigned by:
Erika Prieksat
34F98CE5F1DF46C...

Erika Prieksat,
Chief Investigator

cc: Office of Administrative Hearings
Sylvan Robb, Director CBPL
Glenn Saviers, CBPL Deputy Director
Michael Bowles, Executive Administrator
William "Billy" Homestead, Senior Investigator
Holly Handley, Investigator
Marilyn Zimmerman, Paralegal II
Julienne Kim, Paralegal II
Litigation File 2023-000288 (Original)

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE ALASKA BOARD OF PHARMACY

IMPOSITION OF CIVIL FINE
Case # 2023-000288

I, John Richardson, as an agent for Top Rx, LLC admit and agree the Alaska Board of Pharmacy (Board) has jurisdiction over the subject matter of Out-of-State Wholesale Drug Distributor License No. 191040, and over this Imposition of Civil Fine.

1. On October 02, 2022, we appointed a new Facility Manager in reference to License #191040.
2. On February 06, 2023, the Board received our Change of Facility Manager/ Pharmacist-in-Charge form with the new Facility Manager notification; 131 days after the Facility Manager change occurred.
3. This is a violation of **12 AAC 52.635(a)**.

We admit that as a result of these facts, grounds exist for possible denial of licensure or other disciplinary sanctions of my license pursuant to AS 08.01.75 and 12 AAC 52.635(a). We are agreeing to this Imposition of a Civil Fine of three hundred dollars ($300) in cash, certified check, ~~or money order payable to the "State of Alaska"~~ within ninety (90) days after this Imposition of Civil Fine is accepted by the Board.

We have the right to consult with an attorney, and a right to an administrative hearing on the facts in this case. We understand and agree by voluntarily signing this Imposition of Civil Fine, we are waiving our rights to counsel and to a hearing on this matter.

Agent for Top RX, LLC. (Signature) — Date: 7/26/23

SUBSCRIBED AND SWORN TO before me this 26th day of July, 2023, at BARTLETT, ~~Alaska~~ TENNESSEE

SEAL

Notary Public in and for ~~Alaska~~ TENNESSEE

BH
BH

NOAH H. GRAY
Notary Printed Name
My commission expires: 12-2-2025

NOAH H. GRAY
STATE OF TENNESSEE NOTARY PUBLIC
SHELBY COUNTY
MY COMMISSION EXPIRES 12-2-2025

State of Alaska
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE ALASKA BOARD OF PHARMACY

In the Matter of:)
)
Top RX, LLC.)
)
Respondent)
Case No. 2023-000288

ORDER

The Alaska Board of Pharmacy (Board), having examined the Imposition of Civil Fine, Case No. 2023-000288, regarding License No. #191040, for failure to timely notify the Board of a Facility Manager change, hereby adopts the Imposition of Civil Fine.

The Board has determined this is a technical violation of professional licensing statutes and regulations, therefore this matter can be resolved with a civil fine.

This Imposition of Civil Fine takes effect immediately upon signature of this Order in accordance with the approval of the Board.

DATED this 10th day of August, 2023, at Anchorage, Alaska.

ALASKA BOARD OF PHARMACY

By: Ashley Ackaber
Board Chair

State of Alaska
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

40

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: J M Smith Corporation dba Smith Drug Company

Physical Address: 1104 Jones Road

City: Paragould State: AR Zip: 72450

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: (870) 268-6100 Website: www.smithdrug.com

Name of Designated Representative (DR): Pamela Michele Clements

Licensing Company Email: statelicensing@smithdrug.com DR Email: statelicensing@smithdrug.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others: Prescription, Over the counter, BULK API, Dental, Cosmetics, Injectables, Opthalmic, Topical, etc.	☐ Warehouse
■ Veterinarians		■ Retail pharmacy wholesale distributor
■ Others: Nursing Home		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date 6/27/24

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Novo Nordisk
Address: 800 Scudders Mill Road City: Plaisboro State: NJ Zip: 08536
Name: Lilly and Company
Address: 3613 Knight Arnold Road City: Memphis State: TN Zip: 38118
Name: Bristol M. S/Primary Care Division
Address: 1 Squibb Drive City: New Brunswick State: NJ Zip: 08901
Name: Janssen
Address: 1 Campus Drive City: Somerset State: NJ Zip: 08873

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: South Carolina
Parent Company (if any): N/A
Corporation/Organization Name: J M Smith Corporation
Mailing Address: 1104 Jones Road
City: Paragould, State: AR Zip: 72450
Telephone: (870) 268-6100 Email: statelicensing@smithdrug.com
Contact Person Name: Larry P. Cote

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **ª Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing ª Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

J M Smith Corporation dba Smith Drug Company

Facility Name

Larry P. Cote

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

Date 6/27/24

Board Use Only	Date Received: 6/27/24	Amount: $1000 - ck 6057684

Board of Directors/Corporate Officers – Name, Title, Address

Board of Directors/Corporate Officers					
Full Name	Title	Street Address*	City	State	Zip Code
Paula Harper Bethea	Chair CEO & President	[redacted]	Hilton Head	SC	29926
Robert Wade Lewis	Vice President		Jonesboro	AR	72405
Kyle Patrick Waltz	CFO & Treasurer		Simpsonville	SC	29681
Robert M. Barrett	Secretary		Duncan	SC	29334
Scott Bradley Wilson	Vice President		Franklin	TN	37064
Larry P. Cote	Chief Compliance Officer		Spartanburg	SC	29302
Rogers M. Smith	Vice Chair		Bala Cynwyd	PA	19004
Terry L. Cash	Director		Chesnee	SC	29323
Charles A. Moss Jr.	Director		Raleigh	NC	27606
Billie E. Shelley Jr.	Director		Conway	SC	29526
John A. Bick	Director		New Town	PA	18940

Accredited Drug Distributors

Find an Accredited Drug Distributor

Facility Name

State (All)

Search Reset

Current list of 1 NABP-Accredited Drug Distributors

Accreditation is valid for 3 years

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.

Name	Address	Accreditation Date
J M Smith Corporation dba Smith Drug Company	1104 Jones Rd Paragould, AR 72450	10/10/21

Copyright © 2023 National Association of Boards of Pharmacy® (NABP®).

Contact

Verified 8/17/24 MS

The State of South Carolina

Office of Secretary of State Mark Hammond

Certificate of Existence

I, Mark Hammond, Secretary of State of South Carolina Hereby Certify that:

J M SMITH CORPORATION, a corporation duly organized under the laws of the State of South Carolina on January 24th, 1944, and having a perpetual duration unless otherwise indicated below, has as of the date hereof filed all reports due this office, paid all fees, taxes and penalties owed to the State, that the Secretary of State has not mailed notice to the corporation that it is subject to being dissolved by administrative action pursuant to S.C. Code Ann. §33-14-210, and that the corporation has not filed articles of dissolution as of the date hereof.

Given under my Hand and the Great Seal of the State of South Carolina this 2nd day of April, 2024.

Mark Hammond

Mark Hammond, Secretary of State

Arkansas State Board of Pharmacy

322 South Main Street, Suite 600, Little Rock, Arkansas 72201

2023 - 2024 WHOLESALE DISTRIBUTOR LICENSE

J M Smith Corporation
DBA: Smith Drug Company

located at:

1104 Jones Road, Paragould, AR 72450

License #: WD03067 **Original License Date: 01/25/2005**

This is to certify that the business named above is licensed under the provisions of the Arkansas Pharmacy Practice Act, other Arkansas statutes, and Arkansas Pharmacy Regulations.

License expires: December 31, 2024

This permit is not transferable and must be prominently displayed.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RS0319790	12-31-2024	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	11-03-2023

J M SMITH CORPORATION
DBA SMITH DRUG COMPANY
1104 JONES RD
PARAGOULD, AR 724507579

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RS0319790	12-31-2024	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	11-03-2023

J M SMITH CORPORATION
DBA SMITH DRUG COMPANY
1104 JONES RD
PARAGOULD, AR 724507579

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RS0319790	12-31-2024	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	11-03-2023

J M SMITH CORPORATION
DBA SMITH DRUG COMPANY
1104 JONES RD
PARAGOULD, AR 724507579

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
08/30/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: WTW Certificate Center	
Willis Towers Watson Southeast, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	PHONE (A/C, No, Ext): 1-877-945-7378	FAX (A/C, No): 1-888-467-2378
	E-MAIL ADDRESS: certificates@wtwco.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A: Lloyds Syndicate 3623	C4753
INSURED Smith Drug Company - Arkansas 1104 Jones Road Paragould, AR 72450	INSURER B:	
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** W34591583 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			W2452A240701	09/01/2024	09/01/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$ 1,000,000 $ 500,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ $
	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) $	$ $ $ $ $
	UMBRELLA LIAB OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $						EACH OCCURRENCE AGGREGATE $	$ $ $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N N/A If yes, describe under DESCRIPTION OF OPERATIONS below						PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ $ $

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, NV 89521 United States

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Michael J. Ursin

© 1988-2016 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

SR ID: 26370112 BATCH: 3602201

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. CMS0332704

Application/License No. _____

J M Smith Corporation dba Smith Drug Company (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1104 Jones Road, Paragould, AR 72450 (Address of Applicant/Principal), as PRINCIPAL, and RLI Insurance Company (Surety Company), a corporation organized under the laws of the state of IL (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 9025 N. Lindbergh Drive , Peoria, IL 61615 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 27, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 28th day of June, 2024.

APPLICANT/PRINCIPAL

J M Smith Corporation dba Smith Drug Company

By: _____
Authorized Representative

SURETY COMPANY

RLI Insurance Company

By: _____
Surety Company's Representative

Michelle Anne McMahon, Attorney-in-fact
print name

RLI INSURANCE COMPANY CORPORATE SEAL ILLINOIS

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

_____
Witness Ellis Reid

_____
Witness Stephanie Harvey

Countersigned by:

Not Applicable Per Federal Statute
Nevada Resident Agent

Posted February 20, 2020

POWER OF ATTORNEY

RLI Insurance Company
Contractors Bonding and Insurance Company

9025 N. Lindbergh Dr. Peoria, IL 61615
Phone: 800-645-2402

Know All Men by These Presents:

That this Power of Attorney is not valid or in effect unless attached to the bond which it authorizes executed, but may be detached by the approving officer if desired.

That **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, each an Illinois corporation, (separately and together, the "Company") do hereby make, constitute and appoint:

Joshua Sanford, Michelle Anne McMahon, Samuel Begun, Kathryn Pryor, Gentry Stewart, Jennifer Godere, Jonathan Gleason, Nicholas Miller, Sarah Murtha, Doritza Mojica, Connor Wolpert, Richard Hackner, jointly or severally

in the City of Hartford, State of Connecticut its true and lawful Agent(s) and Attorney(s) in Fact, with full power and authority hereby conferred, to sign, execute, acknowledge and deliver for and on its behalf as Surety, in general, any and all bonds and undertakings in an amount not to exceed **Twenty Five Million** Dollars (**$25,000,000.00**) for any single obligation.

The acknowledgment and execution of such bond by the said Attorney in Fact shall be as binding upon the Company as if such bond had been executed and acknowledged by the regularly elected officers of the Company.

RLI Insurance Company and/or **Contractors Bonding and Insurance Company**, as applicable, have each further certified that the following is a true and exact copy of a Resolution adopted by the Board of Directors of each such corporation, and is now in force, to-wit:

> "All bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, any Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys in Fact or Agents who shall have authority to issue bonds, policies or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile."

IN WITNESS WHEREOF, the **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, as applicable, have caused these presents to be executed by its respective Vice President with its corporate seal affixed this 18th day of September, 2023.

CONTRACTORS BONDING AND INSURANCE COMPANY CORPORATE SEAL ILLINOIS

RLI INSURANCE COMPANY CORPORATE SEAL ILLINOIS

RLI Insurance Company
Contractors Bonding and Insurance Company

By: B. W. D.
Barton W. Davis — Vice President

State of Illinois }
County of Peoria } SS

On this 18th day of September, 2023, before me, a Notary Public, personally appeared Barton W. Davis, who being by me duly sworn, acknowledged that he signed the above Power of Attorney as the aforesaid officer of the **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company** and acknowledged said instrument to be the voluntary act and deed of said corporation.

By: Catherine D. Geiger
Catherine D. Geiger — Notary Public

CATHERINE D. GEIGER
OFFICIAL SEAL
Notary Public - State of Illinois
My Commission Expires
December 05, 2026

CERTIFICATE

I, the undersigned officer of **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, do hereby certify that the attached Power of Attorney is in full force and effect and is irrevocable; and furthermore, that the Resolution of the Company as set forth in the Power of Attorney, is now in force. In testimony whereof, I have hereunto set my hand and the seal of the **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company** this 28th day of June, 2024.

RLI Insurance Company
Contractors Bonding and Insurance Company

By: Jeffrey D Fick
Jeffrey D Fick — Corporate Secretary

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: J M Smith Corporation dba Smith Drug Company — MDEG License # (if applicable): WD03067
Physical Address: 1104 Jones Road
City: Paragould — State: AR — Zip: 72450
Mailing Address (if different from physical address): same as above
City: — State: — Zip:
Telephone: (870) 268-6100 — Website: www.smithdrug.com
Licensing Company Email: statelicensing@smithdrug.com

Section 2: Personal Information

First: Pamela — Middle: Michelle — Last: Clements
Alias(es, nicknames, name changes, etc.): Pam
Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☐ M ☑ F ☐ X
Mailing Address: 1104 Jones Road
City: Paragould — State: AR — Zip: 72450
Telephone: 870-268-6100 — Email: statelicensing@smithdrug.com
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Blytheville High School		08/90 - 03/94	
Address	**City**	**State**	**Zip**
600 N 10th Street	Blytheville	AR	72315
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/19 - Present	[redacted]	Paragould	AR	72450
06/08 - 04/19		Paragould	AR	72450

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Smith Drug Company			09/20-present	
Business Address		**City**	**State**	**Zip**
1104 Jones Road		Paragould	AR	72450
Phone	**Title**		**Number of Employed Hours**	
870-268-6100	General Manager/Director of Operations		2000+	
Description of Duties				
Manager of 78 full & part-time employees, oversees all operations, process improvement, customer service, transportation, receiving, and pick-pack-shipping.				

Business Name			From - To (MM/YY – MM/YY)	
Smith Drug Company			07/16 - 08/20	
Business Address		**City**	**State**	**Zip**
1104 Jones Road		Paragould	AR	72450
Phone	**Title**		**Number of Employed Hours**	
870-268-6100	Senior Manager Reverse Logistics		2000+	
Description of Duties				
Manage all returns in house and outbound to their party processors.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Pamela M Clements

Original Signature (electronic, copies or stamps not accepted)

7/12/2024

Date

I, Pamela Michelle Clements, certify that as the MDEG Administrator for

Smith Drug Company,

that I (initial that you have read and meet the following requirements):

1. PC Have a high school diploma or its equivalent;
2. PC Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. PC Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. PC Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Pamela Clements
Print Name (First, Last)

Pamela M. Clements
Original Signature (electronic, copies or stamps not accepted)

7/12/2024
Date

Board Use Only	Date Received: 7/12/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler J M Smith Corporation dba Smith Drug Company

Pharmacy/Wholesaler License # (if applicable) WD03067

Physical Address 1104 Jones Road

City Paragould State AR Zip 72450

Mailing Address (if different from physical address) same as above

City _____ State _____ Zip _____

Telephone (870) 268-6100 Website www.smithdrug.com

Licensing Company Email statelicensing@smithdrug.com

Section 2: Personal Information

First Pamela Middle Michelle Last Clements

Alias(es, nicknames, name changes, etc.) Pam

Date of Birt[redacted] SSN or ITI[redacted] Sex ☐ M ☒ F ☐ X

Mailing Address 1104 Jones Road

City Paragould State AR Zip 72450

Telephone (870) 268-6100 Email statelicensing@smithdrug.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Blytheville High School		08/90-03/94	
Address	**City**	**State**	**Zip**
600 N 10th Street	Blytheville	AR	72315
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/19 - Present	[redacted]	Paragould	AR	72450
06/08 - 04/19		Paragould	AR	72450
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Smith Drug Company			09/20-present	
Business Address		**City**	**State**	**Zip**
1104 Jones Road		Paragould	AR	72450
Phone	**Title**		**Number of Employed Hours**	
870-268-6100	General Manager/Director of Operations		2000+	
Description of Duties				
Manager of 78 full & part-time employees, oversees all operations, process improvement, customer service, transportation, receiving, and pick-pack-shipping.				

Business Name			From - To (MM/YY – MM/YY)	
Smith Drug Company			07/16 - 08/20	
Business Address		**City**	**State**	**Zip**
1104 Jones Road		Paragould	AR	72450
Phone	**Title**		**Number of Employed Hours**	
870-268-6100	Senior Manager Reverse Logistics		2000+	
Description of Duties				
Manage all returns in house and outbound to their party processors.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Pamela M. Clements
Original Signature (electronic, copies or stamps not accepted)

7/12/2024
Date

I, Pamela Michelle Clements, **certify that as the designated representative for**

Smith Drug Company,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. P.C. I am at least 21 years of age;
3. P.C. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. P.C. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. P.C. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. P.C. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. P.C. I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Pamela Clements

Print Name (First, Last)

Pamela M Clements

Original Signature (electronic, copies or stamps not accepted)

July 12, 2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Pamela Clements

Print Name (First, Last)

Pamela M. Clements

Original Signature (electronic, copies or stamps not accepted)

7/12/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Arkansas, ss. County of Greene

I, Pamela M. Clements, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Pamela M Clements

Original Signature

7-12-2024

Date

Subscribed and Sworn to before me this 12 day of July.

Sheila Overton

Notary Public Signature

SHEILA OVERTON
Notary Public-Arkansas
Greene County
(Seal)
My Commission Expires 06-18-2029
Commission # 12689900

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application
Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: J M Smith Corporation dba Smith Drug Company
Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WD03067
Physical Address: 1104 Jones Road
City: Paragould State: AR Zip: 72450
Mailing Address (if different from physical address): same as above
City: State: Zip:
Telephone: (870) 268-6100 Website: www.smithdrug.com
Licensing Company Email: statelicensing@smithdrug.com

Section 2: Personal Information

First: Pamela Middle: Michelle Last: Clements
Alias(es, nicknames, name changes, etc.): Pam
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex ☐ M ☒ F ☐ X
Mailing Address: 1104 Jones Road
City: Paragould State: AR Zip: 72450
Telephone: 870-268-6100 Email: statelicensing@smithdrug.com
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Blytheville High School		08/90-03/94	
Address	**City**	**State**	**Zip**
600 N 10th Street	Blytheville	AR	
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/19 - Present	[redacted]	Paragould	AR	72450
From - To (MM/YY – MM/YY)		City	State	Zip
06/08 - 04/19		Paragould	AR	72450
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Smith Drug Company			09/20-present	
Business Address		**City**	**State**	**Zip**
1104 Jones Road		Paragould	AR	72450
Phone	**Title**			
870-268-6100	General Manager/Director of Operations			
Description of Duties				
Manager of 78 full & part-time employees, oversees all operations, process improvement, customer service, transportation, receiving, and pick-pack-shipping.				

Business Name			From - To (MM/YY – MM/YY)	
Smith Drug Company			07/16 - 08/20	
Business Address		**City**	**State**	**Zip**
1104 Jones Road		Paragould	AR	72450
Phone	**Title**			
870-268-6100	Senior Manager Reverse Logistics			
Description of Duties				
Manage all returns in house and outbound to their party processors.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Pamela MClements
Original Signature (electronic, copies or stamps not accepted)

7/12/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Pamela Clements

Print Name (First, Last)

Pamela M Clements

Original Signature (electronic, copies or stamps not accepted)

7/12/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Arkansas, ss. County of Greene

I, Pamela M. Clements, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Pamela M Clements

Original Signature

7-12-2024

Date

Subscribed and Sworn to before me this 12 day of July.

Sheila Overton

Notary Public Signature

SHEILA OVERTON
Notary Public-Arkansas
Greene County
My Commission Expires 06-18-2029
Commission # 12609900

(Seal)

J M Smith Corporation dba Smith Drug Company

Employee Name (Last Suffix, First MI)
Clark, Tracey S.
Elston, Edward A.
Miller, Robert C.
Quinn, Ted L.
Shields, Jeffery T.
Waters, Jason C.
Hunt, William C.
Cash, Jonathan A.
Barnette, Sandra F.
Ledbetter, Steven W
Lawson, Sandra M.
Gardner, Mitchell W.
Bagwell, Bradley B.
Gosnell, Karen M.
Steadman, Homer
Mathis, Minnie P.
Lee, Zoua
Burney, Carolyn A.
Nesbitt, Arthur A.
Sam, Robeab
Browning, Marty J.
Clark, Tony
Montgomery, Jennifer L.
Hendley-Murray, Sandra K.
Palmer, Kimberly P.
Luther, Larry S.
Clements, Doreen S.
Toohey, Linda J.
Holbrook, Stephanie Y.
Craft, Julie R.
Thomas, Edith M.
McBride, Edna L.
Lewis, Robert J.
Brown, John T.
Keeler, Blake I.
Robbs, Melissa A.
Douglas V, Clarence A.
Mendez-Cruz, Angie

Sanford, Shaun E.
Sanford, Crystal D.
Bobo, Billy R.
Allen, Vickey P.
Allison, Kathy M.
Ballew, Nancy D.
Bennett, Scott B.
Benson, William D.
Benton, James S.
Burrell, Teresa H.
Blackston, Jennifer C.
Cook, Brandy L.
Copeland, Vanisha Y.
Kimbrell, Alyson L.
Crowder, Dottie H.
Dempsey, Sharon S.
Dillashaw, Tonia
Dittemore, Stacy C.
Edwards Jr., Charles
Fleming-Whisnant, Kim
Foster, Andrea
Franklin, James D.
Gaffney, Donnie W.
Garner, Amy M.
Greer, Johnny
Hamrick, Keith S.
Harris, Brandon E.
Harris, Marty E.
Harrison, James D.
Henderson, Jonathan P.
Hendrix, Kathy
Hurst, Michael P.
Leblanc, Jon A.

Lee, Patricia E.

Lewis, Robert W.

McAbee, Denise P.

McLaughlin, Derek S

Morin, Peter J.

Middlebrooks, Gertrude L.

Clements, Pamela M.

Newham, Glenda K.

Owens, Shannon N.

Purinton, Connie M.

Ragler, Cody

Ramirez, Antonio A.

Riggins, Leonard W.

Stevens, James H.

Thompson, Anthony D.

Tran, Michael

Trotter, Dennis L.

Weeks, Albert L.

Wilson, Brenda J.

Zagotti, Christopher L.

Watson, Pamela W.

Owens, Christopher M.

Bennett, Charles A.

Brown, Tiffany T.

Graziano, Salvatore J.

Ellis, Robert C.

Hunt, Marcus D.

Fowler Jr., Paige W.

Rainey, Angela C.

Hunter, Antonio

Baker, La'rrie A.

Moss, Teresa D.

West III, Lewis M.

Catterton, Lisa A.
Waltz, Kyle P.
Dunn, Ralph M.
Loftis, Elizabeth S.
Rogers, Clint O.
Fritz, Luke M.
King, Kelli
Towery, Melody B.
Beresheim, Eric B.
Bishop, Brian C.
Priester, Richard F.
Kimbrell, Amanda
Gibson Jr., Melvin
Mansfield, Sherrie D.
Westbrook, Daniel P.
McLaughlin, Jada L.
Thompson, Visakha
Semethy Jr., Stephen
Back, Daniel J.
Clark, Sean
Brown, Adam G.
Allison, Julie R.
Hamilton, Christa D.
Smith Jr., David K.
Fuller, Shateria S.
McCain, Cindy S.
Williams, Tyler R.
Xiong, Youa
Wetzel, Jessica
Williams, Robin B.
Barrett, Robert M.
Ownbey, Caren V.
Hall, Chelsea D.

Rollins, Bret D.

Moua, Gae

Moua, Monica

Hall, Tiffany K.

Schneider, Jeffrey L.

Bower, Michael T.

Burnett, David D.

Applegarth, Howard

Kibbe, Steven W.

Anderson, Helene A.

Owens, Christopher J.

Taylor, Shaenna H.

Acevedo, Angel A.

Martin, Cynthia K.

McCraw, Judson R.

Britton, Dustin W.

Taylor, Steffen L.

Woomer, Barrett A.

Meinerding, Lisa C.

Campbell, Robert M.

Williams, Jill E.

Friar, Kody D.

Frazier, Jamie L.

Myers, Rose M.

Wheeler, Diana L.

Trimble, Carl W.

Makeever, Jillian M.

Conley, Yolaine J.

Mullholand, Tyler D.

Oswald, Raymond P.

Bilger, Roy L.

Bouaphanh, Tiffany P.

Robertson, Simpson L.

Sizemore, Judson P.
Hoepf, Sarah E.
Payne, Lucrezia C.
Gill, Ashley N.
Peck, Karen S.
Edwards, Teresa A.
Bethea, Paula H.
Overton, Sheila G.
Burger, Jennifer D.
Gramling, Sherrie L.
Blanton, Pamela C.
Davis, Erica N.
Groff, Stephen H.
Johnson, Paula L.
Whitt, Nathan M.
Suber, Lois J.
Frey, Brenda S.
Long, Brigitte M.
Provost, Tod A.
Stirling, Geoffrey E.
Parsell, Matthew A.
Dennis, Sonya M.
Riddle, Phyllis M.
Bishop, Ashley D.
Cromer, Tessa M.
McCormick, Clayton A.
Helms, James R.
Hollis, Caleb D.
Cox, Pamela J.
Dillard, Jordy W.
Her, Vicky P.
Louis, Zachary H.
Dankert, Denise M.

Bishop, Jerry K.

Mack, Gloria A.

Cheek, Jody E.

Denning, Blake A.

Dowbak, Helen B.

Corley, Crystal S.

Xiong, Tang C.

Lake, Mark J.

Ascolese, Robert J.

Waddell Jr., Jason W.

Greenidge, Paula D.

Emory, Crystal A.

Freeman Jr., David A.

Reini, Cole R.

Ryan, Wayne J.

Branscum Jr., Curtis L.

Jones, Tracy L.

Jones, Nathan C.

Lee, Kaoyong

Wilson, Scott B.

Havens, John M.

Hill, Danny J.

Austen, Thomas M.

Pritchard, Ian T.

Jamison, Kaitlyn A.

Jamison, Julie K.

Byrd, Nicholas R.

Curtwright, Richard G.

BongYang, Khambang

Collins, Pamela M.

Smith, Daniel K.

Gregory, Cody B.

Aguayo, Stephanie

Mooneyham, Jessica C.
Wiseman, Adam W.
Rains, Victoria A.
Dorn, Hannah G.
Russell, Marita L.
Sorensen, Sharron
Hullett, Sharon G.
Diaz-Casasola, Anthony
Bryant, Misty L.
Vincent, Mason L.
Carlin, Tammy J.
Draper, Michelle L.
Durrell, Justin A.
Aquino, Valerie B.
Thompson, Robert D.
Hernandez, Julia M.
Bryant, Rachel N.
Hall, Lakisha D.
Pfeifer, Chrystal L.
Crosby Jr., Bobby G.
Jaques, Dylan J.
Hampton, Sandra K.
Garren, Karen K.
Holden, Daniel C.
Farley, Patrick L.
Morris, Byron J.
Yunitskaya, Aryna
Grooms, Patricia D.
Kim, Boranya E.
Kim, Bometta E.
Mack, Ashlie L.
Dominguez, Yvonne M.
Snyder, Cheyenne N.

Kimbrell, Billy B.

Yang, Mendie

Brewer, Jonathan L.

Wehner, Lois J.

Owens, Matthew P.

Yang, Carson C.

Milligan, Maizy J.

Sam, Pangnha S.

Cote, Larry P.

Quiroz, Grethel A.

Enloe, Heather

Miles, William

Laws, Samuel L.

Rogers, Seth A.

Brown, David B.

Bagley, Bryan E.

George, Tonya G.

Geddings, Cherrie A

Dement, Gracie L.

Owens, Tyler K.

Hull, Joseph R.

McGarity, Katina D.

Diaz-Casasola, Guillermo

Smiddy, Jamie M.

Holbert, Lecretia E.

Pless, Ashton F.

Egger, Devin G.

Ekleberry, Tenneil M.

Gramling, Skyler G.

Gragan, Michele L.

Her, Tim

Dorn, Lucas

Dunn, Alexus D.

Rarrat, Michael J.
Mince, Sylvia L.
Miller, Steven P.
Diven, Zachary G.
Helm, Matthew T.
Rima, Donald
Garrett, Tina N.
Reyes-Chavez, Belen A.
Pillow, Lesley A.
Finney, Joshua S.
Green, Alexander W
Rollings, Cole L.
Holden, Jason M.
Younger, Brodie A.
Caltabiano, Tracy A.
Navarro, Aaron D.
Flavell, Brian J.
Tellez, Brenda L.
Vega, Alexander
Pryor, Lynne B.
Sanchez, Yasaira
Maravilla, Cruz D.
Sica-Hernandez, Edbin K.
Shill, Melissa K.
Catoe, Caroline M.
Whiting, Samuel J.
Goodman, Conner A.
Spangler, Dustin L.
Polley, Jody L.
Kundert, Lauren E.
Hobson, Ethan L.
Cocherell, Michael J.
Jackson, Judy A.

Garcia, Joseph D.

Lanier, Gus M.

Doke, Cole W.

Turner, Michelle L.

Gast, Joseph R.

Pollard, Chase D.

Clark, Carson A.

Holmes, Monique D.

Micheli, Michele A.

Kane, Robert J.

Murphy, Dillon K.

Meade, Darren G.

Sayre, Gabriel D.

Bora, John E.

VeStrand, Christie A.

Mancini, Christopher R.

Rennell, Aaron B.

Peet, Robert S.

Mummert, Jonathan A.

Monahan, Lisa S.

McKenzie, Joan A.

Lambert, Andreas J.

Kane, Daniel M.

Deavitt, Kathy R.

Cunningham, James P.

Bessette, Dale R.

Ashline II, Randall J.

Prizio, Patrick J.

Murray, Priscilla L.

Santoro, Michael

Parah, Charles A.

Mosher, Timothy R.

Austin, Kevin S.

Orr, Christine A.

Tobin, Andrew M.

Machia, Hannah M.

Glover, Lisa L.

Norton, Christopher J.

Brown, Krystopher P.

Cullen, Andrew J.

Huynh, Hoang L.

Geller, Bruce A.

Root-Mixon, Jami-Lyn M.

Daoust, Charles W.

Bourne, Davilyn M.

Garrison, Kendra B.

Aldrich, Noah J.

Hatseliuk, Valentyna

Clark, Tyler A.

Koslowski, Colton A.

Southworth, Ryan D.

Schafer, Isabelle K.

Miner, Christian K.

Farek, Rhiannon N.

Ferdinand, Jean Nixon

Harlow III, Roswell L.

Doyle, Timothy B.

Boucher Jr., David A.

4P

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: 3B Medical, Inc.

Physical Address: 5101 Fruitville Rd. Suite 200

City: Sarasota State: FL Zip: 34232

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (863) 226-6285 Website: https://www.reacthealth.com/

Name of Designated Representative (DR): Noah Chitwood

Licensing Company Email: noah.chitwood@reacthealth.com DR Email: noah.chitwood@reacthealth.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies ■ Practitioners ■ Hospitals ■ Wholesalers ☐ Veterinarians ☐ Others:	☐ Dangerous Drugs ☐ Controlled Substances ■ *Medical devices, equipment, supplies, gases ☐ Others:	■ Manufacturer ☐ Repacker ☐ Reverse Distributor ☐ Warehouse ☐ Retail pharmacy wholesale distributor ☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

January 29 2024
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: SysMed Co., Ltd.
Address: Bldg. 11-2-3 No. 17 Wensu St., Hunnan District City: Shenyang City, Liaoning, China State: Zip: 110179
Name: BMC Medical Co., Ltd.
Address: 5F, Main Bldg. No. 19 Gucheng St. West City: Shijingshan District, Beijing State: Zip: 100043
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida
Parent Company (if any): React Health Holdings, LLC
Corporation/Organization Name: 3B Medical, Inc.
Mailing Address: 5101 Fruitville Rd. Suite 200
City: Sarasota State: FL Zip: 34232
Telephone: (863) 226-6285 Email: Tom.Pontzius@reacthealth.com
Contact Person Name: Tom Pontzius

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

3B Medical, Inc.

Facility Name

Tom Pontzius

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

January 29, 2024

Date

Board Use Only	Date Received: 1/30/24	Amount: $1000-cc

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
3B Medical Inc
5101 Fruitville Road
Suite 200
Sarasota, FL 34232
Registration Number: 3009096682
FEI Number*: 3009096682
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types. Please Review Listings For Further Information.
Date Of Registration Status: 2024

Owner/Operator:
React Health[6]
5101 Fruitville Road
Suite 200
Sarasota, FL US 34232
Owner/Operator Number: 10040143[7]

Official Correspondent:
Chuck Underwood
React Health
5101 Fruitville Road
Suite 200
Sarasota, FL 34232
Phone: 863-2266285

Verified MH 2/6/24

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10040143&OwnerOperatc
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10040143&OwnerOperatc

Page Last Updated: 01/08/2024

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsc | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of Health & Human Services

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases

6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?
start_search=1&establishmentName=@Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10040143&OwnerOperatc
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?
start_search=1&establishmentName=@Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10040143&OwnerOperatc

3B Medical, Inc. d/b/a React Health

Officers:

1. John J. Fiedor : CFO and Secretary
[redacted]

2. Paul Kim: Chief Legal Officer
[redacted]

Directors:

1. Inna Etinberg: [redacted]
2. Richardson M. Roberts: [redacted]
3. Robert Emmet Seibels, IV: [redacted]
4. Luke McGee: [redacted]
5. Sean Heyniger: [redacted]
6. Alan Quasha [redacted]
7. John Liddicoat: [redacted]

Corporation Shareholders:

React Health Holdings, LLC (100%)

Address: 5101 Fruitville Rd. Suite 200, Sarasota, FL 34232

State of Florida
Department of State

I certify from the records of this office that 3B MEDICAL, INC. is a corporation organized under the laws of the State of Florida, filed on December 27, 2011.

The document number of this corporation is P11000108422.

I further certify that said corporation has paid all fees due this office through December 31, 2023, that its most recent annual report/uniform business report was filed on March 9, 2023, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-sixth day of October, 2023



Secretary of State

Tracking Number: 9010902809CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

If you require immediate assistance, please contact me via phone at either number listed below.

Walter Copeland
Director
Division of Drugs, Devices and Cosmetics
Florida Department of Business & Professional Regulation
Voice: 850.717.1172 | Cell: [redacted]
Walter.Copeland@myfloridalicense.com

From: James McFaddin [mailto:mcfaddin@thesoutherngroup.com]
Sent: Monday, September 26, 2022 2:00 PM
To: Copeland, Walter
Subject: device manufacturer exemption and State of Arizona

[NOTICE] This message comes from a system outside of DBPR. Please exercise caution when clicking on links and/or providing sensitive information. If you have concerns, please contact your Knowledge Champion or the DBPR Helpdesk.

Hi Walter, good to chat with you today!

As we discussed, my client 3B Medical, Inc. d/b/a React Health is requesting confirmation from DBPR that it is exempt in Florida from the requirements to obtain a device manufacturer permit since all of its products are approved for marketing by or registered with the Federal Drug Administration. As I mentioned, the State of Arizona is requiring React Health to show proof of permit in its home state (which is Florida) as a condition of permitting in Arizona. However, Arizona is indicating it will waive the requirement if React Health can provide written confirmation from Florida DBPR of the statutory exemption and that, if React Health meets the requirements of the statutory exemption by having all of its products approved by or registered with the FDA, then React Health is de facto permitted in Florida and need not obtain permit from DBPR.

I have attached a letter from Adam Cooper, counsel to React Health, which explains further. We would greatly appreciate written confirmation from you to Adam Cooper. You can feel free to email me the written confirmation and I will pass along to Adam.

Thank you so much!
-James

James McFaddin
The Southern Group

K&L GATES

September 26, 2022

Adam S Cooper
Adam.Cooper@klgates.com

T +1 214 939 4955
F +1 214 939 5849

Via Email

Department of Business & Professional Regulation
2601 Blair Stone Road
Tallahassee, FL 32399-1027

Re: Florida Medical Device Manufacturer Permit

To Whom It May Concern:

K&L Gates LLP represents 3B Medical, Inc. d/b/a React Health ("React") in this request for clarity from the Florida Department of Business & Professional Regulation ("DBPR") regarding Florida regulations relating to the Device Manufacturer Permit. React is a Florida based medical device manufacturer that engages in the manufacture of medical devices that are approved for marketing by, and are registered with, the federal Food and Drug Administration ("FDA") in accordance with federal law for commercial distribution.

Florida statutes exempt a device manufacturer whose products are approved for marketing by or registered with the FDA from the requirement that the device manufacturer obtain a permit. *See* Fla. Stat. Ann. § 499.01(2)(o)(1)(b) (*citing to* Fla. Stat. Ann. § 499.015(8)).

React requests DBPR to confirm that the above interpretation is accurate – that a Florida based medical device manufacturer is exempt from the requirement that it obtain a Device Manufacturer Permit if all devices are approved by or registered with the FDA.

Please let us know if you have any questions, or need any additional information on our end. Thanks for your attention to this matter.

Sincerely,

Adam Cooper

From: Copeland, Walter
To: James McFaddin
Subject: Device manufacturer exemption and State of Arizona
Date: Thursday, September 29, 2022 1:32:06 PM
Attachments: image001.png
3B Medical,React - Letter to Florida re Manufacturer Permit_USW_Active01_506088989_1.pdf

---

James,

In response to your email below and the communication attached from K&L Gates, LLP; I am writing this email to confirm that a medical device manufacturer is not required to be permitted in Florida if all products manufactured are exempt from registration pursuant to s. 499.015(8), F.S. as provided below:

499.015 Registration of drugs and devices; issuance of certificates of free sale.–
(8) Notwithstanding any requirements set forth in this part, a manufacturer of medical devices that is registered with the federal Food and Drug Administration is exempt from this section and s. 499.041(6) if:

(a) The manufacturer's medical devices are approved for marketing by, or listed with the federal Food and Drug Administration in accordance with federal law for commercial distribution; or

(b) The manufacturer subcontracts with a manufacturer of medical devices to manufacture components of such devices.

Based on the communication provided from R&L Gates, LLP (attached), React Health is not required to be permitted as a medical device manufacturer in Florida as the devices they manufacture are approved for marketing by, and are registered with, the federal Food and Drug Administration in accordance with federal law for commercial distribution.

Please feel free to contact me directly at either number below if we can assist further or if we can provide additional clarification.

Sincerely,

WC

****** Please note this is non-binding, informal direction and is subject to change. A Declaratory Statement is the sole means for obtaining a binding interpretation or opinion from the Division of Drugs, Devices and Cosmetics concerning the applicability of statutory provisions, rule or orders over which the Division has authority (Chapters 499, Florida Statutes and Chapter 61N-1, Florida Administrative Code). Refer to Section 120.565, Florida Statutes and Chapter 28-105, Florida Administrative Code, which sets out the requirements for a Petition for Declaratory Statement. ******

T: 850.671.4401
C: [redacted]
E: mcfaddin@thesoutherngroup.com
W: https://thesoutherngroup.com
Influence creates opportunity. Let us show you how. LinkedIn | Twitter

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 6/21/2024 1/4/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Lockton Companies 1185 Avenue of the Americas, Suite 2010 New York NY 10036 646-572-7300	CONTACT NAME: PHONE (A/C, No, Ext): FAX (A/C, No): E-MAIL ADDRESS:	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : Federal Insurance Company	20281
INSURED 1516120 3B Medical Inc. 5101 Fruitville Rd, Suite 200 Sarasota FL 34232	INSURER B : Chubb National Insurance Company	10052
	INSURER C : --- SEE ATTACHMENT ---	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** 19266885 **REVISION NUMBER:** XXXXXXX

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:	N	N	3605-39-98	6/21/2023	6/21/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$ 1,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ XXXXXXX $
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY	N	N	7360-25-29	6/21/2023	6/21/2024	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) $	$ 1,000,000 $ XXXXXXX $ XXXXXXX $ XXXXXXX $ XXXXXXX
A	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $	N	N	7818-79-10	6/21/2023	6/21/2024	EACH OCCURRENCE AGGREGATE $	$ 10,000,000 $ 10,000,000 $ XXXXXXX
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: N If yes, describe under DESCRIPTION OF OPERATIONS below	N/A	N	7183-87-81	6/21/2023	6/21/2024	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $1,000,000 $ $1,000,000 $ $1,000,000
C	Property Product Liability Cyber	N	N	See Attached	6/21/2023	6/21/2024	See Attached See Attached See Attached	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
THIS CERTIFICATE SUPERSEDES ALL PREVIOUSLY ISSUED CERTIFICATES FOR THIS HOLDER, APPLICABLE TO THE CARRIERS LISTED AND THE POLICY TERM(S) REFERENCED.

CERTIFICATE HOLDER

19266885
Proof of Insurance

CANCELLATION See Attachments

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

© 1988-2015 ACORD CORPORATION. All rights reserved.

Other: Property	
New Policy#:	3605-39-98
New Policy Term:	06/21/2023-06/21/2024
Issuing Co.:	Federal Insurance Company
Building	See Attachment
Personal Property	$11,667,000
Business Income	$4,446,354
AOP Deductible	$50,000

Products Liability	
New Policy#:	3605-39-99
New Policy Term:	06/21/2023-06/21/2024
Issuing Co.:	Federal Insurance Company
Bodily Injury and Property Damage Deductible	$100,000
Retention?	$-
Each Occurrence Products-Completed Operations	$10,000,000
Products/Completed Operations Aggregate	$10,000,000

Excess Products Liability (10x10)	
New Policy#:	ADE 6081287508
New Policy Term:	06/21/2023-06/21/2024
Issuing Co.:	Columbia Casualty Company
Ded?	
Retention?	
Each Claim	$10,000,000
Aggregate	$10,000,000

Excess Products Liability (5x20)	
New Policy#:	EX_16617-4
New Policy Term:	06/21/2023-06/21/2024
Issuing Co.:	Gemini Insurance Company
Ded?	
Retention?	
Each Loss Event	$5,000,000
Aggregate	$5,000,000

Healthcare Professional Liability	
New Policy#:	**36069557**
New Policy Term:	**06/25/2023 – 6/21/2024**
Issuing Co.:	**Chubb Custom Insurance Company**
Each Wrongful Act Limit	**$3,000,000**
Aggregate Limit	**$3,000,000**
Ded?	**$100,000**

CYBER (3B Medical)	
New Policy#:	**CYB-107945780-00**
New Policy Term:	**01/01/2024-01/01/2025**
Issuing Co.:	**Travelers Excess and Surplus Lines Company**
Limit	**$5,000,000.00**
Retention?	**$100,000**

EXCESS CYBER (3B Medical, Inc.)	
Policy#:	P03CY0000051210
Policy Term:	01/01/2024-01/01/2025
Issuing Co.:	Vantage Risk Specialty Insurance Company
Limit	$5,000,000
Retention?	

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 39BSBJD8976

Application/License No. _____

3B Medical, Inc., doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
5101 Fruitville Rd, Ste 200, Sarasota, FL 34232, as
Address of Applicant/Principal
PRINCIPAL, and Hartford Fire Insurance Company, a
Surety Company
corporation organized under the laws of the state of Connecticut
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
One Hartford Plaza, Hartford, CT 06155 - 0001 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on January 25, 2024.
Effective Date

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 2nd day of May, 2024.

APPLICANT/PRINCIPAL

3B Medical, Inc.

Authorized Representative

Noah Chitwood

SURETY COMPANY

Hartford Fire Insurance Company

Surety Company's Representative

Julia Zalesky, Attorney-in-fact

print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Holly Tallone

Witness Jordan Fisher

Countersigned by:

Nevada Resident Agent Kathleen M. Coen

Posted February 20, 2020

HARTFORD FIRE INSURANCE COMPANY

Hartford, Connecticut

Financial Statement, June 30, 2023

Statutory Basis

ASSETS		LIABILITIES		
U.S. Government Bonds	$ 979,631,142	Reserve for Claims and Claim Expense	$	10,645,837,683
Bonds of Other Governments	197,619,618	Reserve for Unearned Premiums		2,541,286,769
Miscellaneous Bonds	8,601,157,852	Reserve for Taxes, License and Fees		34,776,316
Stocks	5,766,323,462	Miscellaneous Liabilities		1,113,940,612
Short Term Investments	76,919,024	**Total Liabilities**	$	**14,335,841,380**
	$ **13,601,650,898**			
Real Estate	$ 290,314,677	Capital Paid In	$ 55,320,000	
Cash	42,427,775	Surplus	11,663,964,478	
Agents' Balances (Under 90 Day)	3,704,913,854			
Other Invested Assets	4,513,172,657	**Surplus as regards Policyholders**	$	**11,719,284,478**
Miscellaneous	3,894,645,997	**Total Liabilities, Capital and Surplus**	$	**26,055,125,858**
Total Admitted Assets	$ **26,055,125,858**			

STATE OF FLORIDA
SEMINOLE COUNTY } **SS.**
CITY OF LAKE MARY

Joelle L. LaPierre, Assistant Vice President and Phyllis A. Clark, Assistant Secretary of the Hartford Fire Insurance Company, being duly sworn, each deposes and say that the foregoing is a true and correct statement of the said company's financial condition as of June 30, 2023.

Subscribed and sworn to before me this
18th day of August, 2023.

Mariluz Arce
Notary Public

MARILUZ ARCE
Notary Public - State of Florida
Commission # HH 287363
My Comm. Expires Jul 13, 2026
Bonded through National Notary Assn.

Joelle L. LaPierre, Assistant Vice President

Phyllis A. Clark, Assistant Secretary

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: LOCKTON COMPANIES LLC
Agency Code: 39-427620

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast**, a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint Julia Zalesky

its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by , and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:

Bond No. 39BSBJD8976

Naming 3B Medical, Inc. as Principal,

and Nevada State Board of Pharmacy as Obligee,

in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 20th day of May, 2021, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone

Jessica Ciccone
My Commission HH 122280
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of January 25, 2024.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler 3B Medical, Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 5101 Fruitville Rd. Suite 200

City Sarasota State FL Zip 34232

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (863) 226-6285 Website https://www.reacthealth.com

Licensing Company Email noah.chitwood@reacthealth.com

Section 2: Personal Information

First Noah Middle Robert Last Chitwood

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 5101 Fruitville Rd. Suite 200

City Sarasota State FL Zip 34232

Telephone (863) 226-6285 Email noah.chitwood@reacthealth.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✔	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Duke University		08/22 - 12/22	
Address	City	State	Zip
2138 Campus Dr	Durham	NC	27708
Diploma/Degree obtained, if any			
Executive Certificate			

School Name		From - To (MM/YY – MM/YY)	
Stanford University		05/21 - 08/21	
Address	City	State	Zip
420 Serra Mall Ste 170	Stanford	CA	94306
Diploma/Degree obtained, if any			
Executive Certificate			

School Name		From - To (MM/YY – MM/YY)	
University of South Florida		09/09 - 05/11	
Address	City	State	Zip
4202 E Fowler Ave	Tampa	FL	33620
Diploma/Degree obtained, if any			
Master of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
University of Phoenix		09/05 - 05/09	
Address	City	State	Zip
12802 Tampa Oaks Blvd	Temple Terrace	FL	33637
Diploma/Degree obtained, if any			
Bachelor of Business Administration			

School Name		From - To (MM/YY – MM/YY	
Department of Education, State of Florida		08/93 - 05/97	
Address	City	State	Zip
7977 W 12th Ave	Hialeah	FL	33014
Diploma/Degree obtained, if any			
High School Diploma			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/21 - current	[redacted]	Tampa	FL	33609
07/20 - 01/21		Tampa	FL	33629
05/15 - 06/20		Tampa	FL	33603
03/12 - 03/16		Tampa	FL	33604
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
3B Medical, Inc			04/24 - Current	
Business Address		**City**	**State**	**Zip**
5101 Fruitville Rd., Suite 200		Sarasota	FL	34232
Phone	**Title**		**Number of Employed Hours**	
(863) 226-6285	Chief Operating Officer		>280	
Description of Duties				
Oversee all operating activites of vendors, product intake, supply chain, manufacuting, customer service and distribution operations.				

Business Name			From - To (MM/YY – MM/YY)	
Lincare Holdings			08/16 - 03/24	
Business Address		**City**	**State**	**Zip**
19397 US Hwy 19 N		Clearwater	FL	33764
Phone	**Title**		**Number of Employed Hours**	
(800) 284-20006	VP Operations and Process Improvement		>15,000	
Description of Duties				
Manage general operations of serviing locations providing products and services to patients in their homes, facilities, and through mail order and virtually. Products include oxygen, respiratory equipment, and unit dose medications.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Noah Chitwood, **certify that as the designated representative for**

3B Medical, Inc,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. NC I am at least 21 years of age;
3. NC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. NC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. NC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. NC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. NC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Noah Chitwood
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

May 6th 2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Noah Chitwood

Print Name (First, Last)

Original Signature (~~electronic~~, copies or stamps not accepted)

May 6th 2024

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Hillsborough

I, Noah Chitwood, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

May 6th 2024

Date

Subscribed and Sworn to before me this 6th day of May.

Notary Public Signature

CHRISTINE WINTER
Notary Public, State of Florida
Commission# HH 484086
My comm. expires March 9, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG 3B Medical, Inc. MDEG License # (if applicable) _____

Physical Address 5101 Fruitville Rd., Suite 200

City Sarasota State FL Zip 34232

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (863) 226-6285 Website https://www.reacthealth.com/

Licensing Company Email Tom.Pontzius@reacthealth.com

Section 2: Personal Information

First Tom Middle T Last Pontzius

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITI [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Bradenton State FL Zip 34212

Telephone [redacted] Email Tom.Pontzius@reacthealth.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Columbus State Community College		10/1986 - 01/1987	
Address	**City**	**State**	**Zip**
550 East Spring Street	Columbus	OH	43215
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Hilliard High School		09/1978 -06/1982	
Address	**City**	**State**	**Zip**
4501 Britton Parkway	Hilliard	OH	43026
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/21- Current	[redacted]	Bradenton	FL	34212
From - To (MM/YY – MM/YY)		City	State	Zip
06/20 -05/21		Cedar Falls	IA	50613
From - To (MM/YY – MM/YY)		City	State	Zip
08/12 - 07/20		Cedar Falls	IA	50613
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
React Health			10/21 - Current	
Business Address		**City**	**State**	**Zip**
5101 Fruitville Road		Sarasota	FL	34232
Phone	**Title**		**Number of Employed Hours**	
863.226.6285	President		1120	
Description of Duties				
President				

Business Name			From - To (MM/YY – MM/YY)	
Philips Respironics			07/07-09/21	
Business Address		**City**	**State**	**Zip**
1010 Murry Ridge		Murrysville	PA	15668
Phone	**Title**		**Number of Employed Hours**	
724.387.5200	VP of Sales, Corporate Accounts		6840	
Description of Duties				
Commercial Sales				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Tom Pontzius, **certify that as the MDEG Administrator for**

3B Medical, Inc.,

that I (initial that you have read and meet the following requirements):

1. TP Have a high school diploma or its equivalent;
2. TP Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. TP Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. TP Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tom Pontzius
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

January 29, 2024
Date

Board Use Only	Date Received: 1/30/24

List of 3B Medical, Inc. Employees:

Paul Kim
Christina Krueckeberg
Colleen Lance
Tomi Pontzius
Luke McGee
Mary Tyke
Anna Diaz
Trey Taylor
Ashley Thompson
Lillian Arias
John Fiedor
Robert Latta
Daniel Newberry
Brett Parker
Sara Castello
Yari Gonzalez
Jennifer Jones
Marla Shannon
John Alexander
Kimberley Applegarth
Sherry Benhardt
Erin Bivens
Megan Carpenter
Piotr Czapla
Rachel Dobyns
Laurie Dull
Jay Ellis
Michael Fenton
Ryan Fletcher
Brian Gaden
Michela George
Ann Hensley
Darryl Hidalgo
Kristine Hurt
Charly Hutchison
Ray Illiano
Allison Jones
Michelle Kapp
Kyle Knepshield
Jennifer Marshall
Anthony Mengwasser
Harley Metcalfe
Dana Nania
Kyle Neese
Penney Poole
Theodore Reed
Cecil Register
Kim Ann Schade
Kevin Schultz
Robert Schultz
Nikki Speicher
Benjamin Steele
Kent Stelljes
Jamie Stunkard
Anne Taggart
Willard Taylor
Michael Thomas
James Tyler
Jeffrey Ward
George-Ryan York
Tod York
Chelsea Burrow
Daniel Alamo
Brian Allison
Delaney Anderson-Dunlop
Joseph Baldwin
Taylor Boyles
Kyle Branch
Nicholas Cheek
Mary Dogan
Christopher Golden
Matthew Graf
William Jones
Phuong Lam
Jimmy Lilly
Chester Loggins
Kayla Marshall
Stephanie McArdle
Bryan McNulty
Jacob Meester
Jeffrey Murphy

Brent Myhand
Alejandro Navarro
Danielle Palmer
Mari Pampena
John Poulos
Nathaniel Roemer
James Savery
Christopher Spruck
Jean-Michel Wilson
Ping Wu
Sean Simmons
Mikhail Timokhin
Kelsey Blackshaw
Madeline Bland
Teah Burney
Nicole Lawrence
Jennifer Luckie
Rosanna Monson
Erin Oakley
Stephanie Port
Jordyn Toplovich
Darlene White
Tamara Wilkes
Jacqueline Zastrow
Sydney Cantaley
Rebecka Ehrenpreis
Natalie Genthert
Eric Harman
Jenny Horn
Margaret Mangano
Rica Patel
Christina Rautenstrauch
Tracy Saccone
Philip Thomas
Ulyess Underwood
Christopher Wood
Steven Bordewick
Kevin Bowen
Robert Gliege
Grant Kiefer
Catherine Klein
Daniel O'Donnell
Hyonsuk Vandal
Matthew Solis
Richard Dombrowski
Kelton Stefan
Bradley Rasberry
Michael Roehlig
Jonathan Turner
Pravin Pillai
Angela Richardson
Christopher Lewis
Roman Riner
Erald Bregu
Brieann Daw
Savannah Lawson
Samuel MacDougall
Nicolina Maldonado
Adriana Moore
Alexander Ortiz
Viktoriia Parfan
Derek Rakestraw
Jamell Carver

List of 3B Medical, Inc Contractors:

Emily Sun
Julie Gerharz
Victor Alvarez
Kevin Saforo
Alfredo Costa
Vladlen Mykhailov
Dave Butler

4Q

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Note: Amici Pharma, Inc. would prefer to have a new license issued to it.

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH02870	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Amici Pharma, Inc.

Physical Address: 425 Broadhollow Rd., Suite 315

City: Melville State: NY Zip: 11747

Mailing Address (if different from physical address): 425 Broadhollow Rd., Suite 315

City: Melville State: NY Zip: 11747

Telephone: 631-396-0129 Website: www.amicipharma.com

Name of Designated Representative (DR): Amanda Vacchio

Licensing Company Email: amici@AltaLawGroup.com DR Email: amici@AltaLawGroup.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	■ Dangerous Drugs	■ Manufacturer (Virtual)
☐ Practitioners	■ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH WH02870	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Amici Pharma, Inc.

Physical Address: 425 Broadhollow Rd., Suite 315

City: Melville State: NY Zip: 11747

Mailing Address (if different from physical address): 425 Broadhollow Rd., Suite 315

City: Melville State: NY Zip: 11747

Telephone: 631-396-0129 Website: www.amicipharma.com

Name of Designated Representative (DR): Amanda Vacchio

Licensing Company Email: amici@AltaLawGroup.com DR Email: amici@AltaLawGroup.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	■ Dangerous Drugs	■ Manufacturer (Virtual)
☐ Practitioners	■ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Bausch & Lomb Inc.

Address: 8500 Hidden River Parkway City: Tampa State: FL Zip: 33637

Name: Innogenix, LLC

Address: 8200 New Horizons Blvd. City: Amityville State: NY Zip: 11701

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any):

Corporation/Organization Name: Amici Pharma, Inc.

Mailing Address: 425 Broadhollow Rd., Suite 315

City: Melville State: NY Zip: 11747

Telephone: 631-396-0129 Email: amici@AltaLawGroup.com

Contact Person Name: Tanya Dobash

Section 6: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration FDA labeler code 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Amici Pharma, Inc.

Facility Name

Amanda Vacchio

Print Name of Authorized Person Submitting Application

Amanda Vacchio

Original signature of Authorized Person (copies or stamps not accepted)

August 14, 2024

Date

Board Use Only	Date Received: 8/28/24	Amount: $1000 cc ✓

AMICI PHARMA INC.

FDA Labeler Code

Amici Pharma, Inc. holds FDA Labeler Code 69292.

eDRLS - Electronic Drug Registration & Listing System

Current Date: 15-OCT-14
Labeler DUNS: 079636824
Labeler Name: Amici Pharmaceuticals LLC
Labeler Code: 69292

The Food and Drug Administration (FDA) has assigned the above Labeler Code Number to your firm. The number cannot be used until you have confirmed the assignment. Please resubmit your Labeler Code Request SPL with the assigned number above to confirm the assignment and complete the process. **To do this, open the previous Labeler Code request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new id root and new version number with the original set id root and the appropriate effective time.**

This Labeler Code should be used on all forms related to drug establishment registration and/or drug product listing. Per Title 21, Part 207 of the Code of Federal Regulations (CFR), owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

AMICI PHARMA, INC.

Company Information

Name: Amici Pharma, Inc.

State of Incorporation: Delaware (DE Corporate # 3472051)

Ownership: A&A Consolidation Corporation (100% owner)
425 Broadhollow Rd., Suite 315
Melville, NY 11747

Officers:

Amanda Vacchio,Vice President , Operations
425 Broadhollow Rd., Suite 315
Melville, NY 11747
Phone: 631-396-0109

Aron Berke, Chief Executive Officer
425 Broadhollow Rd., Suite 315
Melville, NY 11747
Phone: 631-396-0109

Nicholas Lovejoy, President
425 Broadhollow Rd., Suite 315
Melville, NY 11747
Phone: 631-396-0109

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "AMICI PHARMA, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SECOND DAY OF JULY, A.D. 2024.

Jeffrey W. Bullock, Secretary of State

3472051 8300

SR# 20243203438

You may verify this certificate online at corp.delaware.gov/authver.shtml

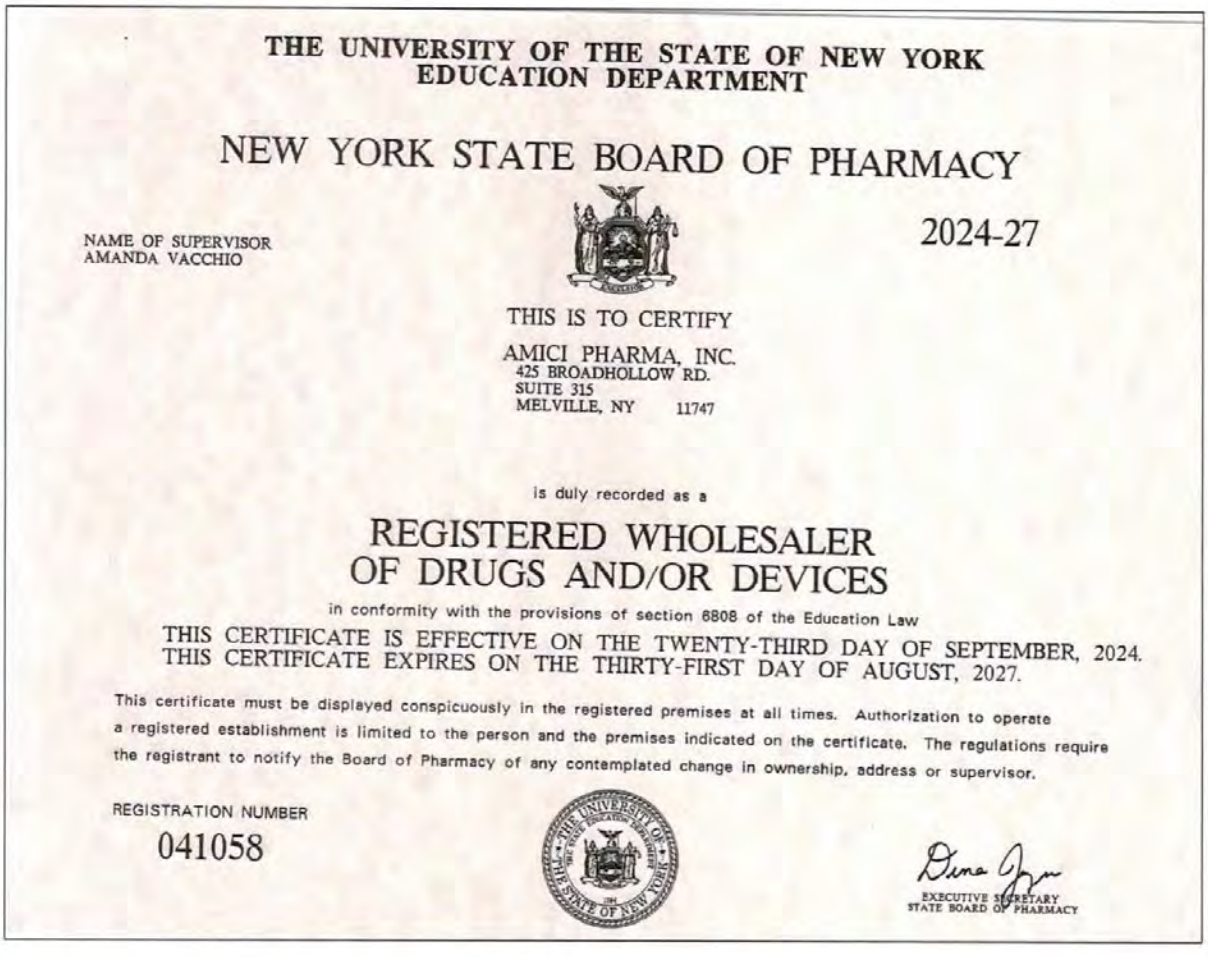
Authentication: 203982446

Date: 07-22-24

AMICI PHARMA, INC.

Resident state (NY) license

Amici Pharma, Inc. holds New York license 041058, which expires 8/31/2027.



THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2024-27

NAME OF SUPERVISOR
AMANDA VACCHIO

THIS IS TO CERTIFY

AMICI PHARMA, INC.
425 BROADHOLLOW RD.
SUITE 315
MELVILLE, NY 11747

is duly recorded as a

REGISTERED WHOLESALER
OF DRUGS AND/OR DEVICES

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE TWENTY-THIRD DAY OF SEPTEMBER, 2024.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF AUGUST, 2027.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER
041058

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

AMICI PHARMA, INC.

DEA Permit for 3PL

Amici Pharma does not handle, possess or ship controlled substances itself and therefore does not have a DEA permit itself. The DEA Permit (RR0577241) for Amici's third party logistics provider, Rx Crossroads, is below:



CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RR0577241	04-30-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-08-2024

RXCROSSROADS 3PL LLC
4200 BINION WAY STE 200
MASON, OH 450369469

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 46BSBJD3998

Application/License No. _____

Amici Pharma, Inc., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
425 Broadhollow Rd. #315, Melville, NY 11747, as
(Address of Applicant/Principal)
PRINCIPAL, and Hartford Fire Insurance Company, a
(Surety Company)
corporation organized under the laws of the state of CT
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
3000 Internet Drive, #600, Frisco, TX 75034 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on August 8, 2024.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 8th day of August, 20 24.

APPLICANT/PRINCIPAL
Amici Pharma, Inc.

Authorized Representative

SURETY COMPANY
Hartford Fire Insurance Company

Surety Company's Representative

Dawn Davis, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Joseph DeDrio

Witness Sherry Minder

SIGNED and SEALED in the presence of:

Witness Donnie Doan

Witness Christen Tyner

Countersigned by:

Nevada Resident Agent Edward Ryan Bowles

Posted February 20, 2020

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: 888-266-3488 *or fax:* 860-757-5835

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: MARSH & MCLENNAN AGENCY LLC
Agency Code: 46-461496

- [X] **Hartford Fire Insurance Company**, *a corporation duly organized under the laws of the State of Connecticut*
- [X] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [X] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast**, a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut, (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint, ***up to the amount of*** Unlimited :

Edward R. Bowles, Dawn Davis, Walter J. DeLaRosa, Donnie Doan, Christen Tyner of DALLAS, Texas

their true and lawful Attorney(s)-in-Fact, each in their separate capacity if more than one is named above, to sign its name as surety(ies) only as delineated above by [X], and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In **Witness Whereof**, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 20th day of May, 2021, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Aicone

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of August 8, 2024

Signed and sealed in Lake Mary, Florida.

Keith Dozois

Keith D. Dozois, Assistant Vice President

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Amici Pharma, Inc.

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 425 Broadhollow Rd., Suite 315

City: Melville State: NY Zip: 11747

Mailing Address (if different from physical address): 425 Broadhollow Rd., Suite 315

City: Melville State: NY Zip: 11747

Telephone: 631-396-0129 Website: www.amicipharma.com

Licensing Company Email: amici@altalawgroup.com

Section 2: Personal Information

First: Amanda Middle: Last: Vacchio

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: 425 Broadhollow Rd., Suite 315

City: Melville State: NY Zip: 11747

Telephone: 631-396-0129 Email: amici@AltaLawGroup.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Stony Brook University		09/14 - 05/15	
Address	**City**	**State**	**Zip**
100 Nicolls RD	Stony Brook	NY	11794
Diploma/Degree obtained, if any			
Masters of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Stony Brook University		09/10 - 05/14	
Address	**City**	**State**	**Zip**
100 Nicolls RD	Stony Brook	NY	11794
Diploma/Degree obtained, if any			
Bachelor of Arts in English			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/20 - present	[redacted]	Smithtown	NY	11787
06/16 - 03/20		Farmingdale	NY	11735
11/14 - 06/16		Stony Brook	NY	11790
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Amici Pharma, Inc.			01/16 - present	
Business Address		**City**	**State**	**Zip**
425 Broadhollow Rd., Suite 315		Melville	NY	11747
Phone	**Title**		**Number of Employed Hours**	
631-396-0129	Vice President, Operations		18,900	
Description of Duties				
Manage operations, including distribution of Amici-label pharmaceutical products.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Amanda Vacchio, **certify that as the designated representative for**

Amici Pharma, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. X I am at least 21 years of age;
3. X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Amanda Vacchio

Print Name (First, Last)

Amanda Vacchio

Original Signature (electronic, copies or stamps not accepted)

August 14 2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Amanda Vacchio
Print Name (First, Last)

Amanda Vacchio
Original Signature (electronic, copies or stamps not accepted)

August 14 2024
Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Suffolk

I, Amanda Vacchio, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Amanda Vacchio
Original Signature

August 14 2024
Date

Subscribed and Sworn to before me this 14 day of August 2024

Notary Public Signature

JOSEPH DEORIO
Notary Public - State of New York
NO. 01DE6073802
Qualified in Nassau County
My Commission Expires Jun 14, 2026

(Seal)

AMICI PHARMA, INC.

Employee List

Amanda Vacchio, Vice President, Operations
Nicholas Lovejoy, President
Aron Berke, CEO
Danielle Sacchitello, Operations Assistant
Mary Quinn, Finance Assistant

4R

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: COUPLER LLC

Physical Address: 1140 MCDERMOTT DRIVE, SUITE 104

City: WEST CHESTER State: PA Zip: 19380

Mailing Address (if different from physical address): SAME AS PHYSICAL ADDRESS

City: _____ State: _____ Zip: _____

Telephone: 215-394-5995 Website: WWW.COUPLERRX.COM

Name of Designated Representative (DR): CRAIG KOBUS

Licensing Company Email: GHUNT@POLARISRX.COM DR Email: CKOBUS@COUPLERRX.COM

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	■ Controlled Substances	■ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		■ Retail pharmacy wholesale distributor
■ Others: CORRECTIONAL FACILITIES, NURSING HOMES		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: AMERISOURCE BERGEN - CENCORA
Address: 1 WEST FIRST AVENUE City: CONSHOHOCKEN State: PA Zip: 19428
Name: BLUPAX
Address: 160 RARITAN CENTER PWKY UNIT 1 City: EDISON State: NJ Zip: 08837
Name: SOUTH POINTE
Address: 321 MATTHEWS MILL ROAD City: GLASGOW State: KY Zip: 42141
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: PENNSYLVANIA / COUPLER LLC
Parent Company (if any): COUPER LLC
Corporation/Organization Name: COUPLER LLC
Mailing Address: 1140 MCDERMOTT DRIVE, SUITE 104
City: WEST CHESTER State: PA Zip:
Telephone: 215-394-5995 Email: GHUNT@POLARISRX.COM
Contact Person Name: GINA HUNT

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification PLEASE NOTE THAT WE ARE IN PROCESS FOR DRUG DISTIBUTOR ACCREDITATION 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at:		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at:		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

COUPLER LLC

Facility Name

DAVID ROMBRO

Print Name of Authorized Person Submitting Application

CEO

Original signature of Authorized Person (copies or stamps not accepted)

10/2/24

Date

Board Use Only	Date Received: 10/10/24	Amount: $1000 EFT 1226

An official website of the United States government Here's how you know

FDA

Search Result

Share Tweet LinkedIn Email Print

Drug Establishments Current Registration Site

New Search

Search Results for *coupler*

Showing 1 to 1 of 1 entries

Show entries

Coupler LLC	3003734940	119003108	REPACK	1140 McDermott Drive, Suite 104, West Chester, Pennsylvania (PA) 19380, United States (USA)	12/31/2024

Data Current Through: Monday, Sep 30, 2024

New Search

Verified 10/17/24 - MH

Coupler LLC

Officer, Ownership & Manager Detail

1140 McDermott Drive, Suite 104
West Chester, PA 19380

Officer Name	DOB	SSN
David W. Rombro (CEO)	[redacted]	

[redacted]

Coupler, LLC
2900 NW 60th Street
Ft Lauderdale, FL 33309

FEIN: 92-3571836
Owned by: David W. Rombro
Managers: David W. Rombro,
Officers: David W. Rombro (CEO)

***David W. Rombro Owns 100%**

Manager	DOB	SSN
David W. Rombro	[redacted]	

[redacted]

Responsible Agent for Board Communication

[redacted]

Pennsylvania Department of State

Bureau of Corporations and Charitable Organizations
PO Box 8722 | Harrisburg, PA 17105-8722
T:717-787-1057
dos.pa.gov/BusinessCharities

Regarding:	Coupler LLC
Request Type:	Subsistence Certificate
Request No.:	025749532
Receipt No.:	000775226
Filing Type:	Domestic Limited Liability Company
Filing Subtype:	Limited Liability Company
Initial Filing Date:	March 31, 2023
Status:	Active

Issuance Date: November 20, 2023
File No.: 0012930554

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

I DO HEREBY CERTIFY THAT

Coupler LLC

is currently subsisting on the records of the Department of State as of the issuance date herein.

I DO FURTHER CERTIFY THAT this Subsistence Certificate shall not imply that all fees, taxes and penalties owed to the Commonwealth of Pennsylvania are paid.

COMMONWEALTH OF PENNSYLVANIA • DEPARTMENT OF STATE •

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the seal of my office to be affixed, the day and year above written

Albert Schmidt
Secretary of the Commonwealth

Verify this certificate online at www.file.dos.pa.gov

Certificate of Registration

Certificate No. 1000004407
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Category:

Manufacturer (Prescription)

Drug & Device Registration
2525 North 7th Street
SUITE 210D
HARRISBURG, PA 17110
(717) 787-4779

COUPLER LLC
1140 MCDERMOTT DRIVE
SUITE 104
WEST CHESTER, PA 19380

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Controlled Substance, Drug, Device and Cosmetic Act #64, approved September 9, 1972.

Issuance Date: May 23, 2023
Expiration Date: The Last Day of June, 2025

Jeanne Parisi
Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

Debra L. Bogen, MD, FAAP
Acting Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

Certificate of Licensure

Certificate No. 8000003149
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Category:

Wholesaler/Distributor

Drug & Device Registration
2525 North 7th Street
SUITE 210D
HARRISBURG, PA 17110
(717) 787-4779

COUPLER LLC
1140 MCDERMOTT DRIVE
SUITE 104
WEST CHESTER, PA 19380

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Wholesale Prescription Drug License Act, Act #145, approved December 14, 1992.

Issuance Date: May 23, 2023
Expiration Date: The Last Day of June, 2025

Jeanne Parisi
Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

Debra L. Bogen, MD, FAAP
Acting Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RC0659574	08-31-2025	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	MANUFACTURER	07-12-2024

COUPLER, LLC
1140 MCDERMOTT DR STE 104
WEST CHESTER, PA 193804043

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RC0659574	08-31-2025	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	MANUFACTURER	07-12-2024

COUPLER, LLC
1140 MCDERMOTT DR STE 104
WEST CHESTER, PA 193804043

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RC0659574	08-31-2025	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	MANUFACTURER	07-12-2024

COUPLER, LLC
1140 MCDERMOTT DR STE 104
WEST CHESTER, PA 193804043

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:
   Drug Enforcement Administration
   P.O. Box 2639
   Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Drug Codes
2100 4000

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 101283741

Application/License No. _____

Coupler, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1140 McDermott Drive, Suite 104 West Chester, PA 19380 (Address of Applicant/Principal), as PRINCIPAL, and Merchants Bonding Company (Mutual) (Surety Company), a corporation organized under the laws of the state of Iowa (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 6700 Westown Parkway, West Des Moines, IA 50266 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on September 30, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 27th day of September, 20 24.

APPLICANT/PRINCIPAL

Coupler, LLC

Authorized Representative

SURETY COMPANY

Merchants Bonding Company (Mutual)
Surety Company's Representative

, Attorney-in-fact
print name D W Matson III

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Indiana Espinoza

Witness Deleida Munecas

Countersigned by:

N/A
Nevada Resident Agent

LP 4229 NV (5/21)

Posted February 20, 2020

MERCHANTS
BONDING COMPANY

POWER OF ATTORNEY

Know All Persons By These Presents, that MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., both being corporations of the State of Iowa, d/b/a Merchants National Indemnity Company (in California only) (herein collectively called the "Companies") do hereby make, constitute and appoint, individually,

D W Matson III

their true and lawful Attorney(s)-in-Fact, to sign its name as surety(ies) and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

This Power-of-Attorney is granted and is signed and sealed by facsimile under and by authority of the following By-Laws adopted by the Board of Directors of Merchants Bonding Company (Mutual) on April 23, 2011 and amended August 14, 2015 and April 27, 2024 and adopted by the Board of Directors of Merchants National Bonding, Inc., on October 16, 2015 and amended on April 27, 2024.

"The President, Secretary, Treasurer, or any Assistant Treasurer or any Assistant Secretary or any Vice President shall have power and authority to appoint Attorneys-in-Fact, and to authorize them to execute on behalf of the Company, and attach the seal of the Company thereto, bonds and undertakings, recognizances, contracts of indemnity and other writings obligatory in the nature thereof."

"The signature of any authorized officer and the seal of the Company may be affixed by facsimile or electronic transmission to any Power of Attorney or Certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the Company, and such signature and seal when so used shall have the same force and effect as though manually fixed."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and aut hority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner-Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

In Witness Whereof, the Companies have caused this instrument to be signed and sealed this 27th day of September , 2024 .

MERCHANTS NATIONAL BONDING, INC. -o- INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

MERCHANTS BONDING COMPANY (MUTUAL)
MERCHANTS NATIONAL BONDING, INC.
d/b/a MERCHANTS NATIONAL INDEMNITY COMPANY

By Larry Taylor
President

STATE OF IOWA
COUNTY OF DALLAS ss.

On this 27th day of September , 2024 , before me appeared Larry Taylor, to me personally known, who being by me duly sworn did say that he is President of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC.; and that the seals affixed to the foregoing instrument are the Corporate Seals of the Companies; and that the said instrument was signed and sealed in behalf of the Companies by authority of their respective Boards of Directors.

NOTARIAL SEAL IOWA

Penni Miller
Commission Number 787952
My Commission Expires
January 20, 2027

Notary Public

(Expiration of notary's commission does not invalidate this instrument)

I, Elisabeth Sandersfeld, Secretary of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., do hereby certify that the above and foregoing is a true and correct copy of the POWER-OF-ATTORNEY executed by said Companies, which is still in full force and effect and has not been amended or revoked.

In Witness Whereof, I have hereunto set my hand and affixed the seal of the Companies on this 27th day of September , 2024 .

MERCHANTS NATIONAL BONDING, INC. -o- INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

Secretary

POA 0018 (6/24)

Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler COUPLER LLC

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 1140 MCDERMOTT DRIVE, SUITE 104

City WEST CHESTER State PA Zip 19380

Mailing Address (if different from physical address) SAME AS PHYSICAL ADDRESS

City _____ State _____ Zip _____

Telephone 215-394-5995 Website WWW.COUPLERRX.COM

Licensing Company Email GHUNT@POLARISRX.COM

Section 2: Personal Information

First CRAIG Middle S Last KOBUS

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN _____ Sex ■ M ☐ F ☐ X

Mailing Address [redacted]

City DOWNINGTOWN State PA Zip 19335

Telephone [redacted] Email CKOBUS@COUPLERRX.COM

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Widener University		9/88-5/92	
Address	**City**	**State**	**Zip**
1 University Pl	Chester	PA	19013
Diploma/Degree obtained, if any			
B.S. Business Management			

School Name		From - To (MM/YY – MM/YY)	
Concord High School		9/84-6/88	
Address	**City**	**State**	**Zip**
2501 Ebright Rd	Wilmington	DE	19810
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
5/17-Present	[redacted]	Downingtown	PA	19335
2/14-5/17	[redacted]	Downingtown	PA	19335
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Coupler LLC			3/24-Present	
Business Address		**City**	**State**	**Zip**
1140 McDermott Drive, Suite 104		West Chester	PA	19380
Phone	**Title**		**Number of Employed Hours**	
215-394-5995	Director, Coupler LLC		1,120	
Description of Duties				
Manage Daily Operations of Repackaging facility. Manage relationships with DEA, NABP and FDA. Procurement Overview and Strategy and analytical review of Purchasing, Dispensing and Margins.				

Business Name			From - To (MM/YY – MM/YY)	
Polaris Pharmacy Services			8/23-3/24	
Business Address		**City**	**State**	**Zip**
2900 NW 60th Street		Fort Lauderdale	FL	33309
Phone	**Title**		**Number of Employed Hours**	
800-589-9747	Senior Director, Procurement		1,120	
Description of Duties				
Manage Wholesaler and Direct Manufacturer Relationships. Procurement Overview and Strategy. Analytical review of Purchasing and Margins.				

Business Name			From - To (MM/YY – MM/YY)	
AmerisourceBergen(Cencora)			3/99-8/23	
Business Address		**City**	**State**	**Zip**
1 W First Ave		Conshohocken	PA	19428
Phone	**Title**		**Number of Employed Hours**	
610-727-7000	Director, Key Accounts		46,000	
Description of Duties				
Managing the ongoing strategic relationships with Key LTC accounts. Implemented go market strategy, value proposition and sales strategy. Analytical review and strategy of customer's purchases and dispensing.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✔	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
9/2012		PA	Exton	Chester
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		East Whiteland Police		
Reason/Charge				
Simple Assault- Misdemeanor				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
			N/A	
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

Had an altercation with an adult. Pleaded out after several months of litigation. This happened back in 2012

Original Signature (electronic, copies or stamps not accepted)

9/27/24
Date

CRAIG KOBUS

[redacted]

0742

I-787a (Rev. 08-10-2016)

U.S. Department of Justice
Federal Bureau of Investigation
Criminal Justice Information Services Division
Clarksburg, WV 26306

CRAIG KOBUS
[redacted]

Date: 10-03-2024

The Criminal Justice Information Services (CJIS) Division of the Federal Bureau of Investigation (FBI) has completed the following fingerprint submission:

Subject Name

CRAIG KOBUS

Search Completed Result 10-03-2024 E2024277000000188726

A SEARCH OF THE FINGERPRINTS PROVIDED BY THIS INDIVIDUAL HAS REVEALED PRIOR ARREST DATA AT THE FBI. THIS DOES NOT PRECLUDE FURTHER CRIMINAL HISTORY AT THE STATE OR LOCAL LEVEL.

Social Security number: XXX-XX-XXXX

The result of the above response is only effective for the date the submission was originally completed. For more updated information, please submit new fingerprints of the Subject.

In order to protect Personally Identifiable Information, as of August 17, 2009, FBI policy has changed to no longer return the fingerprint cards. This form will serve as the FBI's official response.

This Identity History Summary (IdHS) is provided pursuant to 28 CFR 16.30-16.34 solely for you to conduct a personal review and/or obtain a change, correction, or updating of your record. **This IdHS is not provided for the purpose of licensing or employment or any other purpose enumerated in 28 CFR 20.33.**

Any questions may be addressed to the Customer Service Group at 304-625-5590. You may also visit the website at www.fbi.gov/checks for further instructions.

Chris Ormerod
Section Chief
Biometric Services Section
Criminal Justice Information
Services Division

UNITED STATES DEPARTMENT OF JUSTICE
FEDERAL BUREAU OF INVESTIGATION
CRIMINAL JUSTICE INFORMATION SERVICES DIVISION
CLARKSBURG, WV 26306

DC000001Z

NCN E2024277000000188726

DC000001Z
DO 556-73 REQ
FBI-CJIS-WV
BIOMETRIC TECHNOLOGY CTR
1000 CUSTER HOLLOW RD
CLARKSBURG,WV 26306

UNITED STATES DEPARTMENT OF JUSTICE
FEDERAL BUREAU OF INVESTIGATION
CRIMINAL JUSTICE INFORMATION SERVICES DIVISION
CLARKSBURG, WV 26306

DC000001Z
TCN WVFBIJM0Z-20241003125844-EDO-0000-71003
AGENCY CASE D52500824248

THE FBI IDENTIFIED YOUR TEN-PRINT SUBMISSION WHICH CONTAINED THE FOLLOWING DESCRIPTORS:

NAME KOBUS,CRAIG

SEX	RACE	BIRTH DATE	HEIGHT	WEIGHT	EYES	HAIR
M	W	[redacted]	000	UNK	UNK	UNK

STATE ID	BIRTH PLACE
NULL	UNITED STATES

CITIZENSHIP
UNITED STATES

OTHER BIRTH DATES	SCARS-MARKS-TATTOOS	SOCIAL SECURITY	MISC NUMBERS
NONE	NONE	NONE	NONE

ALIAS NAME(S)
NONE

END OF COVER SHEET

UNITED STATES DEPARTMENT OF JUSTICE
FEDERAL BUREAU OF INVESTIGATION
CRIMINAL JUSTICE INFORMATION SERVICES DIVISION
CLARKSBURG, WV 26306

DC000001Z NCN E2024277000000188726

BECAUSE ADDITIONS OR DELETIONS MAY BE MADE AT ANY TIME, A NEW COPY SHOULD BE REQUESTED WHEN NEEDED FOR SUBSEQUENT USE.
- FBI IDENTIFICATION RECORD -

WHEN EXPLANATION OF A CHARGE OR DISPOSITION IS NEEDED, COMMUNICATE DIRECTLY WITH THE AGENCY THAT FURNISHED THE DATA TO THE FBI.

NAME	FBI UCN	DATE REQUESTED
KOBUS,CRAIG STEVEN	651465RD2	2024/10/03

SEX	RACE	BIRTH DATE	HEIGHT	WEIGHT	EYES	HAIR
M	W	[redacted]	[redacted]			

BIRTH PLACE
PENNSYLVANIA

PATTERN CLASS
LS LS LS LS LS LS AU AU LS LS

CITIZENSHIP
UNITED STATES

1-ARRESTED OR RECEIVED 2012/09/08 SID- PA40127917
AGENCY-TREDYFFRIN TWP PD BERWYN (PA0151200)
AGENCY CASE-1206963

FINGERPRINT INFORMATION
BSI/2000168426724
PRINT DATE/2012/09/08

CHARGE 1-SIMPLE ASSAULT 1 COUNTS
CHARGE 2-FALSE IMPRISONMENT 1 COUNTS
CHARGE 3-HARASSMENT 1 COUNTS
CHARGE 4-DISORDERLY CONDUCT 1 COUNTS

RECORD UPDATED 2024/10/03

ALL ENTRIES CONTAINED IN THIS FBI RECORD ARE BASED ON FINGERPRINT COMPARISONS AND PERTAIN TO THE SAME INDIVIDUAL.

THE USE OF THIS RECORD IS REGULATED BY LAW. IT IS PROVIDED FOR OFFICIAL USE ONLY AND MAY BE USED ONLY FOR THE PURPOSE REQUESTED.

I, Craig Kobus, **certify that as the designated representative for**

Coupler LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CSK I am at least 21 years of age;
3. CSK I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CSK I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CSK I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CSK I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CSK I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Craig Kobus

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/27/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Craig Kobus

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/27/24

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Chester

I, Craig Kobus, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/27/24

Date

Subscribed and Sworn to before me this 27 day of September, 2024

Notary Public Signature

Commonwealth of Pennsylvania-Notary Seal
ALEXANDRA P FAULKNER, NOTARY PUBLIC
CHESTER COUNTY
MY COMMISSION EXPIRES FEBRUARY 9, 2027
COMMISSION NUMBER 1431700

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site COUPLER LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 1140 MCDERMOTT DRIVE, SUITE 104

City WEST CHESTER State PA Zip 19380

Mailing Address (if different from physical address) SAME AS PHYSICAL ADDRESS

City _____ State _____ Zip _____

Telephone 215-394-5995 Website WWW.COUPLERRX.COM

Licensing Company Email GHUNT@POLARISRX.COM

Section 2: Personal Information

First DAVID Middle _____ Last ROMBRO

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City FORT LAUDERDALE State FL Zip 33309

Telephone 800-589-9747 Email DROMBRO@POLARISRX.COM

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF MARYLAND, BALTIMORE		05/81	
Address	**City**	**State**	**Zip**
620 W LEXINGTON ST	BALTIMORE	MD	21201
Diploma/Degree obtained, if any			
B.S. OF PHARMACY			
School Name		From - To (MM/YY – MM/YY)	
BALTIMORE POLYTECHNIC INSTITUE			
Address	**City**	**State**	**Zip**
1400 COLD SPRINGS LN	BALTIMORE	MD	21209
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/20 - CURRENT	[redacted]	PARKLAND	FL	33076
06/16 - 09/20		FORT LAUDERDALE	FL	33309
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
POLARIS PHARMACY SERVICES			07/15 - CURRENT
Business Address	**City**	**State**	**Zip**
2900 NW 60TH STREET	FORT LAUDERDALE	FL	33309
Phone	**Title**		
954-919-1818	CEO		
Description of Duties			
PLEASE SEE ATTACHED RESUME			

Business Name			From - To (MM/YY – MM/YY)
OMNICARE			06/08 - 04/14
Business Address	**City**	**State**	**Zip**
2955 W CORPORATE LAKES BLVD #600	WESTON	FL	33331
Phone	**Title**		
954-660-5555	GM		
Description of Duties			
PLEASE SEE ATTACHED RESUME			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

[redacted]

C-Level Senior Executive

Results-driven, highly accomplished senior level operational professional with the demonstrated ability to streamline business operations, execute solid decision-making that drives growth and increases efficiency while developing talent that improves customer relations that increases the bottom line within multi-billion dollar and small business organizations.

Professional Experience

Polaris Pharmacy Services, LLC,

Chief Executive Officer and Member, (2015 - present)

Overall leadership and vision for of the business.

Selected Achievements:

- Successfully led a startup in 2015 to an $800 million dollar company in 2023.
- Leveraged experience and team members to become the 6th largest long term care pharmacy in the US.

Omnicare, Inc., Cincinnati, OH
General Manager – Weston, Florida (2009-2014)

Selected Achievements:

- Led the largest pharmacy in Florida with over 21,000 licensed beds.

First Choice Pharmacy, Hollywood, Florida
Chief Executive Officer and Owner (2005-2009)

Selected Achievements:

- Led the pharmacy from start up to 7500 licensed beds and eventually sold to Omnicare.

Education

Bachelor of Science, Pharmacy, University of Maryland

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4, 5, 6 **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
02/06/2023	PENDING	CA	LOS ANGELES	LOS ANGELES COUNTY
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
23STCV02582		STANLEY MOSK COURTHOUSE		
Reason/Charge				
BREACH OF CONTRACT				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
MED-PLUS PHARMACY, INC VS ANAHEIM HEALTHCARE			LAWSUIT	
Name of Business/Industry/Entity				
MED-PLUS PHARMACY, INC				

Provide explanation below:

PLEASE SEE ATTACHED

CEO 10/2/24

Original Signature (electronic, copies or stamps not accepted) Date

CASE INFORMATION

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

Case Number: 23STCV02582

MED-PLUS PHARMACY, INC. VS ANAHEIM HEALTHCARE CENTER, LLC, ET AL

Filing Courthouse: Stanley Mosk Courthouse

Filing Date: 02/06/2023
Case Type: Contract/Warranty Breach - Seller Plaintiff (no fraud/negligence) (General Jurisdiction)
Status: Request for Dismissal - Before Trial not following ADR or more than 60 days since ADR 05/14/2024

Click here to access document images for this case

If this link fails, you may go to the Case Document Images site and search using the case number displayed on this page

FUTURE HEARINGS

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

None

PARTY INFORMATION

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

Click on any of the below link(s) to see Register of Action Items on or before the date indicated:

A - P R - W

ANAHEIM HEALTHCARE CENTER LLC DBA ANAHEIM HEALTHCARE CENTER - Defendant

BARTLETT CARE CENTER LLC DBA FRENCH PARK CARE CENTER - Defendant

BERGMAN ROBERT DAVID - Attorney for Plaintiff

BRUCKER GARY KEITH - Attorney for Defendant

CITRUS NURSING CENTER DBA CITRUS NURSING CENTER - Defendant

COLLEGE VISTA LLC DBA COLLEGE VISTA CARE CENTER - Defendant

COMMUNITY CARE REHAB CENTER LLC DBA COMMUNITY CARE REHABILITATION CENTER - Defendant

COUNTRY OAKS PARTNERS LLC DBA COUNTRY OAKS CARE CENTER - Defendant

DOES 1-20 - Defendant

F. & B. HEALTHCARE DBA EXTENDED CARE HOSPITAL OF RIVERSIDE - Defendant

GARDEN PARK CARE CENTER LLC DBA GARDEN PARK CARE CENTER - Defendant

GIBRALTAR CONVALESCENT HOSPITAL INC. DBA DEL MAR CONVALESCENT HOSPITAL DBA SUNSET MANOR CONVALESCENT HOSPITAL - Defendant

GORDON LANE HEALTHCARE LLC DBA GORDON LANE CARE CENTER - Defendant

HERITAGE MANOR HEALTHCARE LLC DBA HERITAGE MANOR HEALTHCARE - Defendant

INLAND MEDICAL ENTERPRISES INC. DBA ALCOTT REHABILITATION HOSPITAL - Defendant

MED-PLUS PHARMACY LLC DBA MED-PLUS PHARMACY LTC - Plaintiff

MJB PARTNERS LLC DBA POMONA VISTA CARE CENTER - Defendant

MONTERREY PARK CONVALESCENT HOSPITAL INC. DBA MONTERREY PARK CONVALESCENT HOSPITAL - Defendant

PARAMOUNT CONVALESCENT GROUP INC. DBA PARAMOUNT CONVALESCENT HOSPITAL - Defendant

PARK REGENCY CARE LLC DBA PARK REGENCY CARE CENTER - Defendant

PC CARE LLC DBA PACIFIC CONVALESCENT CENTER - Defendant

PUENTE PARTNERS LLC DBA VICTORIA CARE CENTER - Defendant

Click on any of the below link(s) to see Register of Action Items on or before the date indicated:
TOP A - P R - W

RIVERSIDE EQUITIES LLC DBA MISSION CARE CENTER - Defendant

SIERRA VIEW CARE HOLDINGS LLC DBA SIERRA VIEW CARE CENTER - Defendant

SUN MAR HEALTHCARE INC. DBA SUN-MAR NURSING CENTER - Defendant

VILLA RANCHO BERNARDO HEALTH CARE LLC DBA VILLA RANCHO BERNARDO CARE CENTER - Defendant

WYNGATE NURSING CENTER DBA NORTH VALLEY NURSING CENTER - Defendant

Click on any of the below link(s) to see Register of Action Items on or before the date indicated:
TOP A - P R - W

DOCUMENTS FILED

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

Documents Filed (Filing dates listed in descending order)

Click on any of the below link(s) to see Register of Action Items on or before the date indicated:
05/18/2023

05/15/2024 Notice of Case Reassignment and Order for Plaintiff to Give Notice
Filed by Clerk

05/14/2024 Request for Dismissal
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

04/05/2024 Stipulation and Order (TO VACATE TRIAL DATES; [PROPOSED] ORDER)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

01/16/2024 Stipulation and Order (Stipulation and Proposed Order RE Precedential Effect of Plaintiff's Contemplated Initial Motions to Compel Further Discovery Responses)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/12/2024 Undertaking (bond)

01/12/2024 Undertaking (bond)

01/12/2024 Right to Attach Order After Hearing and Order for Issuance of Writ of Attachment
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/12/2024 Right to Attach Order After Hearing and Order for Issuance of Writ of Attachment
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/11/2024 Order Appointing Court Approved Reporter as Official Reporter Pro Tempore
Filed by COMMUNITY CARE REHAB CENTER, LLC (Defendant)

01/11/2024 Decision on applications for right to attach orders: granted in part
Filed by Clerk

01/11/2024 Objection (Evidentiary)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/11/2024 Objection (Evidentiary)
Filed by COMMUNITY CARE REHAB CENTER, LLC (Defendant)

01/11/2024 Minute Order ((Hearing on Application for Writ of Attachment Against Defenda...))
Filed by Clerk

01/08/2024 Proof of Service (not Summons and Complaint)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/08/2024 Objection (Plaintiff's Evidentiary Objections to Declarations and Evidence Filed in Support of Defendant's Opposition to Its Applications for Right to Attach Orders Against Defendants Community Care Rehab Ctr, LLC and Villa Rancho Bernardo Health Care)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/08/2024 Reply (Plaintiff's Reply Brief in Support of Applications for Right to Attach Orders Against Defendants Community Care Rehab Center, LLC and Villa Rancho Bernardo Health Care, LLC)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/04/2024 Declaration (DECLARATION OF ADRIAN DEHGHANMANESH IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TOPLAINTIFF'S APPLICATION__ FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC__)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Objection (DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC's JOINT EVIDENTIARY OBJECTIONS TO DECLARATIONS OF NEIL FARAGE IN SUPPORT OF PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDER AGAINST DEFENDANTS)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration (DECLARATION OF GARY K. BRUCKER, JR. IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Notice of Opposition to Right to Attach Order and Claim of Exemption
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Notice of Opposition to Right to Attach Order and Claim of Exemption
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration (DECLARATION OF ADRIAN DEHGHANMANESH IN SUPPORT OF DEFENDANT COMMUNITY CARE REHAB CENTER, LLC'S NOTICE OF OPPOSITION TO RIGHT TO ATTACH ORDER AND CLAIM OF EXEMPTION)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration (DECLARATION OF ADRIAN DEHGHANMANESH IN SUPPORT OF DEFENDANT VILLA RANCHO BERNARDO HEALTH CARE, LLC'SNOTICE OF OPPOSITION TO RIGHT TO ATTACH ORDER AND CLAIM OF EXEMPTION)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Proof of Service (not Summons and Complaint)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration (DECLARATION OF MICAH RHEAD IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration (DECLARATION OF JORDAN MADER IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATION FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Opposition (DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

01/04/2024 Stipulation and Order (Stipulation and Proposed Order Amending the Complaint)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/03/2024 Proof of Service (not Summons and Complaint)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Application for Right to Attach Order, Temporary Protective Order, etc.
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Proof of Service by Mail
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Memorandum of Points & Authorities
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Memorandum of Points & Authorities
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Proof of Service by Mail
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Application for Right to Attach Order, Temporary Protective Order, etc.
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

07/27/2023 Notice of Ruling
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

07/14/2023 Certificate of Mailing for ((Non-Appearance Case Review) of 07/14/2023)
Filed by Clerk

07/14/2023 Minute Order ((Non-Appearance Case Review))
Filed by Clerk

06/29/2023 Decision on Applications for Right to Attach Orders
Filed by Clerk

06/29/2023 Objections to Declaration of Adrian Dehghanmanesh Submitted in Opposition to Applications for Right to Attach Orders
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/29/2023 Minute Order ((Hearing on Application for Writ of Attachment against (1) Def...))
Filed by Clerk

06/27/2023 Objection (to Decl. of A. Dehghanmanesh Submitted in Opp to Appl. for Right to Attach Order)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/27/2023 Reply (Brief ISO Application for Right to Attach Order)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/22/2023 Declaration (Declaration Of John Kimball In Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Declaration (Declaration Of Channon Balana Yin Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Declaration (Declaration Of Adrian Dehghanmanesh In Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Objection (Defendants Anaheim Healthcare Center, LLC And Bartlett Care Center, LLC Joint Evidentiary Objections To Declarations Of Neil Farage In Support Of Plaintiffs Applications For Right To Attach Order Against Defendants)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Notice of Opposition to Right to Attach Order and Claim of Exemption
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

06/22/2023 Notice of Opposition to Right to Attach Order and Claim of Exemption
Filed by BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Opposition (To Plaintiffs Application For Right To Attach Orders Against Defendants Anaheim Healthcare Center, LLC And Bartlett Care Center, LLC)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/06/2023 Application for Right to Attach Order, Temporary Protective Order, etc.
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/06/2023 Memorandum of Points & Authorities
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/06/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/06/2023 Application for Right to Attach Order, Temporary Protective Order, etc.
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/06/2023 Memorandum of Points & Authorities
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/06/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

05/31/2023 Certificate of Mailing for ((Non-Appearance Case Review) of 05/31/2023)
Filed by Clerk

05/31/2023 Minute Order ((Non-Appearance Case Review))
Filed by Clerk

05/24/2023 Case Management Statement
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

05/23/2023 Case Management Statement
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

05/19/2023 Minute Order ((Hearing on Ex Parte Application of Plaintiff for Temporary Pr...))
Filed by Clerk

Click on any of the below link(s) to see Register of Action Items on or before the date indicated:
TOP 05/18/2023

05/18/2023 Opposition (Opposition To Plaintiffs Ex Parte Applications For Temporary Protective Orders Against Defendants Anaheim Healthcare Center And Bartlett Care Center; Declaration Of Gary K. Brucker, Jr.)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

05/18/2023 Declaration (of Richard Fond re Ex Parte for Temporary Protective Order)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

05/18/2023 Declaration (In support of Temporary Protective Order)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

05/18/2023 Ex Parte Application (for Temporary Protective Order)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

03/30/2023 Answer
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

03/01/2023 Proof of Service (not Summons and Complaint)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

03/01/2023 Notice and Acknowledgment of Receipt
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

02/15/2023 Notice (of Case Management Conference)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

02/10/2023 Notice of Case Management Conference
Filed by Clerk

02/06/2023 Notice of Case Assignment - Unlimited Civil Case
Filed by Clerk

02/06/2023 Voluntary Efficient Litigation Stipulation Packet
Filed by Clerk

02/06/2023 First Amended General Order re: Mandatory Electronic Filing
Filed by Clerk

02/06/2023 Alternate Dispute Resolution Packet
Filed by Clerk

02/06/2023 Summons (on Complaint)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

02/06/2023 Civil Case Cover Sheet
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

02/06/2023 Complaint
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

Click on any of the below link(s) to see Register of Action Items on or before the date indicated:
TOP 05/18/2023

PROCEEDINGS HELD

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

Proceedings Held (Proceeding dates listed in descending order)

06/25/2024 at 08:30 AM in Department 39
Trial Setting Conference - **Not Held - Vacated by Court**

06/24/2024 at 08:30 AM in Department 39
Post-Mediation Status Conference - **Not Held - Vacated by Court**

01/11/2024 at 09:30 AM in Department 85, James C. Chalfant, Presiding
Hearing on Application for Writ of Attachment (CCP 484.040) - **Held - Motion Granted**

01/11/2024 at 09:30 AM in Department 85
Hearing on Application for Writ of Attachment (CCP 484.040) - **Held - Motion Granted**

07/26/2023 at 08:30 AM in Department 39
Case Management Conference - **Not Held - Advanced and Vacated**

07/14/2023 at 3:41 PM in Department 39, Stephen I. Goorvitch, Presiding
Non-Appearance Case Review

06/29/2023 at 09:30 AM in Department 85, James C. Chalfant, Presiding
Hearing on Application for Writ of Attachment (CCP 484.040) - **Held - Motion Denied**

06/08/2023 at 08:30 AM in Department 39
Case Management Conference - **Not Held - Advanced and Continued - by Court**

05/31/2023 at 2:34 PM in Department 39, Stephen I. Goorvitch, Presiding
Non-Appearance Case Review

05/19/2023 at 08:30 AM in Department 85, James C. Chalfant, Presiding
Hearing on Ex Parte Application (In support of Temporary Protective Order) - **Held - Motion Denied**

REGISTER OF ACTIONS

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

05/20/2024 Case reassigned to Stanley Mosk Courthouse in Department 39 - Hon. Tony L. Richardsoneffective 05/20/2024; Reason: Inventory Transfer

05/15/2024 Notice of Case Reassignment and Order for Plaintiff to Give Notice; Filed by: Clerk

05/14/2024 On the Complaint filed by MED-PLUS PHARMACY, INC. on 02/06/2023, entered Request for Dismissal with prejudice filed by MED-PLUS PHARMACY, LLC as to the entire action

05/14/2024 Request for Dismissal; Filed by: MED-PLUS PHARMACY, LLC (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

05/14/2024 Order to Show Cause re: Payment of Waived Fees; by:

05/14/2024 Trial Setting Conference scheduled for 06/25/2024 at 08:30 AM in Stanley Mosk Courthouse at Department 39 Not Held - Vacated by Court on 05/14/2024

04/05/2024 Trial Setting Conference scheduled for 06/25/2024 at 08:30 AM in Stanley Mosk Courthouse at Department 39

04/05/2024 Stipulation and Order TO VACATE TRIAL DATES; [PROPOSED] ORDER, Signed and Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant); COLLEGE VISTA, LLC (Defendant); COUNTRY OAKS PARTNERS, LLC (Defendant); COMMUNITY CARE REHAB CENTER, LLC (Defendant); F. & B. HEALTHCARE (Defendant); GARDEN PARK CARE CENTER, LLC (Defendant); GIBRALTAR CONVALESCENT HOSPITAL, INC. (Defendant); GORDON LANE HEALTHCARE, LLC (Defendant); HERITAGE MANOR HEALTHCARE, LLC (Defendant); INLAND MEDICAL ENTERPRISES, INC. (Defendant); MJB PARTNERS, LLC (Defendant); MONTERREY PARK CONVALESCENT HOSPITAL, INC. (Defendant); PARAMOUNT CONVALESCENT GROUP, INC. (Defendant); PARK REGENCY CARE, LLC (Defendant); PC CARE, LLC (Defendant); PUENTE PARTNERS, LLC (Defendant); RIVERSIDE EQUITIES, LLC (Defendant); SIERRA VIEW CARE HOLDINGS, LLC (Defendant); SUN MAR HEALTHCARE, INC. (Defendant); VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant); WYNGATE NURSING CENTER

04/05/2024 Updated -- Stipulation and Order TO VACATE TRIAL DATES; [PROPOSED] ORDER; Filed By: COLLEGE VISTA, LLC (Defendant),CITRUS NURSING CENTER (Defendant),BARTLETT CARE CENTER, LLC (Defendant),ANAHEIM HEALTHCARE CENTER, LLC (Defendant),GARDEN PARK CARE CENTER, LLC (Defendant),F. & B. HEALTHCARE (Defendant),COMMUNITY CARE REHAB CENTER, LLC (Defendant),COUNTRY OAKS PARTNERS, LLC (Defendant),SIERRA VIEW CARE HOLDINGS, LLC (Defendant),RIVERSIDE EQUITIES, LLC (Defendant),PUENTE PARTNERS, LLC (Defendant),PC CARE, LLC (Defendant),WYNGATE NURSING CENTER (Defendant),VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant),SUN MAR HEALTHCARE, INC. (Defendant),INLAND MEDICAL ENTERPRISES, INC. (Defendant),HERITAGE MANOR HEALTHCARE, LLC (Defendant),GORDON LANE HEALTHCARE, LLC (Defendant),GIBRALTAR CONVALESCENT HOSPITAL, INC. (Defendant),PARK REGENCY CARE, LLC (Defendant),PARAMOUNT CONVALESCENT GROUP, INC. (Defendant),MONTERREY PARK CONVALESCENT HOSPITAL, INC. (Defendant),MJB PARTNERS, LLC (Defendant);

04/05/2024 Post-Mediation Status Conference scheduled for 06/24/2024 at 08:30 AM in Stanley Mosk Courthouse at Department 39 Not Held - Vacated by Court on 04/05/2024

04/05/2024 Final Status Conference scheduled for 10/18/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 39 Not Held - Vacated by Court on 04/05/2024

04/05/2024 Jury Trial scheduled for 10/29/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 39 Not Held - Vacated by Court on 04/05/2024

01/16/2024 Stipulation and Order Stipulation and Proposed Order RE Precedential Effect of Plaintiff's Contemplated Initial Motions to Compel Further Discovery Responses; Signed and Filed by: MED-PLUS PHARMACY, LLC

(Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

01/16/2024 Updated -- Stipulation and Order Stipulation and Proposed Order RE Precedential Effect of Plaintiff's Contemplated Initial Motions to Compel Further Discovery Responses: Filed By: MED-PLUS PHARMACY, LLC (Plaintiff); Result: Granted ; Result Date: 01/16/2024

01/12/2024 Right to Attach Order After Hearing and Order for Issuance of Writ of Attachment; Signed and Filed by: MED-PLUS PHARMACY, LLC (Plaintiff)

01/12/2024 Updated -- Right to Attach Order After Hearing and Order for Issuance of Writ of Attachment: As To Parties: VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant)

01/12/2024 Right to Attach Order After Hearing and Order for Issuance of Writ of Attachment; Signed and Filed by: MED-PLUS PHARMACY, LLC (Plaintiff); As to: COMMUNITY CARE REHAB CENTER, LLC (Defendant)

01/12/2024 Undertaking bond; Filed by:

01/12/2024 Undertaking bond; Filed by:

01/11/2024 Objection Evidentiary; Filed by: COMMUNITY CARE REHAB CENTER, LLC (Defendant)

01/11/2024 Objection Evidentiary; Filed by: MED-PLUS PHARMACY, LLC (Plaintiff)

01/11/2024 Decision on applications for right to attach orders: granted in part; Filed by: Clerk

01/11/2024 Order Appointing Court Approved Reporter as Official Reporter Pro Tempore; Filed by: COMMUNITY CARE REHAB CENTER, LLC (Defendant)

01/11/2024 Minute Order (Hearing on Application for Writ of Attachment Against Defenda...)

01/11/2024 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 01/11/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 85 updated: Result Date to 01/11/2024; Result Type to Held - Motion Granted

01/11/2024 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 01/11/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 85 updated: Result Date to 01/11/2024; Result Type to Held - Motion Granted

01/08/2024 Reply Plaintiff's Reply Brief in Support of Applications for Right to Attach Orders Against Defendants Community Care Rehab Center, LLC and Villa Rancho Bernardo Health Care, LLC; Filed by: MED-PLUS PHARMACY, LLC (Plaintiff)

01/08/2024 Objection Plaintiff's Evidentiary Objections to Declarations and Evidence Filed in Support of Defendant's Opposition to Its Applications for Right to Attach Orders Against Defendants Community Care Rehab Ctr, LLC and Villa Rancho Bernardo Health Care; Filed by: MED-PLUS PHARMACY, LLC (Plaintiff)

01/08/2024 Proof of Service (not Summons and Complaint); Filed by: MED-PLUS PHARMACY, LLC (Plaintiff); As to: MED-PLUS PHARMACY, LLC (Plaintiff); ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant) et al.

01/05/2024 Updated -- MED-PLUS PHARMACY, LLC (Plaintiff): Organization Name changed from MED-PLUS PHARMACY, INC. to MED-PLUS PHARMACY, LLC

01/04/2024 Opposition DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

01/04/2024 Declaration DECLARATION OF JORDAN MADER IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATION FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS

COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration DECLARATION OF MICAH RHEAD IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Proof of Service (not Summons and Complaint); Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration DECLARATION OF ADRIAN DEHGHANMANESH IN SUPPORT OF DEFENDANT VILLA RANCHO BERNARDO HEALTH CARE, LLC'SNOTICE OF OPPOSITION TO RIGHT TO ATTACH ORDER AND CLAIM OF EXEMPTION; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration DECLARATION OF ADRIAN DEHGHANMANESH IN SUPPORT OF DEFENDANT COMMUNITY CARE REHAB CENTER, LLC'S NOTICE OF OPPOSITION TO RIGHT TO ATTACH ORDER AND CLAIM OF EXEMPTION; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Notice of Opposition to Right to Attach Order and Claim of Exemption; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Notice of Opposition to Right to Attach Order and Claim of Exemption, Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration DECLARATION OF GARY K. BRUCKER, JR. IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Objection DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC's JOINT EVIDENTIARY OBJECTIONS TO DECLARATIONS OF NEIL FARAGE IN SUPPORT OF PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDER AGAINST DEFENDANTS; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration DECLARATION OF ADRIAN DEHGHANMANESH IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TOPLAINTIFF'S APPLICATION__ FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC__; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Stipulation and Order Stipulation and Proposed Order Amending the Complaint; Signed and Filed by: MED-PLUS PHARMACY, LLC (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

01/04/2024 Updated -- Stipulation and Order Stipulation and Proposed Order Amending the Complaint; Filed By: MED-PLUS PHARMACY, INC. (Plaintiff); Result: Granted ; Result Date: 01/04/2024

01/03/2024 Proof of Service (not Summons and Complaint); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

11/07/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Application for Right to Attach Order, Temporary Protective Order, etc. Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: COMMUNITY CARE REHAB CENTER, LLC (Defendant)

11/07/2023 Proof of Service by Mail; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: COMMUNITY CARE REHAB CENTER, LLC (Defendant); After Substituted Service of Summons and Complaint ?: No

11/07/2023 Memorandum of Points & Authorities; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 01/11/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 85

11/07/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Memorandum of Points & Authorities; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Proof of Service by Mail; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant); After Substituted Service of Summons and Complaint ?: No

11/07/2023 Application for Right to Attach Order, Temporary Protective Order, etc; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant)

11/07/2023 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 01/11/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 85

07/27/2023 Notice of Ruling; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

07/14/2023 Final Status Conference scheduled for 10/18/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 39

07/14/2023 Jury Trial scheduled for 10/29/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 39

07/14/2023 Post-Mediation Status Conference scheduled for 06/24/2024 at 08:30 AM in Stanley Mosk Courthouse at Department 39

07/14/2023 Minute Order (Non-Appearance Case Review)

07/14/2023 Certificate of Mailing for (Non-Appearance Case Review) of 07/14/2023; Filed by: Clerk

07/14/2023 On the Court's own motion, Case Management Conference scheduled for 07/26/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 39 Not Held - Advanced and Vacated on 07/14/2023

06/29/2023 Objections to Declaration of Adrian Dehghanmanesh Submitted in Opposition to Applications for Right to Attach Orders; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/29/2023 Decision on Applications for Right to Attach Orders; Filed by: Clerk

06/29/2023 Minute Order (Hearing on Application for Writ of Attachment against (1) Def...)

06/29/2023 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 06/29/2023 at 09:30 AM in Stanley Mosk Courthouse at Department 85 updated: Result Date to 06/29/2023; Result Type to Held - Motion Denied

06/27/2023 Reply Brief ISO Application for Right to Attach Order; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/27/2023 Objection to Decl. of A. Dehghanmanesh Submitted in Opp to Appl. for Right to Attach Order; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/22/2023 Opposition To Plaintiffs Application For Right To Attach Orders Against Defendants Anaheim Healthcare Center, LLC And Bartlett Care Center, LLC; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Notice of Opposition to Right to Attach Order and Claim of Exemption; Filed by: BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Notice of Opposition to Right to Attach Order and Claim of Exemption; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

06/22/2023 Objection Defendants Anaheim Healthcare Center, LLC And Bartlett Care Center, LLC Joint Evidentiary Objections To Declarations Of Neil Farage In Support Of Plaintiffs Applications For Right To Attach Order Against

Defendants; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Declaration Declaration Of Adrian Dehghanmanesh In Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Declaration Declaration Of Channon Balana Yin Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Declaration Declaration Of John Kimball In Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/06/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/06/2023 Memorandum of Points & Authorities; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/06/2023 Application for Right to Attach Order, Temporary Protective Order, etc. Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

06/06/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/06/2023 Memorandum of Points & Authorities; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/06/2023 Application for Right to Attach Order, Temporary Protective Order, etc. Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: BARTLETT CARE CENTER, LLC (Defendant)

06/06/2023 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 06/29/2023 at 09:30 AM in Stanley Mosk Courthouse at Department 85

05/31/2023 Minute Order (Non-Appearance Case Review)

05/31/2023 Certificate of Mailing for (Non-Appearance Case Review) of 05/31/2023; Filed by: Clerk

05/31/2023 Updated -- Gary Keith Brucker (Attorney): Organization Name: Lewis Brisbois Bisgaard & Smith LLP; Middle Name changed from K. to Keith

05/31/2023 Address for Gary Keith Brucker (Attorney) null

05/31/2023 On the Court's own motion, Case Management Conference scheduled for 06/08/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 39 Not Held - Advanced and Continued - by Court was rescheduled to 07/26/2023 08:30 AM

05/24/2023 Case Management Statement; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant); COLLEGE VISTA, LLC (Defendant); COUNTRY OAKS PARTNERS, LLC (Defendant); COMMUNITY CARE REHAB CENTER, LLC (Defendant); F. & B. HEALTHCARE (Defendant); GARDEN PARK CARE CENTER, LLC (Defendant); GIBRALTAR CONVALESCENT HOSPITAL, INC. (Defendant); GORDON LANE HEALTHCARE, LLC (Defendant); HERITAGE MANOR HEALTHCARE, LLC (Defendant); INLAND MEDICAL ENTERPRISES, INC. (Defendant); MJB PARTNERS, LLC (Defendant); MONTERREY PARK CONVALESCENT HOSPITAL, INC. (Defendant); PARAMOUNT CONVALESCENT GROUP, INC. (Defendant); PARK REGENCY CARE, LLC (Defendant); PC CARE, LLC (Defendant); PUENTE PARTNERS, LLC (Defendant); RIVERSIDE EQUITIES, LLC (Defendant); SIERRA VIEW CARE HOLDINGS, LLC (Defendant); SUN MAR HEALTHCARE, INC. (Defendant); VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant); WYNGATE NURSING CENTER (Defendant)

05/23/2023 Case Management Statement; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

05/19/2023 Updated -- Ex Parte Application for Temporary Protective Order: Name Extension changed from In support of Temporary Protective Order to for Temporary Protective Order ; As To Parties changed from ANAHEIM HEALTHCARE CENTER, LLC (Defendant) to ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

05/19/2023 Updated -- Ex Parte Application for Temporary Protective Order: Filed By: MED-PLUS PHARMACY, INC. (Plaintiff); Result: Denied ; Result Date: 05/19/2023

05/19/2023 Minute Order (Hearing on Ex Parte Application of Plaintiff for Temporary Pr...)

05/19/2023 Hearing on Ex Parte Application In support of Temporary Protective Order scheduled for 05/19/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 85 updated: Result Date to 05/19/2023; Result Type to Held - Motion Denied

05/18/2023 Ex Parte Application In support of Temporary Protective Order; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

05/18/2023 Declaration In support of Temporary Protective Order; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

05/18/2023 Declaration of Richard Fond re Ex Parte for Temporary Protective Order; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

05/18/2023 Hearing on Ex Parte Application In support of Temporary Protective Order scheduled for 05/19/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 85

05/18/2023 Opposition Opposition To Plaintiffs Ex Parte Applications For Temporary Protective Orders Against Defendants Anaheim Healthcare Center And Bartlett Care Center; Declaration Of Gary K. Brucker, Jr. Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant); COLLEGE VISTA, LLC (Defendant); COUNTRY OAKS PARTNERS, LLC (Defendant); COMMUNITY CARE REHAB CENTER, LLC (Defendant); F. & B. HEALTHCARE (Defendant); GARDEN PARK CARE CENTER, LLC (Defendant); GIBRALTAR CONVALESCENT HOSPITAL, INC. (Defendant); GORDON LANE HEALTHCARE, LLC (Defendant); HERITAGE MANOR HEALTHCARE, LLC (Defendant); INLAND MEDICAL ENTERPRISES, INC. (Defendant); MJB PARTNERS, LLC (Defendant); MONTERREY PARK CONVALESCENT HOSPITAL, INC. (Defendant); PARAMOUNT CONVALESCENT GROUP, INC. (Defendant); PARK REGENCY CARE, LLC (Defendant); PC CARE, LLC (Defendant); PUENTE PARTNERS, LLC (Defendant); RIVERSIDE EQUITIES, LLC (Defendant); SIERRA VIEW CARE HOLDINGS, LL

03/30/2023 Answer; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant); COLLEGE VISTA, LLC (Defendant); COUNTRY OAKS PARTNERS, LLC (Defendant); COMMUNITY CARE REHAB CENTER, LLC (Defendant); F. & B. HEALTHCARE (Defendant); GARDEN PARK CARE CENTER, LLC (Defendant); GIBRALTAR CONVALESCENT HOSPITAL, INC. (Defendant); GORDON LANE HEALTHCARE, LLC (Defendant); HERITAGE MANOR HEALTHCARE, LLC (Defendant); INLAND MEDICAL ENTERPRISES, INC. (Defendant); MJB PARTNERS, LLC (Defendant); MONTERREY PARK CONVALESCENT HOSPITAL, INC. (Defendant); PARAMOUNT CONVALESCENT GROUP, INC. (Defendant); PARK REGENCY CARE, LLC (Defendant); PC CARE, LLC (Defendant); PUENTE PARTNERS, LLC (Defendant); RIVERSIDE EQUITIES, LLC (Defendant); SIERRA VIEW CARE HOLDINGS, LLC (Defendant); SUN MAR HEALTHCARE, INC. (Defendant); VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant); WYNGATE NURSING CENTER (Defendant); As to: MED-PLUS PHARMACY, INC. (Plaintiff)

03/01/2023 Notice and Acknowledgment of Receipt; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

03/01/2023 Proof of Service (not Summons and Complaint); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al

02/15/2023 Notice of Case Management Conference; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS

NURSING CENTER (Defendant) et al.

02/10/2023 Case Management Conference scheduled for 06/08/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 39

02/10/2023 Case Management Conference scheduled for 07/26/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 39

02/10/2023 Address for Robert David Bergman (Attorney) updated

02/10/2023 Notice of Case Management Conference; Filed by: Clerk

02/07/2023 Case assigned to Hon. Stephen I. Goorvitch in Department 39 Stanley Mosk Courthouse

02/06/2023 Complaint; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

02/06/2023 Civil Case Cover Sheet; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

02/06/2023 Summons on Complaint; Issued and Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

02/06/2023 Alternate Dispute Resolution Packet; Filed by: Clerk

02/06/2023 First Amended General Order re: Mandatory Electronic Filing; Filed by: Clerk

02/06/2023 Voluntary Efficient Litigation Stipulation Packet; Filed by: Clerk

02/06/2023 Notice of Case Assignment - Unlimited Civil Case; Filed by: Clerk

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4, 5, 6. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
02/15/2023	PENDING	DE	WILMINGTON	NEW CASTLE COUNTY
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N23C-02-128		NEW CASTLE SUPERIOR COURT		
Reason/Charge				
BREACH OF CONTRACT				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
POLARIS PHARMACY SERVICES VS BONAMOUR HEALTH			LAWSUIT	
Name of Business/Industry/Entity				
POLARIS PHARMACY SERVICES OF PENNSYLVANIA				

Provide explanation below:

CEO

Original Signature (electronic, copies or stamps not accepted)

10/2/24

Date

Report Selection Criteria

Case ID: N23C-02-128
Docket Start Date:
Docket Ending Date:

Case Description

Case ID: N23C-02-128 - POLARIS PHARM SERV V BONAMOUR HEALTH
Filing Date: Wednesday, February 15th, 2023
Type: C2 - CCLD: COMPLEX COM LIT DIVISION
Status: BANRUPTCY - BANKRUPTCY

Related Cases

No related cases were found.

Case Event Schedule

No case events were found.

Case Parties

Seq #	Assoc	Party End Date	Type	ID	Name
1	2		PLAINTIFF	@3764760	**POLARIS PHARMACY SERVICES**
Address:	*unavailable*		**Aliases:**	*none*	
2	1		ATTORNEY FOR PLAINTIFF	004356	**FIRTH III, WILLIAM R**
Address:	COHEN SEGLIAS PALLAS GREENHALL 500 DELAWARE AVENUE, SUITE 730 WILMINGTON DE 198010000		**Aliases:**	*none*	
3	7		DEFENDANT	@3764761	**BONAMOUR HEALTH GROUP**

Address:	*unavailable*		**Aliases:**	*none*	
4		09-MAY-2023	JUDGE	004673	**LEGROW, ABIGAIL M**
Address:	SUPERIOR COURT 500 NORTH KING STREET SUITE 11400 WILMINGTON DE 19801 (302)651-3963		**Aliases:**	*none*	
5			SHERIFF	KCSHRF	**KENT COUNTY, SHERIFF**
Address:	*unavailable*		**Aliases:**	*none*	
6			SHERIFF	NCSHRF	**NEW CASTLE COUNTY, SHERIFF**
Address:	87 READS WAY NEW CASTLE DE 19720		**Aliases:**	*none*	
7	3		ATTORNEY FOR DEFENDANT	003496	**FASIC, G. KEVIN**
Address:	OFFIT KURMAN 222 DELAWARE AVENUE SUITE 1105 WILMINGTON DE 19801		**Aliases:**	FASIC, G KEVIN	
8		10-MAY-2023	JUDGE	TBAJ	**JUDGE, TO BE ASSIGNED**
Address:	*unavailable*		**Aliases:**	*none*	
9			JUDGE	004981	**ADAMS, MEGHAN A**
Address:	SUPERIOR COURT LEONARD L. WILLIAMS JUSTICE CT 500 NORTH KING		**Aliases:**	*none*	

	STREET WILMINGTON DE 19801		

Docket Entries

Filing Date	Description	Name	Monetary
15-FEB-2023 01:26 PM	INIT FILING CCLD	FIRTH III, WILLIAM R	
Entry:	INITIAL FILING CCLD - COMPLEX COMMERCIAL LITIGATION DIVISION DATE DOCKETED: FEBRUARY 18, 2023		
15-FEB-2023 01:26 PM	INITIAL COMPLAINT	FIRTH III, WILLIAM R	
Entry:	INITIAL COMPLAINT DATE DOCKETED: FEBRUARY 18, 2023 COMPLAINT CASE INFORMATION STATEMENT EXHIBIT A TO COMPLAINT EXHIBIT B TO COMPLAINT EXHIBIT C TO COMPLAINT EXHIBIT D TO COMPLAINT EXHIBIT E TO COMPLAINT EXHIBIT F TO COMPLAINT EXHIBIT G TO COMPLAINT PRAECIPE TO COMPLAINT SUMMONS TO COMPLAINT ACCEPTED BY: JDB TRANSACTION ID: 69155555		
21-FEB-2023 03:32 PM	WRIT ISSUED		
Entry:	WRIT(S) ISSUED ON DATE DOCKETED: FEBRUARY 22, 2023 (1) WRIT ISSUED ON 2-20-23, CHECK #5611 $30.00, TO NEW CASTLE COUNTY SHERIFF ACCEPTED BY: RH TRANSACTION ID: 69188972		
27-FEB-2023 09:16 AM	WRIT RETURN (GENERIC)	NEW CASTLE COUNTY, SHERIFF	
Entry:	WRIT RETURNED: DATE DOCKETED: MARCH 1, 2023 ENTITY - BONAMOUR HEALTH GROUP, LLC. ON 2/22/2023 AT 12:14 PM A COPY OF THE WITHIN WRIT TOGETHER WITH A COPY OF THE SUMMONS AND COMPLAINT WERE SERVED UPON LITIGATION MANAGEMENT REPRESENTATIVE, A REPRESENTATIVE FOR THE REGISTERED AGENT CORPORATION SERVICE COMPANY 251 LITTLE FALLS DRIVE WILMINGTON, DE 19808. ACCEPTED BY: RH TRANSACTION ID: 69223030		
14-MAR-2023 11:55 AM	ANSWER & COUNTERCLAIM	FASIC, G. KEVIN	

Entry:	ANSWER AND COUNTERCLAIM DATE DOCKETED: MARCH 15, 2023 DEFENDANT'S ANSWER WITH COUNTERCLAIMS CERTIFICATE OF SERVICE TO DEFENDANT'S ANSWER WITH COUNTERCLAIMS CASE INFORMATION STATEMENT TO DEFENDANT'S ANSWER WITH COUNTERCLAIMS ENTRY OF APPEARANCE OF G. KEVIN FASIC ON BEHALF OF DEFENDANT ACCEPTED BY: SD TRANSACTION ID: 69336247		
16-MAR-2023 08:28 AM	REFERRED TO CASE SCHEDULING		
Entry:	REFERRED TO CASE SCHEDULING DATE DOCKETED: MARCH 16, 2023		
30-MAR-2023 12:57 PM	ANSWER TO COUNTERCLAIM	FIRTH III, WILLIAM R	
Entry:	ANSWER TO COUNTERCLAIM DATE DOCKETED: MARCH 31, 2023 PLAINTIFF'S ANSWER TO DEFENDANT'S COUNTERCLAIM CERTIFICATE OF SERVICE TO PLAINTIFF'S ANSWER TO DEFENDANT'S COUNTERCLAIM ACCEPTED BY: TNW TRANSACTION ID: 69693405		
11-MAY-2023 01:45 PM	LETTER		
Entry:	LETTER DATE DOCKETED: MAY 12, 2023 THE ABOVE CAPTIONED CASE HAS BEEN REASSIGNED TO JUDGE MEGHAN A ADAMS. PLEASE REMEMBER THAT ON ALL FUTURE DOCUMENTS AND FILINGS ON THIS CASE, COUNSEL MUST REFERENCE THE ASSIGNED JUDGE BY INCLUDING THE JUDGE'S INITIALS (MAA-CCLD) AS A SUFFIX TO THE CIVIL ACTION NUMBER. ACCEPTED BY: TNW TRANSACTION ID: 69996405		
19-MAY-2023 10:13 AM	NOTICE	ADAMS, MEGHAN A	
Entry:	NOTICE DATE DOCKETED: MAY 20, 2023 ORDER SIGNED BY: ADAMS, MEGHAN PER THE EMAIL CORRESPONDENCE BETWEEN CHAMBERS AND COUNSEL ON 5-19-23, A STATUS CONFERENCE WILL BE HELD ON MAY 19TH, 2023 AT 10:45 A.M. VIA ZOOM ACCEPTED BY: TRANSACTION ID: 70046520		
19-MAY-2023 02:39 PM	JUDICIAL ACTION FORM		
Entry:	JUDICIAL ACTION FORM DATE DOCKETED: MAY 20, 2023 JUDICIAL ACTION FORM FROM STATUS CONFERENCE HELD ON FRIDAY, MAY 19,		

	2023 AT 10:45 A.M. VIA ZOOM ACCEPTED BY: SR TRANSACTION ID: 70050068		
06-JUN-2023 12:23 PM	STIPULATION	FASIC, G. KEVIN	
Entry:	STIPULATION DATE DOCKETED: JUNE 7, 2023 JOINT STIPULATED CASE MANAGEMENT ORDER ACCEPTED BY: SR TRANSACTION ID: 70148008		
08-JUN-2023 07:42 PM	ORDER	ADAMS, MEGHAN A	
Entry:	ORDER DATE DOCKETED: JUNE 10, 2023 ORDER SIGNED BY: ADAMS, MEGHAN GRANTED (JOINT STIPULATED CASE MANAGEMENT ORDER) ADAMS, J. 6-8-23. ACCEPTED BY: SR TRANSACTION ID: 70168936		
29-JUN-2023 10:45 AM	LETTER	FIRTH III, WILLIAM R	
Entry:	LETTER DATE DOCKETED: JUNE 30, 2023 LETTER TO JUDICIAL CASE MANAGER FOR JUDGE ADAMS DATED JUNE 29, 2023 FROM WILLIAM R. FIRTH, III, ESQUIRE RE: NEW ADDRESS AND CONTACT INFORMATION ACCEPTED BY: SR TRANSACTION ID: 70283800		
29-JUN-2023 11:14 AM	NOTICE SRV REQUEST PRODUCTION	FIRTH III, WILLIAM R	
Entry:	NOTICE OF SERVICE OF REQUEST FOR PRODUCTION DATE DOCKETED: JUNE 30, 2023 NOTICE OF SERVICE OF POLARIS PHARMACY SERVICES OF PENNSYLVANIA, LLC'S FIRST REQUEST FOR PRODUCTION OF DOCUMENTS DIRECTED TO DEFENDANT - SERVED VIA EMAIL ON JUNE 29, 2023 ACCEPTED BY: SR TRANSACTION ID: 70284205		
30-JUN-2023 01:37 PM	NOTICE SRV REQUEST PRODUCTION	FASIC, G. KEVIN	
Entry:	NOTICE OF SERVICE OF REQUEST FOR PRODUCTION DATE DOCKETED: JULY 2, 2023 NOTICE OF SERVICE FOR DEFENDANT'S REQUEST FOR FIRST SET OF INTERROGATORIES AND REQUESTS FOR PRODUCTION OF DOCUMENTS TO PLAINTIFF CERTIFICATE OF SERVICE TO NOTICE OF SERVICE FOR DEFENDANT'S REQUEST FOR FIRST SET OF INTERROGATORIES AND REQUESTS FOR PRODUCTION OF DOCUMENTS TO PLAINTIFF ACCEPTED BY: VP TRANSACTION ID: 70293778		

22-AUG-2023 11:22 AM	NOTICE SRV OF INTERROGATORIES	FIRTH III, WILLIAM R	
Entry:	NOTICE OF SERVICE OF INTERROGATORIES DATE DOCKETED: AUGUST 23, 2023 NOTICE OF SERVICE OF POLARIS PHARMACY SERVICES OF PENNSYLVANIA, LLC'S FIRST SET OF INTERROGATORIES DIRECTED TO DEFENDANT - SERVED VIA EMAIL ON AUGUST 22, 2023 ACCEPTED BY: OA TRANSACTION ID: 70689234		
22-AUG-2023 12:59 PM	LETTER FOR JUDICIAL REVIEW	FASIC, G. KEVIN	
Entry:	LETTER FOR JUDICIAL REVIEW DATE DOCKETED: AUGUST 24, 2023 LETTER TO THE HONORABLE JUDGE ADAMS REGARDING THE PARTIES CONFIDENTIALITY STIPULATION AND ORDER STIPULATION AND PROPOSED ORDER GOVERNING THE PRODUCTION AND EXCHANGE OF CONFIDENTIAL AND HIGHLY CONFIDENTIAL INFORMATION AGREEMENT TO DISCOVERY CONFIDENTIALITY STIPULATION AND ORDER ACCEPTED BY: TRANSACTION ID: 70690752		
23-AUG-2023 10:55 AM	ORDER	ADAMS, MEGHAN A	
Entry:	ORDER DATE DOCKETED: AUGUST 24, 2023 ORDER SIGNED BY: ADAMS, MEGHAN GRANTED (STIPULATION AND PROPOSED ORDER GOVERNING THE PRODUCTION AND EXCHANGE OF CONFIDENTIAL AND HIGHLY CONFIDENTIAL INFORMATION) ACCEPTED BY: OA TRANSACTION ID: 70698845		
30-OCT-2023 05:05 PM	LETTER FOR JUDICIAL REVIEW	FASIC, G. KEVIN	
Entry:	LETTER FOR JUDICIAL REVIEW DATE DOCKETED: NOVEMBER 2, 2023 LETTER TO THE HONORABLE MEGHAN A. ADAMS REGARDING STIPULATION A PROPOSED ORDER TO EXTEND DOCUMENT PRODUCTION DEADLINE PROPOSED STIPULATION AND AMENDED CASE MANAGEMENT ORDER ACCEPTED BY: TRANSACTION ID: 71234189		
01-NOV-2023 02:15 PM	ORDER	ADAMS, MEGHAN A	
Entry:	ORDER DATE DOCKETED: NOVEMBER 3, 2023 ORDER SIGNED BY: ADAMS, MEGHAN DENIED IN PART - STIPULATION AND AMENDED CASE MANAGEMENT ORDER. ADAMS, J. NOVEMBER 1, 2023 ACCEPTED BY: AK TRANSACTION ID: 71282675		

08-NOV-2023 10:31 AM	NOTICE OF SERVICE	FASIC, G. KEVIN	
Entry:	NOTICE OF SERVICE DATE DOCKETED: NOVEMBER 9, 2023 NOTICE OF SERVICE OF DISCOVERY RESPONSES DIRECTED TO PLAINTIFF CERTIFICATE OF SERVICE TO THE NOTICE OF SERVICE OF DISCOVERY RESPONSES DIRECTED TO PLAINTIFF ACCEPTED BY: OA TRANSACTION ID: 71355583		
17-NOV-2023 02:28 PM	NOTICE SRV ANS INTERROGATORIES	FIRTH III, WILLIAM R	
Entry:	NOTICE OF SERVICE OF ANSWERS TO INTERROGATORIES DATE DOCKETED: NOVEMBER 18, 2023 NOTICE OF SERVICE OF PLAINTIFF POLARIS PHARMACY SERVICES OF PENNSYLVANIA, LLC'S RESPONSES TO DEFENDANT'S FIRST SET OF INTERROGATORY REQUESTS CERTIFICATE OF SERVICE ACCEPTED BY: OA TRANSACTION ID: 71440418		
11-JAN-2024 02:17 PM	NOTICE OF SERVICE	FIRTH III, WILLIAM R	
Entry:	NOTICE OF SERVICE DATE DOCKETED: JANUARY 13, 2024 NOTICE OF SERVICE OF SUBPOENA DUCES TECUM ON SPECIALTY RX PA HOLDINGS, LLC CERTIFICATE OF SERVICE ACCEPTED BY: OA TRANSACTION ID: 71792059		
11-JAN-2024 02:20 PM	NOTICE OF SERVICE	FIRTH III, WILLIAM R	
Entry:	NOTICE OF SERVICE DATE DOCKETED: JANUARY 13, 2024 NOTICE OF SERVICE OF SUBPOENA DUCES TECUM ON SPECIALTY RX INC. CERTIFICATE OF SERVICE ACCEPTED BY: OA TRANSACTION ID: 71792122		
06-FEB-2024 02:41 PM	NOTICE OF DEPOSITION	FIRTH III, WILLIAM R	
Entry:	NOTICE OF DEPOSITION OF DATE DOCKETED: FEBRUARY 8, 2024 PLAINTIFF POLARIS PHARMACY SERVICES OF PENNSYLVANIA, LLC'S NOTICE OF DEPOSITION OF DEFENDANT BONAMOUR HEALTH GROUP, LLC'S CORPORATE DESIGNEE ON FEBRUARY 28, 2024 AT 9:30 A.M. CERTIFICATE OF SERVICE ACCEPTED BY: OA TRANSACTION ID: 71964550		

13-FEB-2024 01:33 PM	MOTION FOR PRO HAC VICE	FIRTH III, WILLIAM R	
Entry:	MOTION FOR PRO HAC VICE DATE DOCKETED: FEBRUARY 14, 2024 MOTION FOR ADMISSION PRO HAC VICE OF GERARD J. GAENG, ESQUIRE AND CERTIFICATE OF SERVICE CERTIFICATION OF GERARD J. GAENG, ESQUIRE IN SUPPORT OF PRO HAC VICE ADMISSION NOTICE OF MOTION FOR ADMISSION PRO HAC VICE OF GERARD J. GAENG, ESQUIRE GAENG, GERARD J.: PROPOSED ORDER GRANTING ADMISSION PRO HAC VICE OF GERARD J. GAENG, ESQUIRE ACCEPTED BY: AK TRANSACTION ID: 72028188		
14-FEB-2024 11:17 AM	ORDER - PRO HAC VICE	ADAMS, MEGHAN A	
Entry:	ORDER - PRO HAC VICE DATE DOCKETED: FEBRUARY 15, 2024 ORDER SIGNED BY: ADAMS, MEGHAN GRANTED (GAENG, GERARD J.: PROPOSED ORDER GRANTING ADMISSION PRO HAC VICE OF GERARD J. GAENG, ESQUIRE) ACCEPTED BY: OA TRANSACTION ID: 72035735		
14-FEB-2024 02:54 PM	LETTER FOR JUDICIAL REVIEW	FASIC, G. KEVIN	
Entry:	LETTER FOR JUDICIAL REVIEW DATE DOCKETED: FEBRUARY 15, 2024 LETTER TO THE HONORABLE MEGHAN ADAMS REGARDING SECOND STIPULATION AND PROPOSED ORDER AMENDING CASE MANAGEMENT ORDER SECOND STIPULATION AND PROPOSED ORDER AMENDING CASE MANAGEMENT ORDER ACCEPTED BY: OA TRANSACTION ID: 72039799		
15-FEB-2024 11:15 AM	ORDER	ADAMS, MEGHAN A	
Entry:	ORDER DATE DOCKETED: FEBRUARY 16, 2024 ORDER SIGNED BY: ADAMS, MEGHAN GRANTED (SECOND STIPULATION AND PROPOSED ORDER AMENDING CASE MANAGEMENT ORDER) ACCEPTED BY: OA TRANSACTION ID: 72046867		
26-FEB-2024 01:20 PM	MOTION	FASIC, G. KEVIN	
Entry:	MOTION DATE DOCKETED: FEBRUARY 27, 2024 MOTION TO WITHDRAW AS COUNSEL NOTICE OF MOTION TO WITHDRAW AS COUNSEL PROPOSED ORDER TO MOTION TO WITHDRAW AS COUNSEL CERTIFICATE OF SERVICE TO MOTION TO WITHDRAW AS COUNSEL ACCEPTED BY: KC TRANSACTION ID: 72147092		

04-MAR-2024 01:04 PM	RE-NOTICE	FASIC, G. KEVIN	
Entry:	RE-NOTICE DATE DOCKETED: MARCH 5, 2024 RE-NOTICE OF MOTION TO WITHDRAW AS COUNSEL SCHEDULED FOR THURSDAY, MARCH 14, 2024 AT 9:15 AM CERTIFICATE OF SERVICE TO RE-NOTICE OF MOTION TO WITHDRAW AS COUNSEL SCHEDULED FOR THURSDAY, MARCH 14, 2024 AT 9:15 AM ACCEPTED BY: KC TRANSACTION ID: 72230740		
07-MAR-2024 02:06 PM	RESPONSE	FIRTH III, WILLIAM R	
Entry:	RESPONSE DATE DOCKETED: MARCH 8, 2024 RESPONSE OF PLAINTIFF POLARIS PHARMACY SERVICES OF PENNSYLVANIA, LLC TO MOTION TO WITHDRAW AS COUNSEL PROPOSED ORDER CERTIFICATE OF SERVICE ACCEPTED BY: KC TRANSACTION ID: 72326050		
14-MAR-2024 09:27 AM	ORDER	ADAMS, MEGHAN A	
Entry:	ORDER DATE DOCKETED: MARCH 15, 2024 ORDER SIGNED BY: ADAMS, MEGHAN GRANTED WITH AMENDMENTS (PROPOSED ORDER TO MOTION TO WITHDRAW AS COUNSEL) ACCEPTED BY: KC TRANSACTION ID: 72514416		
14-MAR-2024 09:33 AM	JUDICIAL ACTION FORM		
Entry:	JUDICIAL ACTION FORM DATE DOCKETED: MARCH 15, 2024 JUDICIAL ACTION FORM FROM MARCH 14, 2024 DEFENDANTS MOTION TO WITHDRAW. MOTION IS GRANTED. ACCEPTED BY: KC TRANSACTION ID: 72514430		
14-MAR-2024 02:58 PM	NOTICE OF SERVICE	FASIC, G. KEVIN	
Entry:	NOTICE OF SERVICE DATE DOCKETED: MARCH 15, 2024 NOTICE OF SERVICE OF ORDER GRANTING OFFIT KURMAN, P.A. TO WITHDRAW AS COUNSEL ACCEPTED BY: KC TRANSACTION ID: 72522130		
22-APR-2024 02:29 PM	LETTER FOR JUDICIAL REVIEW	FIRTH III, WILLIAM R	
Entry:	LETTER FOR JUDICIAL REVIEW DATE DOCKETED: APRIL 23, 2024 LETTER FROM WILLIAM R FIRTH, ESQ. TO THE HONORABLE MEGHAN A. ADAMS RE; POLARIS V. BONAMOUR MOTION FOR DEFAULT JUDGMENT AND DEFENDANT'S INVOLUNTARY CHAPTER 7 BANKRUPTCY FILING		

	EXHIBIT A CERTIFICATE OF SERVICE ACCEPTED BY: ERM TRANSACTION ID: 72798811		
25-APR-2024 11:11 AM	SO NOTED	ADAMS, MEGHAN A	
Entry:	SO NOTED DATE DOCKETED: APRIL 27, 2024 ORDER SIGNED BY: ADAMS, MEGHAN SO NOTED (LETTER FROM WILLIAM R FIRTH, ESQ. TO THE HONORABLE MEGHAN A. ADAMS RE; POLARIS V. BONAMOUR MOTION FOR DEFAULT JUDGMENT AND DEFENDANT'S INVOLUNTARY CHAPTER 7 BANKRUPTCY FILING) ACCEPTED BY: JH TRANSACTION ID: 72828630		
23-JUL-2024 01:14 PM	EVENT CONTINUED / RESCHEDULED		
Entry:	EVENT CONTINUED / RESCHEDULED DATE DOCKETED: SEPTEMBER 11, 2024		
23-JUL-2024 01:14 PM	EVENT CONTINUED / RESCHEDULED		
Entry:	EVENT CONTINUED / RESCHEDULED DATE DOCKETED: SEPTEMBER 11, 2024		
23-JUL-2024 01:15 PM	EVENT CONTINUED / RESCHEDULED		
Entry:	EVENT CONTINUED / RESCHEDULED DATE DOCKETED: SEPTEMBER 11, 2024		
23-JUL-2024 02:23 PM	BANKRUPTCY LETTER		
Entry:	BANKRUPTCY LETTER DATE DOCKETED: JULY 24, 2024 BANKRUPTCY DORMANT DOCKET LETTER TO COUNSEL ON JULY 23, 2024. ACCEPTED BY: AK TRANSACTION ID: 73771556		

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4, 5, 6. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
03/19/2019	12/08/2021	MN	MINNEAPOLIS	RAMSEY
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
265679		MINNESOTA BOARD OF PHARMACY		
Reason/Charge				
PHARMACY WAS ALLOWING REMOTE ORDER ENTRY				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
PLEASE SEE ATTACHED			HEARING	
Name of Business/Industry/Entity				
POLARIS PHARMACY SERVICES OF MINNESOTA, LLC				

Provide explanation below:

CEO

Original Signature (electronic, copies or stamps not accepted)

10/2/24

Date

MINNESOTA
BOARD OF PHARMACY

DISCIPLINARY ACTIVITY: September, October, and December 2021

The Board took the following disciplinary action involving **pharmacists** during these meetings:

Anderson, Jared Joel, License # 119950. In 2013, Licensee self-reported to the Minnesota Health Professionals Services Program ("HPSP") due to alcohol use. Licensee was satisfactorily discharged from HPSP in 2016.

On February 7, 2018, Licensee contacted HPSP to report a relapse to alcohol use and enrolled in HPSP on February 7, 2018. At the time Licensee was employed as Operations Manager of a Minnesota hospital pharmacy ("Pharmacy"). On February 9, 2018, Licensee signed another three-year Participation Agreement with HPSP.

On June 26, 2020, Licensee falsified his urine screening documentation submitted to HPSP by whiting out the dates from his June 17, 2020 form and writing in June 26, 2020. The following day, Licensee notified HPSP of the falsification. Subsequent testing confirmed Licensee had not relapsed with alcohol.

Licensee was satisfactorily discharged from HPSP in February 2021. Subsequently, in February 2021, Licensee relapsed with alcohol.

On March 5, 2021 Licensee diverted an unknown quantity of diazepam 10 mg tablets from the Pharmacy. Licensee falsely reported that a retired medical doctor

removed 10 tablets of diazepam 10 mg for a patient that had been discharged an hour prior to the time the diazepam was reported dispensed. Licensee diverted the diazepam for his own use, to offset the effects of his continued alcohol use. Diazepam is a schedule IV-controlled substance. During the month of March 2021, Licensee diverted additional quantities of diazepam 10 mg tablets from the Pharmacy, including on the dates of March 12, March 19, and March 22. On March 24, 2021, Licensee reported to work at the Pharmacy while under the influence of alcohol. In April 2021, Licensee self-reported to HPSP and entered into a four-year participation agreement.

Due to these facts, the Board adopted a Stipulation and Consent Order, suspending Dr. Anderson's license, staying the suspension, and ordering him to successfully complete his HPSP participation agreement.

Lindberg, Larry W. License # 112356. Licensee owns pharmacies licensed by the Board. Licensee and his staff engaged in sterile compounding in a manner that was not consistent with USP Chapter 797 standards. As a result, licensee signed Stipulations to Cease Sterile Compounding and Other Practices on May 31, 2016. However, licensee continued to compound allergen extracts, relying on guidelines within USP 797 that only applied to specially trained physicians. The Board directed Licensee to stop compounding the extracts. However, Licensee continued compounding them by leasing office space in a strip mall, moving compounding equipment into the office space, and instructing a pharmacy technician that had been in his employ to compound the extracts in that space. The hood that was used was not recertified after it was moved, the office space was not licensed by the Board as a pharmacy, and it did not meet USP Chapter 797 environmental

standards. Consequently, the Board issued a Stipulation and Consent Order revoking his license.

Mulrooney, Deana L., License # 119041. On May 20, 2020, Licensee and the Board entered into a Stipulation and Consent Order ("Order"). The Order suspended Licensee's license to practice as a pharmacist in the State of Minnesota. The Order stayed the suspension and placed certain conditions upon Licensee's license to practice pharmacy, including that she:

a. Comply with all the terms and requirements set forth in her Participation Agreement and Monitoring Plan with the Health Professionals Services Program ("HPSP"); and,

b. Successfully complete her Participation Agreement with the HPSP and be discharged from any additional monitoring.

On August 24, 2021, Licensee was unsatisfactorily discharged from the HPSP for voluntary withdrawal. Licensee's unsatisfactory discharge from the HPSP for voluntary withdrawal is a violation of the May 20, 2020 Order. Consequently, the Board issued a Stipulation and Consent Order for Voluntary Surrender of her license.

The Board took the following disciplinary action involving **pharmacy technicians** during these meetings:

Drabant, Marissa Rayann, Registration # 738866. During the months of April and May, 2021, the Pharmacist-In-Charge of the pharmacy at which registrant worked, discovered shortages in various controlled substances, including hydrocodone/APAP. A review of the Pharmacy's security video shows that on May 13, 2021, Registrant can be

seen removing a stock bottle of hydrocodone/APAP 7.5/325mg from the pharmacy shelf, opening the bottle, pouring an unknown quantity of tablets into her hand, and then placing her hand and the drugs into the pocket of her clothes. Consequently, the Board issued a Stipulation and Consent Order for Voluntary Surrender.

Hill, Constance, Registration # 744620. In or around December 2020, while working as a pharmacy technician at a community pharmacy ("Pharmacy") in Minnesota, registrant diverted from the Pharmacy 362 alprazolam one milligram tablets; 1,084 alprazolam two milligram tablets; and 250 diazepam two milligram tablets. Registrant failed to cooperate with the Board's investigation and failed to respond to any communication about this case. Consequently, the Board issued a Findings of Fact, Conclusions and Order, revoking her registration.

The Board took the following disciplinary action involving **pharmacies** during these meetings:

904 Prospect Pharmacy, Inc., d/b/a Boca Pharmacy, License # 265165. Licensee Boca Pharmacy is an assumed business name held by 904 Prospect Pharmacy, Inc., a New York State domestic business corporation. Jacob Jamron, R.Ph., is the Chief Executive Office and sole shareholder of 904 Prospect Pharmacy, Inc. and is the current Pharmacist-In-Charge ("PIC") for Licensee. Licensee employed an individual ("Individual 1") whose job responsibilities included submitting original and renewal pharmacy license applications to state boards of pharmacy, on behalf of Licensee. Individual 1 was authorized by Jacob Jamron to sign his name to documents, including pharmacy renewal applications, on behalf of Licensee. On May 28, 2019, and on behalf

of Licensee, Individual 1 submitted to the Board a pharmacy renewal application ("2019 Application"). Individual 1 signed Jacob Jamron's name to the attestation/signature page of the 2019 Application, which read: "I, the undersigned, do hereby certify that all of the information contained in this renewal application is true and correct, and that the firm will be operated in compliance with all applicable laws and regulations."

On June 10, 2019, in response to the 2019 Application, the Board sent Licensee a deficiency letter requesting a copy of an inspection from the home state or a Board approved accreditation program that was not more than twenty-four months old, as required by Minn. Stat. § 151.19, subd. 1(f). On June 27, 2019, Licensee submitted to the Board a copy of a 2016 National Association of Boards of Pharmacy Verified Pharmacy Program Inspection report ("Report"). However, Individual 1 first modified the date of the Report, changing it to November 19, 2018. The date of the Report was modified to make it appear to have been issued within twenty-four months of Licensee's 2019 Application. Licensee admits the Board's approval of the 2019 Application was based in part upon intentionally misleading information submitted by Individual 1.

On June 26, 2020, Licensee submitted to the Board a pharmacy renewal application ("2020 Application"). Licensee failed to disclose within the 2020 Application, a denial of licensure by the Iowa Board of Pharmacy in February of 2020.Licensee submits it did not learn of the Iowa Board of Pharmacy's denial until July 2020, because of the use of an email address Licensee did not closely monitor.

Consequently, the Board issued a Stipulation and Consent Order, reprimanding Licensee and assessing a civil penalty in the amount of $5,000.

CVS Pharmacy #05992, License # 263341. On February 25, 2019, Licensee received a new electronic prescription for a 2-month-old pediatric patient ("Patient A") written for a quantity of 60 ml of ranitidine 75 mg/5 ml syrup ("Rx1"), with instructions to take 1 ml twice a day orally for 30 days and two refills. Licensee's pharmacy staff members incorrectly entered, filled, and labeled Rx1 with prednisolone 15 mg/5 ml solution. On March 23, 2019 and April 24, 2019, Rx1 was refilled, each time incorrectly filled, labeled, and dispensed as prednisolone 15 mg/5 ml solution. Licensee's processes for data entry certification, certification of a filled prescription, and quality assurance second-check, failed to discover and prevent each of the three dispensing errors for Rx1.

On March 14, 2019, Licensee received a new hard copy prescription for an adult patient ("Patient B") written for a quantity of twenty-four buprenorphine-naloxone 4-1 mg sublingual ("SL") films ("Rx2") with instructions to dissolve one film SL three times daily (6a, 12n, 6p), for a total daily dose ("TDD") of 12 mg buprenorphine. Licensee's pharmacy staff members incorrectly entered and filled Rx2 with the wrong strength of the medication, as buprenorphine-naloxone 8-2 mg SL films for a TDD of 24 mg buprenorphine. Licensee's processes for data entry certification, certification of a filled prescription, and quality assurance second-check, failed to discover and prevent the dispensing error for Rx2. Counseling was indicated for Rx2, which Patient B refused. Licensee's Pharmacy Counseling Documentation Log did not include documentation that Patient B refused counseling when Rx2 was initially dispensed, nor the reason counseling was refused.

On March 20, 2019, Licensee was notified by Patient B's clinic of the dispensing error for Rx2. Licensee re-dispensed to Patient B, Rx2 entered and filled with the correct medication strength of buprenorphine-naloxone 4-1 mg SL films, without obtaining a prescription to cover the original dispensing of Rx2 filled with the wrong strength. Licensee dispensed prescriptions to Patient B for the full quantity of two different strengths of buprenorphine-naloxone from one prescription.

Consequently, the Board issued a Stipulation and Consent Order, reprimanding Licensee and assessing a civil penalty in the amount of $5,000.

Polaris Pharmacy Services of Minnesota, LLC, License #265679. Licensee is a closed door, long-term care ("LTC") pharmacy that prepares sterile and non-sterile compounded drug products for dispensing. Licensee has two affiliated pharmacy locations in Florida, both licensed by the Board.

On or about March 19, 2019, two Board Surveyors visited Licensee for the purpose of completing a routine inspection, met with the pharmacist-in-charge, and identified the following:

c. Seven pharmacy technicians registered by the Board and employed by the affiliated Florida pharmacies, were living in Florida but listed their current physical address as Licensee's address in Minnesota.

d. During the inspection, the Board Surveyors cited Licensee for engaging in central services with the affiliated Florida pharmacies, by allowing pharmacy technicians working in Florida to remotely perform data entry of prescription drug information for Minnesota patients into Licensee's Frameworks LTC prescription processing and dispensing software system ("FW- LTC"), followed by verification of the data entry by Licensee's pharmacist staff members working in Minnesota ("Central Service").

Prior to beginning Central Service, Licensee failed to submit a copy of its policy and procedure manual and failed to obtain Board approval to participate in a Central Service arrangement with the affiliated Florida pharmacies. Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the March 2019 citation.

Licensee's nonsterile compounding records failed to include an assigned beyond use date ("BUD") for the final compounded drug product, or included a BUD exceeding those recommended within United States Pharmacopeia, General Chapter 795 for Pharmaceutical Compounding - Nonsterile Preparations ("USP 795"), without documentation of a reference for literature or a stability study applicable to the specific drug product allowing for extension of the BUD. Licensee avers that it responded to these findings by providing education to its staff to ensure compounded components included lot numbers, expiration dates, and BUDs, along with noting the supporting reference sources. Licensee states that it is not aware of any other issues regarding its compliance with BUD requirements since 2019.

On or about March 20, 2019, the Board received a complaint alleging that Licensee was utilizing pharmacy technicians from outside of Minnesota to enter prescription data. On or about April 9, 2019, a Board Surveyor reminded Licensee, after expanding its operations to 24-hours, that pharmacy technicians working outside of its Minnesota location could not be used to help with covering the additional hours that the pharmacy is open, due to the lack of Board approved policies for Central Services with the affiliated Florida

pharmacies. As noted above, Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the Board's concern regarding the use of out-of-state technicians to enter prescription data.

On June 11, 2019, two Board Surveyors visited Licensee for the purpose of an investigation, met with representatives of the Licensee, and identified the following:

a. The pharmacist-in-charge stated that, as far as she was aware, the Florida affiliated pharmacies were the only two locations providing Central Services for Licensee.

b. Licensee utilized a company named IND Consulting ("IND") for emergency kit ("E-kit") billing and entry of patient information when pharmacy services are initiated in a new LTC facility. IND's website states its staff are able to provide services including, but not limited to, billing services, medical record entry, and data entry solutions, with guaranteed staffing in fully operational data centers that are open 24 hours a day and 365 days a year, located within or outside of the United States across the globe in Mexico, India, the Philippines, and Florida. During the conference with the Committee, Licensee admitted that IND consulting had been used to enter prescription data for prescription drug orders ultimately dispensed by its Minnesota pharmacy. Licensee cannot definitively state where individuals affiliated with IND were licensed or physically located when entering such data.

At the end of the visit, the Board Surveyor's provided an Investigative Report requesting additional information and reminding Licensee again that it cannot engage in Central Services without Board approval.

On February 12, 2020, two Board Surveyors visited Licensee for the purposes of an investigation, met with representatives of Licensee, and identified the following:

a. After arriving at 4:36 a.m., one of the Board Surveyors observed two of Licensee's pharmacy technicians were allowed badge access to the pharmacy entrance prior to the arrival of RPh 3 at around 5:55 a.m. One technician was found to be working in the sterile compounding area and another was logged into Licensee's computer. A representative of Licensee later stated that three pharmacy technicians had been given keys and passcodes to access Licensee's pharmacy. During its conference with the Committee, Licensee admitted that this allegation is true, but stated that senior management took corrective action upon learning of the situation, including immediately revoking the access code of all non-pharmacists and physically rekeying all doors within the pharmacy. Licensees avers that periodic security assessments confirm that no unauthorized persons have had access to the pharmacy since February 2020.

b. Six pharmacy technicians, including the IV pharmacy technician, were present in the "filling area" with only one pharmacist, who was the second pharmacist to arrive. Another pharmacist was in an "order entry" area, a distinctly different area separated by a wall and door. The Board Surveyors were told that additional pharmacy technicians were scheduled that morning to perform non-technician "staging or stocking" duties. However, the Board Surveyors observed that the additional pharmacy technicians that were supposedly scheduled to perform non-technician duties, were filling orders in the "filling area" to be checked by the one pharmacist.

Licensee avers that is does not have sufficient information to admit or deny the Board surveyors' observations, but that company policy requires compliance with required technician-to-pharmacist ratios.

Consequently, the Board issued a Stipulation and Consent Order, reprimanding the licensee and imposing a civil penalty of $50,000.

Challenges Polaris Faced in Minnesota

Polaris entered the Minnesota market in November 2018. The company operates only one pharmacy in Minnesota, which is located at 5220 Park Glen Road, St. Louis Park. Polaris' early experience in Minnesota was not without its challenges, but the company has made a good faith effort to address its challenges and is constantly looking to improve.

When Polaris entered the Minnesota market, it was surprised to find a labor market (particularly for pharmacy technicians) that was much tighter than other markets in which Polaris operates and experienced more staff turnover in Minnesota than it is accustomed to in other markets. The Covid-19 pandemic obviously put an incredible amount of stress on every stakeholder in the pharmacy industry, and Polaris was no exception. The pandemic made it even more difficult for Polaris to recruit, hire, and retain talented staff.

Polaris continues to believe it did not engage in central services by having Minnesota-licensed technicians located in Florida perform remote order entry tasks in connection with prescription orders filled in Minnesota. In letters to the Board dated July 19, 2019, Polaris explained why it began using Minnesota-licensed technicians based in Florida to assist Polaris Minnesota with order entry tasks.

In sum, during its initial months of operation, Polaris faced an unanticipated and unacceptable backlog of prescription orders that needed to be filled in Minnesota. The backlog resulted largely from Polaris' inability to recruit and retain enough capable pharmacy technicians in Minnesota during the early months of operation. To address the backlog and ensure the timely delivery of prescriptions to Minnesota patients, Polaris initially had Minnesota-licensed technicians based in Florida perform order entry services on behalf of Polaris Minnesota. These technicians were experienced technicians who were licensed in Minnesota before they performed order entry work for Polaris Minnesota. Further, while performing remote order entry work from a Polaris Florida location, these technicians were connected virtually to Polaris Minnesota's physical workspace through Polaris' FrameworkLTC software platform, which is commonly used across the long-term care pharmacy industry. At all times, the work of these technicians was overseen by a licensed pharmacist at the Florida pharmacy (where the data was entered into FrameworkLTC), as well as a Minnesota-licensed pharmacist in the Minnesota pharmacy, who ultimately controlled and was responsible for the technicians' work and any prescriptions filled in connection with data they entered into the system. Additionally, until May 2019, Polaris had IND Consulting and its "Team X" do some remote order entry work for Polaris Minnesota. Aside from the order entry function, Polaris Minnesota's prescription processing and filling functions have always taken place entirely in the Minnesota pharmacy. Polaris has at times relied on similar remote order entry processes in other states without triggering central service pharmacy requirements.

Accordingly, when Polaris started using this process to help deal with the Minnesota backlog, it did not anticipate that it might be triggering central services pharmacy requirements. For this reason, Polaris initially did not submit or seek approval from the Board for a central prescription drug processing policy or procedure. In March 2019, after Board staff expressed a

view that Polaris' use of Minnesota-licensed technicians based in Florida to perform remote entry work constituted an unauthorized central service arrangement, Polaris took immediate steps to address the issue. Polaris initially flew Minnesota-licensed technicians from Florida to Minnesota, so they could be physically present in the Polaris Minnesota pharmacy while performing the same order entry functions they had been performing in Florida.

Finally, Polaris sought Board approval of several remote order entry variances, with the goal of being authorized to resume using Minnesota-licensed technicians based in Florida to perform remote order entry for Polaris Minnesota, and particularly to deal with emergencies or backlogs. When Board staff initially raised this issue in March 2019, Polaris did not believe it could immediately shift all order entry functions to its limited staff in Minnesota without compromising patient safety and welfare. At the time, Polaris was still working through the backlog, onboarding new care facilities, and working hard to locate, hire, train, and retain technicians and other staff in Minnesota in a challenging labor market. Under the circumstances, Polaris determined it was necessary to continue using Minnesota licensed, Florida-based technicians for a period of time in order to deal with the backlog and continue filling prescriptions in a timely manner for patients who needed them, while simultaneously building up its Minnesota workforce and making the changes necessary to meet the expectations of Board staff. As soon as Polaris was staffed and equipped to perform all order entry functions in Minnesota, it stopped utilizing technicians who were not physically located in Minnesota altogether. Accordingly, from June 2019 to the present, Polaris has only used Minnesota-licensed technicians physically located in the Polaris Minnesota pharmacy to perform order entry work on prescription orders filled in Minnesota. Polaris took concerns raised by Board staff over remote order entry issues seriously, and it believes it acted reasonably under the circumstances to address those concerns, while also maintaining high levels of patient care.

Polaris remained committed to working cooperatively with the Board to better understand what it must do in order to utilize remote order entry processes in the future. Polaris would always attempt to rely on technicians physically located in its Minnesota pharmacy to perform data entry and other prescription filling functions. The Board acknowledged granting variance requests to many pharmacy chains and health-systems that authorize the use of remote order entry processes. In March 2020, the Board also issued Covid-19 related guidance acknowledging that pharmacists and technicians could perform various prescription drug filling functions while working remotely—including data entry of prescriptions and orders; verifying prescriptions; certifying data entry and the finished prescriptions (i.e., the product check); conducting profile and prospective drug utilization reviews; and stage-checking for compounding—so long as affiliated pharmacies were using adequate computer software and hardware for the tasks being performed. While the Board's Covid-19 guidance evolved after Governor Walz's Peacetime Emergency declaration was rescinded, Polaris continues to believe remote order entry processes like those implemented during the first few months of Polaris' operations in Minnesota were safe, effective, and should have a place in the delivery of modern pharmacy services.

The Board approved the central services variance #265679-010 on July 13, 2022 between Polaris Pharmacy Services of Minnesota, LLC and both the Polaris Pharmacies located in Tampa and Ft. Lauderdale Florida for urgent or emergent needs.

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Polaris Pharmacy Services of Minnesota, LLC
License No. 265679

STIPULATION AND CONSENT ORDER

STIPULATION

Polaris Pharmacy Services of Minnesota, LLC ("Licensee") and the Minnesota Board of Pharmacy Committee on Professional Standards ("Committee") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to license and regulate pharmacies and to take disciplinary action as appropriate.

2. Licensee holds a pharmacy license from the Board and is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On August 18, 2021, Licensee met with the Committee to discuss the allegations described in a Notice of Conference. Board members Kendra Metz and Stuart Williams comprised the Committee. The Board's Executive Director, Cody Wiberg; Deputy Director, Jennell Bilek; and staff attorney, Brian Park, were also present. Alex Mountain, Assistant Attorney General, represented the Committee. Brian A. Dillon, of Lathrop GPM LLP, represented licensee and was

accompanied by Licensee's Pharmacist-in-Charge, Neil Uitto; Polaris' Chief Operating Officer, Steven Baker; and Polaris' Executive Vice President of Operations, Todd Zisek.

III.

FACTS

4. On or about November 1, 2018, the Board licensed Licensee as a pharmacy in Minnesota.

5. Licensee is a closed door, long-term care ("LTC") pharmacy that prepares sterile and non-sterile compounded drug products for dispensing.

6. Licensee has two affiliated pharmacy locations in Florida, both licensed by the Board as follows:

a. On or about July 8, 2016, the Board issued Polaris Rx, located in Fort Lauderdale, Florida ("Pharmacy 1"), non-resident pharmacy license #265101.

b. On or about December 5, 2018, the Board issued Polaris Pharmacy Services of Tampa, located in Tampa, Florida ("Pharmacy 2"), non-resident pharmacy license #265721.

7. On or about March 19, 2019, two Board Surveyors visited Licensee for the purpose of completing a routine inspection, met with the pharmacist-in-charge, and identified the following:

a. Seven pharmacy technicians registered by the Board and employed by Pharmacy 1 and Pharmacy 2, were living in Florida but listed their current physical address as Licensee's address in Minnesota.

b. During the inspection, the Board Surveyors cited Licensee for engaging in central services with Pharmacy 1 and Pharmacy 2, by allowing pharmacy technicians working in Florida to remotely perform data entry of prescription drug information for Minnesota patients into

Licensee's Frameworks LTC prescription processing and dispensing software system ("FW-LTC"), followed by verification of the data entry by Licensee's pharmacist staff members working in Minnesota ("Central Service").

c. Prior to beginning Central Service, Licensee failed to submit a copy of its policy and procedure manual and failed to obtain Board approval to participate in a Central Service arrangement with Pharmacy 1 and Pharmacy 2.

d. Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the March 2019 citation.

e. Licensee's nonsterile compounding records failed to include an assigned beyond use date ("BUD") for the final compounded drug product, or included a BUD exceeding those recommended within United States Pharmacopeia, General Chapter 795 for Pharmaceutical Compounding - Nonsterile Preparations ("USP 795"), without documentation of a reference for literature or a stability study applicable to the specific drug product allowing for extension of the BUD. Licensee avers that it responded to these findings by providing education to its staff to ensure compounded components included lot numbers, expiration dates, and BUDs, along with noting the supporting reference sources. Licensee states that it is not aware of any other issues regarding its compliance with BUD requirements since 2019.

8. On or about March 20, 2019, the Board received a complaint alleging that Licensee was utilizing pharmacy technicians from outside of Minnesota to enter prescription data. On or about April 9, 2019, a Board Surveyor reminded Licensee, after expanding its operations to 24-

hours, that pharmacy technicians working outside of its Minnesota location could not be used to help with covering the additional hours that the pharmacy is open, due to the lack of Board approved policies for Central Services with Pharmacy 1 and Pharmacy 2. As noted above, Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the Board's concern regarding the use of out-of-state technicians to enter prescription data.

9. On June 11, 2019, two Board Surveyors visited Licensee for the purpose of an investigation, met with representatives of the Licensee, and identified the following:

a. The pharmacist-in-charge stated that, as far as she was aware, Pharmacy 1 and Pharmacy 2, both located in Florida, were the only two locations providing Central Services for Licensee.

b. Licensee utilized a company named IND Consulting ("IND") for emergency kit ("E-kit") billing and entry of patient information when pharmacy services are initiated in a new LTC facility. IND's website states its staff are able to provide services including, but not limited to, billing services, medical record entry, and data entry solutions, with guaranteed staffing in fully operational data centers that are open 24 hours a day and 365 days a year, located within or outside of the United States across the globe in Mexico, India, the Philippines, and Florida. During the conference with the Committee, Licensee admitted that IND consulting had been used to enter prescription data for prescription drug orders ultimately dispensed by its

Minnesota pharmacy. Licensee cannot definitively state where individuals affiliated with IND were licensed or physically located when entering such data.

c. At the end of the visit, the Board Surveyor's provided an Investigative Report requesting additional information and reminding Licensee again that it cannot engage in Central Services without Board approval.

10. On February 12, 2020, two Board Surveyors visited Licensee for the purposes of an investigation, met with representatives of Licensee, and identified the following:

a. After arriving at 4:36 a.m., one of the Board Surveyors observed two of Licensee's pharmacy technicians were allowed badge access to the pharmacy entrance prior to the arrival of RPh 3 at around 5:55 a.m. One technician was found to be working in the sterile compounding area and another was logged into Licensee's computer. A representative of Licensee later stated that three pharmacy technicians had been given keys and passcodes to access Licensee's pharmacy. During its conference with the Committee, Licensee admitted that this allegation is true, but stated that senior management took corrective action upon learning of the situation, including immediately revoking the access code of all non-pharmacists and physically rekeying all doors within the pharmacy. Licensees avers that periodic security assessments confirm that no unauthorized persons have had access to the pharmacy since February 2020.

b. Six pharmacy technicians, including the IV pharmacy technician, were present in the "filling area" with only one pharmacist, who was the second pharmacist to arrive. Another pharmacist was in an "order entry" area, a distinctly different area separated by a wall and door. The Board Surveyors were told that additional pharmacy technicians were scheduled that morning to perform non-technician "staging or stocking" duties. However, the Board Surveyors observed that the additional pharmacy technicians that were supposedly scheduled to perform non-technician duties, were filling orders in the "filling area" to be checked by the one pharmacist.

Licensee avers that is does not have sufficient information to admit or deny the Board surveyors' observations, but that company policy requires compliance with required technician-to-pharmacist ratios.

IV.

LAWS

11. Licensee acknowledges the conduct described in section III above constitutes a violation of Minn. Stat. § 151.071, subd. 2(7), and warrants the disciplinary action described below.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

12. The Board **REPRIMANDS** Licensee and imposes a **CIVIL PENALTY** in the amount of $50,000 for the conduct described in section III above. The civil penalty shall be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of entry of this Order.

13. The Board places the following **CONDITION** on Licensee's License: every six months, for a period of three years, Licensee's CEO must certify to the Board's Executive Director that Licensee's licensed pharmacies that provide services to Minnesota residents are in full compliance with all applicable Minnesota statutes and rules.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

14. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Committee may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Committee shall schedule a hearing before the Board. At least 20 days before the hearing, the Committee must mail Licensee a notice of the violation(s) alleged by the Committee. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee shall submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Committee, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Committee and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Committee and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Committee will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations, but may present argument concerning the appropriateness of additional discipline. Pursuant to this process, Licensee waives a hearing before an administrative law judge, discovery, cross-examination of

adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but does not limit the Board's authority to impose discipline for the violation. A decision by the Committee not to seek discipline when it first learns of a violation does not waive the Committee's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's license is in a suspended status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's license, a period of suspension, conditions of reinstatement, or revocation of Licensee's license.

f. Nothing herein limits the Committee's or the Board's right to temporarily suspend Licensee's license as provided in Minnesota Statutes chapters 151 and 214, based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII. ADDITIONAL INFORMATION

15. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

16. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the

investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

17. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter shall constitute the entire record and may be reviewed by the Board in its consideration of this matter.

18. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

19. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

20. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it. If the Board rejects this Stipulation and Consent Order, the parties agree that this Stipulation and Consent Order will not be admissible in any proceedings.

21. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis

of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action, and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

22. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed health professional, and as such, is classified as confidential data pursuant to Minnesota Statutes section 13.41, subdivision 4.

23. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

POLARIS PHARMACY SERVICES OF MINNESOTA, LLC (LICENSEE)

Dated: 12-3-2021

MINNESOTA BOARD OF PHARMACY
COMMITTEE ON PROFESSIONAL STANDARDS

BOARD MEMBER

Dated: 12/8/21

ORDER

Upon consideration of the Stipulation, the Board **REPRIMANDS** Licensee, imposes a **CIVIL PENALTY**, and **CONDITIONS** Licensee's license and adopts all of the terms described above on this 8TH day of December, 2021.

MINNESOTA BOARD OF PHARMACY

CODY WIBERG
Executive Director

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Romano

Print Name (First, Last)

CEO

Original Signature (electronic, copies or stamps not accepted)

10/2/24

Date

Please have this section completed in the presence of a Notary Public.

State of FL, ss. County of Broward

I, Ivor Stewart, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

CEO

Original Signature

10/2/24

Date

Subscribed and Sworn to before me this 2 day of Oct 2024.

Notary Public Signature

IVOR STEWART
Notary Public - State of Florida
Commission # HH 339460
My Comm. Expires Apr 2, 2027
Bonded through National Notary Assn.

(Seal)

COUPLER LLC

List of Employees

KOBUS, CRAIG – Director of Coupler LLC & Designated Representative
KERR, CHELSEA – Lead Quality Assurance
MIRODDI, SARAH – Quality Assurance
WIDGER, DENISE – Fill Tech
BOOKER, NICOLE SUZETTE – Fill Tech
LLEWELLYN, EMILY JOSEPHINE – Fill Tech
WEATHERILL, JESSICA – Shipping/Receiving Clerk

4S

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH N/A	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ■ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Everest Life Sciences LLC

Physical Address: 31 Schalks crossing road,

City: Plainsboro, State: New Jersey Zip: 08536

Mailing Address (if different from physical address): N/A

City: State: Zip:

Telephone: 6097792934 Website: www.everest-life.com

Name of Designated Representative (DR): Mr. Mallikarjuna Desireddy

Licensing Company Email: DR Email: malli.desireddy@everest-life.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Branded and Generics or OTC	☐ Warehouse
☐ Veterinarians		■ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:
N/A

Original Signature (electronic, copies or stamps not accepted)

09/18/2022
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: Mr. Mallikarjuna Desireddy

Business Name: Everest Life Sciences LLC

Business Address: 31 Schalks crossing road,

City: Plainsboro State: NJ Zip: 08536

Telephone: 6097792934 Email: malli.desireddy@everest-life.com

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [3]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [3]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

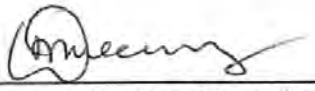
I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Everest Life Sciences LLC

Facility Name

Mallikarjuna Desireddy

Print Name of Authorized Person Submitting Application



Original signature of Authorized Person (copies or stamps not accepted)

09/18/2022

Date

Board Use Only	Date Received: _____	Amount: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Form is found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Form is found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **A list containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered.				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mallikarjuna Desireddy

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

06/25/2024

Date

Board Use Only	Date Received: 7/1/24	Amount: $1000-cc

Drug Establishments Current Registration Site everest life | FDA

Firm Name	FDA Establishme	DUNS	Business Operations	Address	Registration
Everest Life Sciences LLC	2243092	110774649	ANALYSIS; API MANUFACTURE; MANUFACTURE	31 SCHALKS CROSSING RD, PLAINSBORO, New Jersey (NJ) 08536, United States (USA	12/31/2024

Verified
M.H 7/5/24

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

EVEREST LIFE SCIENCES LLC
0450863505

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic Limited Liability Company was registered by this office on September 16, 2022.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

MALLIKARJUNA R DESIREDDY
8 SHELLER DRIVE
MONROE, NJ 08831-8402

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 20th day of September, 2024

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6157288800

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0749701

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☒ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

31 SCHALKS CROSSING RD PLAINSBORO, NJ 08536-

Reg. No.
5006273

EVEREST LIFE SCIENCES LLC
31 SCHALKS CROSSING RD
PLAINSBORO, NJ 08536-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2025

Establishment Copy

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 812043

Application/License No. _____

EVEREST LIFE SCIENCES LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 31 SCHALK'S CROSSING ROAD PLAINSBORO, NJ 08536 (Address of Applicant/Principal), as PRINCIPAL, and HUDSON INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of DELAWARE (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 8777 N. GAINEY CENTER DRIVE STE 240 SCOTTSDALE, AZ 85258 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on JUNE 18, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 18TH day of JUNE, 2024.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

ERIC FAUERBACH, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Not Needed
Nevada Resident Agent

Hudson Insurance Company CORPORATE SEAL 1918 DELAWARE 8503

Posted February 20, 2020

HUDSON INSURANCE GROUP

Bond Number: 812043

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That HUDSON INSURANCE COMPANY, a corporation of the State of Delaware, with offices at 100 William Street, New York, New York, 10038, has made, constituted and appointed, and by these presents, does make, constitute and appoint

Eric Fauerbach

of the State of South Carolina

its true and lawful Attorney(s)-in-Fact, at New York, New York, each of them alone to have full power to act without the other or others, to make, execute and deliver on its behalf, as Surety, bonds and undertakings given for any and all purposes, also to execute and deliver on its behalf as aforesaid renewals, extensions, agreements, waivers, consents or stipulations relating to such bonds or undertakings provided, however, that no single bond or undertaking shall obligate said Company for any portion of the penal sum thereof in excess of the sum of

Twenty Five Thousand And 00/100 Dollars ($25,000.00)

Such bonds and undertakings when duly executed by said Attorney(s)-in-Fact, shall be binding upon said Company as fully and to the same extent as if signed by the President of said Company under its corporate seal attested by its Secretary.

In Witness Whereof, HUDSON INSURANCE COMPANY has caused these presents to be of its Senior Vice President thereunto duly
d, on this 2nd day of June, 20 22 at New York, New York.
e seal)

HUDSON INSURANCE COMPANY

Attest.....
Dina Daskalakis No. 01MU6067553
Corporate Secretary

By.....
Michael P. Cifone
Senior Vice President

STATE OF NEW YORK
COUNTY OF NEW YORK. SS.

On the 2nd day of June, 20 22 before me personally came Michael P. Cifone to me known, who being by me duly sworn did depose and say that he is a Senior Vice President of **HUDSON INSURANCE COMPANY**, the corporation described herein and which executed the above instrument, that he knows the seal of said Corporation, that the seal affixed to said instrument is such corporate seal, that it was so affixed by order of the Board of Directors of said Corporation, and that he signed his name thereto by like order.

(Notarial Seal)

.....
ANN M. MURPHY
Notary Public, State of New York
No. 01MU6067553
Qualified in Nassau County
Commission Expires December 10, 2025

CERTIFICATION

STATE OF NEW YORK
COUNTY OF NEW YORK. SS.

The undersigned **Dina Daskalakis** hereby certifies:

That the original resolution, of which the following is a true and correct copy, was duly adopted by unanimous written consent of the Board of Directors of Hudson Insurance Company dated July 27th, 2007, and has not since been revoked, amended or modified:

"RESOLVED, that the President, the Executive Vice Presidents, the Senior Vice Presidents and the Vice Presidents shall have the authority and discretion, to appoint such agent or agents, or attorney or attorneys-in-fact, for the purpose of carrying on this Company's surety business, and to empower such agent or agents, or attorney or attorneys-in-fact, to execute and deliver, under this Company's seal or otherwise, bonds obligations, and recognizances, whether made by this Company as surety thereon or otherwise, indemnity contracts, contracts and certificates, and any and all other contracts and undertakings made in the course of this Company's surety business, and renewals, extensions, agreements, waivers, consents or stipulations regarding undertakings so made; and

FURTHER RESOVLED, that the signature of any such Officer of the Company and the Company's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seal when so used whether heretofore or hereafter, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed."

THAT the above and foregoing is a full, true and correct copy of Power of Attorney issued by said Company, and of the whole of the original and that the said Power of Attorney is still in full force and effect and has not been revoked, and furthermore that the Resolution of the Board of Directors, set forth in the said Power of Attorney is now in force.

Witness the hand of the undersigned and the seal of said Corporation this 18th day of June, 2024.
(Corporate seal)

By.....
Dina Daskalakis, Corporate Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Everest Life Sciences LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 31 Schalks crossing road

City Plainsboro State NJ Zip 08536

Mailing Address (if different from physical address) NA

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Mallikarjuna Middle R Last Desireddy

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Monroe State NJ Zip 08831

Telephone [redacted] Email malli.desireddy@everest-life.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Birla Institute of Technology & Science		1995-1997	
Address	**City**	**State**	**Zip**
Pilani Campus	Pilani	Rajasthan	333031
Diploma/Degree obtained, if any			
Pilani Campus			

School Name		From - To (MM/YY – MM/YY)	
Gulbarga University		1987-1991	
Address	**City**	**State**	**Zip**
Jnana Ganga	Kalaburagi (Gulbarga	Karnataka	585106
Diploma/Degree obtained, if any			
Bachelor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2011-02/2021	[redacted]	Commack	NY	11725
03/2021- present	[redacted]	Monroe	NJ	08831
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Everest Life Sciences LLC			09/2022-present
Business Address	**City**	**State**	**Zip**
31 Schalks crossing road	Plainsboro	NJ	08536
Phone	**Title**	**Number of Employed Hours**	
6318339482	CEO/President	Full Time	
Description of Duties			
Responsible for all business operations and development opportunities, including product development, commercial production, and sales.			

Business Name			From - To (MM/YY – MM/YY)
Neopharma INC			07/2018-04/2022
Business Address	**City**	**State**	**Zip**
21college RD E, suite 101	Princeton	NJ	08540
Phone	**Title**	**Number of Employed Hours**	
6318339482	Vice president/CEO	Full Time	
Description of Duties			
Responsible for all operations of an antibiotic manufacturing plant, including sales, marketing, business development, CMO opportunities, product development, and FDA filings.			

Business Name			From - To (MM/YY – MM/YY)
Granules Pharmaceuticals, INC			11/2015-06/2018
Business Address	**City**	**State**	**Zip**
3701 concorde parkway	Chantilly	VA	20151
Phone	**Title**	**Number of Employed Hours**	
6318339482	Sr. Vice President	Full Time	
Description of Duties			
Involved in plant design and construction, utility and machinery installation, overseeing cGMP implementation, facility qualification, SOP and cGMP documentation, and guiding personnel in product development and ANDA filings.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

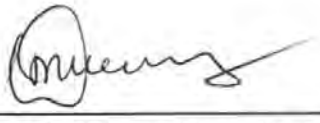
Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NA **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted)

06/25/2024

Date

I, Mallikarjuna Desireddy, **certify that as the designated representative for**

Everest Life Sciences LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. Yes I am at least 21 years of age;
3. Yes I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. Yes I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. Yes I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. Yes I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. Yes I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Mallikarjuna Desireddy

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/25/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mallikarjuna Deireddy

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/25/2024

Date

Please have this section completed in the presence of a Notary Public.

State of NJ, ss. County of MIDDLESEX

I, MALLIKARJUNA DEIREDDY, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

06/17/2024

Date

Subscribed and Sworn to before me this 17 day of JUNE 2024.

Notary Public Signature

VIKAS MEHTA
NOTARY PUBLIC OF NEW JERSEY
ID #2316152
MY COMMISSION EXPIRES 06/22/2029

Seal

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Everest Life Sciences LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 31 Schalks crossing road

City: Plainsboro State: NJ Zip: 08536

Mailing Address (if different from physical address): NA

City: State: Zip:

Telephone: Website:

Licensing Company Email:

Section 2: Personal Information

First: Mallikarjuna Middle: R Last: Desireddy

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Monroe State: NJ Zip: 08831

Telephone: [redacted] Email: malli.desireddy@everest-life.co

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Birla Institute of Technology & Science		1995-1997	
Address	**City**	**State**	**Zip**
Pilani Campus	Pilani	Rajasthar	333031
Diploma/Degree obtained, if any			
Master of Science (Pharmacy)			

School Name		From - To (MM/YY – MM/YY)	
Gulbarga University		1987-1991	
Address	**City**	**State**	**Zip**
Jnana Ganga	Kalaburagi (Gulbarga)	Karnataka	585106
Diploma/Degree obtained, if any			
Bachelor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2011-02/2021	[redacted]	Commack	NY	11725
03/2021- present		Monroe	NJ	08831
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Everest Life sciences LLC			09/2022-present
Business Address	**City**	**State**	**Zip**
31 schalks crossing road	plainsboro	NJ	08536
Phone	**Title**		
6318339482	President/CEO		

Description of Duties: Responsible for all business operations and development opportunities, including product development, commercial production, and sales.

Business Name			From - To (MM/YY – MM/YY)
Neopharma INC			Jul/2018-04/2022
Business Address	**City**	**State**	**Zip**
21 college RD E, suite 101	Princeton	NJ	08540
Phone	**Title**		
6318339482	Vice president/CEO		

Description of Duties: Responsible for all operations of an antibiotic manufacturing plant, including sales, marketing, business development, CMO opportunities, product development, and FDA filings.

Business Name			From - To (MM/YY – MM/YY)
Granules Pharmaceuticals, INC			11/2015-06/2018
Business Address	**City**	**State**	**Zip**
3701 concorde parkway	Chantilly	VA	20151
Phone	**Title**		
6318339482	Sr. Vice President		

Description of Duties: Involved in plant design and construction, utility and machinery installation, overseeing cGMP implementation, facility qualification, SOP and cGMP documentation, and guiding personnel in product development and ANDA filings.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties:

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties:

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

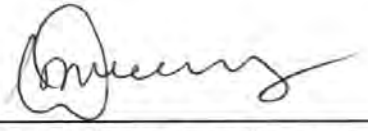
Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NA **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted)

06/25/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mallikarjuna Desireddy

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/25/2024

Date

Please have this section completed in the presence of a Notary Public.

State of NJ, ss. County of MIDDLESEX

I, MALLIKARJUNA DESIREDDY, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

06/17/2024

Date

Subscribed and Sworn to before me this 17 day of JUNE, 2024.

Notary Public Signature

VIKAS MEHTA
NOTARY PUBLIC OF NEW JERSEY
ID #2316152
MY COMMISSION EXPIRES 06/22/2029

(Seal)

EVEREST LIFE SCIENCES LLC

Employees List:

Mr. Mallikarjuna Desireddy CEO/President

QA Department:

1. Srujana Paka, QA Associate
2. Chaitanya Uppugalla, QA Associate
3. Margi Shah, QA, Associate

QC Department:

1. Srinivas Patibandla, AR&D, QC Manager
2. Swetha Udumula, QC Analyst
3. Sirisha Dusi, Senior QC Analyst
4. Subba Reddy Alla, AR&D Specialist

Production Or Operations Department:

1. Narender Uppugalla, Director operations and FR&D
2. Milton Santa Cruz, Supervisor, Production Specialist
3. Sunney Joseph, Production operator

Marketing Department:

1. Bhuvaneswari Sapavathu, Sales & Marketing Executive

4T

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☐ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Fresenius Kabi USA, LLC

Physical Address: 3159 Staley Road

City: Grand Island State: NY Zip: 14072

Mailing Address (if different from physical address): 7000 Cardinal Place, QRA

City: Dublin State: OH Zip: 43017

Telephone: 716-773-0800 Website: www.Fresenius-Kabi.com/us

Name of Designated Representative (DR): Shannon Pellerite

Licensing Company Email: licensure@cardinalhealth.com DR Email: Shannon.Pellerite@fresenius-kabi.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

See Attached

Original Signature (electronic, copies or stamps not accepted)

9/12/24
Date

Fresenius Kabi USA, LLC
(formerly known as APP Pharmaceuticals, LLC)
Description of Past Disciplinary Actions

Fresenius Kabi USA, LLC provides this summary of actions taken by other states against licenses held in the name of APP Pharmaceuticals, LLC ("APP"). The actions described below were made against the **Bensenville, Illinois distribution facility only** and resulted from late filing of various documents in the state licensing process and were not due to misconduct by APP. The delay in filing resulted from the 2007 reorganization and name change of APP, a complex corporate transaction of which each state was notified. None of the actions involved controlled substances or resulted in harm to any patient.

Please note that the Bensenville, Illinois facility that was the subject of these actions is no longer operated by Fresenius Kabi USA, LLC effective January 1, 2018. Fresenius Kabi USA, LLC currently maintains a valid license and is good standing in each state, as required. No disciplinary actions are pending.

Colorado License Denial and Subsequent Issuance*

Action: Although a license renewal and change of name were timely filed by APP in Colorado, the State of Illinois failed to provide a verification document in the required format. During the period between APP's filing and discovery of the inadequacy of the Illinois document, APP made a single shipment of prescription drugs to a Colorado pharmacy on or around December 17, 2007. As a result of that shipment, Colorado issued a Cease and Desist Order, effective September 7, 2008, at which time APP immediately ceased shipping prescription drugs into Colorado. At its next regular meeting on November 20, 2008, the Colorado Board of Pharmacy denied APP's Wholesaler application.

Outcome: On December 19, 2008, APP and the Colorado Board of Pharmacy entered into a Stipulation and Agreed Agency Order whereby APP was granted an Out-of-State Wholesaler License (#7467). The license is currently in the name of Fresenius Kabi, LLC.

Montana Disciplinary Action*

Action: After accepting APP's renewal application and issuing a Wholesale Drug Distributor License (#1187) effective as of March 8, 2008, the Montana Board of Pharmacy issued a board-generated complaint against APP dated May 19, 2008 alleging (a) the late renewal of a Wholesale Drug Distributor license and (b) unlicensed practice by APP in Montana that occurred between January 16 and March 7, 2008. The delay in filing the renewal application resulted from delays by the State of Illinois in processing the name change so that APP could file the required verification documents showing the APP name. It is important to note that during the period of alleged unlicensed practice, APP became the sole U.S. supplier of heparin products causing APP to ship heparin products into Montana on an emergency basis.

Outcome: On January 9, 2009, APP entered a Stipulation and a Final Order was executed by the Montana Board of Pharmacy under which APP's Wholesale Drug Distributor License (#1187) was affirmed. The license remained in effect until it was closed on May 7, 2018.

Michigan Administrative Action

Action: An Administrative Complaint was issued by the State of Michigan Dept. of Licensing and Regulatory Affairs on April 10, 2014, which alleged that Fresenius Kabi USA violated Michigan's Public Health Code based solely on disciplinary actions taken against Fresenius Kabi USA by the Colorado and Montana Boards of Pharmacy in 2008 and 2009, respectively. Importantly, under the Board's Complaint, Fresenius Kabi USA did not commit any violations of Michigan law that impacted the safety or healthcare needs of Michigan's citizens.

Outcome: On September 8, 2014 the Michigan Dept. of Licensing and Regulatory Affairs executed a Consent citing the Stipulation of Fresenius Kabi USA and imposing a monetary fine of $1,000.00 in resolution of the matter.

*** These disciplinary actions occurred while operating under the name of APP Pharmaceuticals, LLC. On August 1, 2012, the company changed its name to Fresenius Kabi USA, LLC.**

January 18, 2019

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

FRESENIUS KABI USA LLC
d/b/a/ APP Pharmaceuticals LLC
License Number: 53-06-001870

File Number: 53-13-130653
CONSENT ORDER AND STIPULATION

CONSENT ORDER

An Administrative Complaint, hereafter Complaint, was executed on April 10, 2014, charging Fresenius Kabi USA LLC, d/b/a APP Pharmaceuticals LLC, hereafter Respondent Wholesaler, with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq; and

Respondent Wholesaler has admitted, by Stipulation submitted herewith, that the facts alleged in the Complaint dated April 10, 2014, are true and constitute a violation of the Public Health Code; and

The Disciplinary Subcommittee has reviewed the Stipulation and, based upon the matters asserted therein, agrees that the public interest is best served by resolution of the outstanding Complaint; therefore,

IT IS FOUND that the facts alleged in the Complaint are true and constitute a violation of section 17768(2)(d) of the Public Health Code, supra.

Accordingly,

IT IS ORDERED that for the cited violation of the Public Health Code, Respondent Wholesaler is FINED in the amount of $1,000.00 to be paid to the State of Michigan within 60 days of the effective date of this Order.

IT IS FURTHER ORDERED that the fine shall be mailed to the **Department of Licensing and Regulatory Affairs, Enforcement Division, Sanction Monitoring, P.O. Box 30189, Lansing, MI 48909**. The fine shall be paid by check or money order, made payable to the State of Michigan, and the check or money order shall clearly display file number **53-13-130653**.

IT IS FURTHER ORDERED that in the event Respondent Wholesaler violates any provision of this Order, the Disciplinary Subcommittee may proceed to take disciplinary action pursuant to 1996 AACS, R 338.1632 and section 16221(h) of the Public Health Code, supra.

CONTINUED ON NEXT PAGE

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee, as set forth below.

Dated: September 8, 2014

MICHIGAN BOARD OF PHARMACY

By: Pamela L. Wyett
Chairperson, Disciplinary Subcommittee

STIPULATION

1. The facts alleged in the Complaint dated April 10, 2014, are true and constitute a violation of section 17768(2)(d) of the Public Health Code, supra.

2. Respondent Wholesaler understands and intends that by signing this Stipulation Respondent Wholesaler is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq, to require the Department of Licensing and Regulatory Affairs, hereafter Department, to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent Wholesaler is waiving the right to appear with an attorney and such witnesses as Respondent Wholesaler may desire to present a defense to the charges.

3. Respondent Wholesaler and the Department further agree that this matter is a public record required to be published and made available to the public

pursuant to section 11(1)(a) of the Michigan Freedom of Information Act, 1976 PA 442, as amended; MCL 15.241(1)(a); and this action will be reported to the National Practitioner's Data Bank, and any other entity as required by state or federal law, in accordance with 42 USC 11101-11152.

4. Dhafer Almaklani, R.Ph., a member of the Michigan Board of Pharmacy who supports this proposal, and the Department's representative are both free to discuss this matter with the Disciplinary Subcommittee and recommend acceptance of the resolution set forth in the foregoing Consent Order.

5. This Consent Order is approved as to form and substance by Respondent Wholesaler and the Department and may be entered as the final order of the Disciplinary Subcommittee in this cause.

CONTINUED ON NEXT PAGE

6. This proposal is conditioned upon acceptance by the Disciplinary Subcommittee, Respondent Wholesaler and the Department expressly reserving the right to further proceedings without prejudice should the Consent Order be rejected.

AGREED TO BY:

S. Ostro Deputy Director for

Carole H. Engle, Director
Bureau of Health Care Services
Department of Licensing and
Regulatory Affairs

Dated: July 8, 2014

AGREED TO BY:

Fred Foss
Authorized Representative
for Respondent Wholesaler

Dated: 6/24/14

This is the final page of a Consent Order and Stipulation in the matter of Fresenius Kabi USA LLC, d/b/a APP Pharmaceuticals LLC, File Number 53-13-130653, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of five pages, this page included.

CBS

BEFORE THE BOARD OF PHARMACY
DEPARTMENT OF LABOR AND INDUSTRY
STATE OF MONTANA

IN THE MATTER OF THE PROPOSED DISCIPLINARY TREATMENT OF THE LICENSE OF APP PHARMACEUTICALS, LLC Wholesale Drug Distributor License No. 1187	) Docket No. CC-09-0016) Complaint No. PHA-2008-0090)) FINAL ORDER)

Based upon the Stipulation entered into herein by the Department of Labor and Industry, Business Standards Division (Department) and APP Pharmaceuticals, LLC (Licensee), and good cause appearing therefore,

IT IS HEREBY ORDERED that the parties' Stipulation is approved, adopted, and incorporated by reference with the same force and effect as if its terms were recited in this Final Order verbatim, with the exception that paragraph 9(C) is deleted in its entirety and removed from the Stipulation, and that the Licensee must comply with the terms and conditions thereof.

IT IS FURTHER ORDERED that APP Pharmaceuticals, LLC is adjudged to have violated certain statutes and regulations under the jurisdiction of the Montana Board of Pharmacy warranting sanctions under Mont. Code Ann. §37-1-312.

As required by Mont. Code Ann. §37-1-312(2), the Board has first considered the sanctions that are necessary to protect and compensate the public and now enters the following order designed to rehabilitate the license applicant.

DATE: 2-16-09

Presiding Officer
Montana Board of Pharmacy
Adjudication Panel

RECEIVED
OCT 09 2008
LEGAL SERVICES

BEFORE THE BOARD OF PHARMACY
DEPARTMENT OF LABOR AND INDUSTRY
STATE OF MONTANA

IN THE MATTER OF THE PROPOSED DISCIPLINARY TREATMENT OF THE LICENSE OF APP PHARMACEUTICALS, LLC Wholesale Drug Distributor License No. 1187	) Docket No. CC-09-0016-PHA) Complaint No. PHA-2008-0090)) STIPULATION AND FINAL ORDER

The Professional and Occupational Licensing Division of the Department of Labor and Industry of the State of Montana (Department), by and through its legal counsel, Anjeanette C. Lindle, and APP Pharmaceuticals, LLC (Licensee), by and through J. Frank Harmon, EVP & COO, hereby stipulate and agree as follows:

1. Licensee is a licensed Wholesale Drug Distributor, licensed in the state of Montana, license No. 1187.

2. The Montana Board of Pharmacy has a statutory obligation to protect the public health, safety and welfare under Mont. Code Ann. §37-7-102 et seq.

3. Licensee admits the jurisdiction of the Board of Pharmacy over the subject matter of the above-entitled proceeding. Licensee desires to avoid unnecessary expenditure of time and other valuable resources in resolving the issues in this action. Therefore, Licensee specifically and affirmatively waives a contested case hearing in the above-entitled matter and all rights to appeal under the Montana Administrative Procedure Act, and elects to resolve this matter on the terms and conditions set forth herein.

4. Licensee acknowledges that Licensee has read and understands the terms of this Stipulation and the Notice of Proposed Board Action issued in this matter. Licensee acknowledges that Licensee enters into this Stipulation voluntarily, and without reservation. Licensee acknowledges that no promise, other than those contained herein, and no threat has been made by the Department or by any of its members, officers, agents or representatives, to induce Licensee to enter into this Stipulation.

5. Based upon the information received, the Department contends as set forth in the Facts and Violations section of the Notice of Proposed Board Action herein issued in this matter. Licensee admits the Department's contentions in that section and agrees that settlement of this matter is in the best interest of all parties involved.

6. The Department and the Licensee agree that this Stipulation shall be a final compromise and settlement of grounds for license discipline as a result of Licensee's conduct. In the event that the Board, in its discretion, does not approve this settlement or a lesser remedy than indicated in this settlement, this Stipulation is withdrawn and shall be of no evidentiary value and shall not be relied upon or introduced by either party. Licensee agrees that if the Board rejects this stipulation and this case proceeds to hearing, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this stipulation or of any records relating thereto.

7. The Department and the Licensee agree that this Stipulation shall be incorporated and made a part of the final order issued by the Montana Board of Pharmacy herein.

8. The Department and the Licensee agree that this Stipulation and the attached final order are public documents. Licensee understands that this disciplinary action will be reported to data banks as required by federal law, including the Healthcare Integrity and Protection Data Bank (HIPDB) and the National Practitioners Data Bank (NPDB).

9. The following conditions shall apply to the continued licensure of Licensee in the state of Montana:

A. Licensee shall pay an administrative fine in the amount of five hundred dollars ($500.00). Licensee shall pay by certified check or money order, made payable to the Montana Board of Pharmacy, P. O. Box 200513, Helena, Montana, 59620-0513, within 30 days of the Final Order;

B. Licensee shall ensure that any changes in the location or ownership of the company shall cause a new application for licensure to be filed with the Montana Board of Pharmacy at least 30 days prior to the change and that any changes to name, telephone number, trade or business names of the Licensee and any changes in the

name, address, telephone number, and title of the designated person in charge of the facility will be submitted to the Montana Board of Pharmacy within 30 days of the change, pursuant to ARM 24.174.1202.

C. If, at any time after Licensee's signing the Stipulation in this matter, the Board finds, after Licensee has an opportunity to respond, reasonable cause that Licensee has violated any of the terms and conditions of this Stipulation, Licensee's license shall automatically be suspended pending a prompt post-suspension hearing. Further action will be taken depending upon the results of a contested case hearing on any factual disputes as to whether the Licensee violated the terms and conditions of probation or any statutes or rules governing the conduct of pharmacists in the state of Montana.

10. In the event the Board of Pharmacy, in its discretion, does not approve this settlement, this Stipulation shall be withdrawn and shall be of no evidentiary value and shall not be relied upon nor introduced in any disciplinary action by either party hereto. Licensee agrees that should the Board reject this Stipulation, and if this case proceeds to a contested case hearing, Licensee will assert no claim that the Board of Pharmacy was prejudiced by its review and discussion of this Stipulation or of any records relating hereto.

THIS AGREEMENT IS SUBJECT TO FINAL APPROVAL BY THE MONTANA BOARD OF PHARMACY

Anjeanette C. Lindle
Legal Counsel
Department of Labor and Industry

10/9/08
DATE

J. Frank Harmon
Executive Vice President
and Chief Operating Officer
APP Pharmaceuticals, LLC

10-7-08
DATE

CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of February, 2009, I caused a true and accurate copy of the foregoing FINAL ORDER together with a copy of the fully executed Stipulation, to be served upon the Licensee by placing it in the U.S. mail, postage prepaid, addressed as follows:

Christina McGahan
Regulatory Affairs - Labeling,
Licensing and Registration
APP Pharmaceuticals, LLC
1501 East Woodfield Road
Suite 300 East
Schaumburg IL 60173

Brian Kunz
Person in Charge
APP Pharmaceuticals, LLC
1501 East Woodfield Road
Suite 300 East
Schaumburg IL 60173

Cristina Medina

Anjeanette C. Lindle
DEPARTMENT OF LABOR AND INDUSTRY
Business Standards Division
301 South Park
P.O. Box 200513
Helena, MT 59620-0513
(406) 841-2318

Attorney for the Department

BEFORE THE BOARD OF PHARMACY
DEPARTMENT OF LABOR AND INDUSTRY
STATE OF MONTANA

IN THE MATTER OF THE PROPOSED DISCIPLINARY TREATMENT OF THE LICENSE OF APP PHARMACEUTICALS, LLC Wholesale Drug Distributor License No. 1187	) Docket No. CC-09-0016-PHA) Complaint No. PHA-2008-0090) NOTICE OF PROPOSED BOARD ACTION AND OPPORTUNITY FOR HEARING

TO: Christina McGahan
Regulatory Affairs - Labeling,
Licensing and Registration
APP Pharmaceuticals, LLC
1501 East Woodfield Road
Suite 300 East
Schaumburg IL 60173

PLEASE TAKE NOTICE:

1. The State of Montana Board of Pharmacy (Board), has considered the complaint filed against APP Pharmaceuticals, LLC (Licensee) and has voted to initiate disciplinary action pursuant to its authority under §§37-1-131 and 37-1-136, Mont. Code Ann.

COPY

2. During its Screening Panel meeting, the Screening Panel of the Board reviewed all documentation regarding the above action and determined that there is reasonable cause to believe that Licensee violated one or more of the statutes or rules cited in paragraph one of this notice.

3. Accordingly, the Screening Panel directed that this Notice be served upon Licensee pursuant to Mont. Code Ann. §37-1-309.

FACT ASSERTIONS

1. At all times relevant to these proceedings, Licensee was and is a licensed Wholesale Drug Distributor, Montana License number 1187. This license was issued by the Montana Board of Pharmacy.

2. Board records indicate Licensee's license to practice as a wholesale drug distributor expired on January 15, 2008.

3. On March 11, 2008, the Board office sent Licensee a letter asking whether APP Pharmaceuticals, LLC has operated in the state of Montana since January 16, 2008.

4. On April 10, 2008, the Board office received Licensee's letter from the Board office dated March 11, 2008, answering in the affirmative that APP Pharmaceuticals, LLC has operated in the state of Montana since January 16, 2008. This information was affirmed and signed by Christina McGahan, Regulatory Affairs - Labeling, Licensing and Registration. Also included with the letter was documentation affirming that drugs were sold in Montana subsequent to the Licensee's license expiration.

5. On April 10, 2008 a board-generated complaint was filed against the

Licensee for possible violations of the Board of Pharmacy rules and statutes in Montana.

6. The Board office received a response to the complaint authored by Christina McGahan, wherein she agrees that APP was late in filing for its renewed license in Montana but requested the Board to consider the following exigent circumstances:

A. Abraxis Bioscience, LLC. (ABI) went from being one company in the business of both generic drugs and nongeneric drugs to two separate businesses on November 14, 2007. The ABI facility licensed by Montana was retained by APP.

B. Although the Illinois licenses were applied for in a timely manner, they were only issued on January 18, 2008. The DEA license was awarded on February 21, 2008. Because these licenses are required for renewal, it was only after receiving these documents that the Licensee was able to apply for the renewal of the Montana license.

C. A total of 70 of the 76 shipments sent during the January to March time period in Montana were heparin. In December of 2007, supplies of heparin from a number of sources, including Baxter International, were found to be contaminated and were recalled, and a crisis situation was anticipated. However, APP Pharmaceuticals, LLC also sells heparin and was able to increase its manufacturing to replace much of the heparin no longer sold by Baxter and other suppliers. Without the APP-supplied heparin,

many surgeries and dialysis procedures, to name a few, would not have been able to proceed.

7. The actions referred to in the above-referenced letter relate to the propriety of the practice or fitness to practice as a Wholesale Drug Distributor, specifically, the Licensee's license expired January 15, 2008, however, APP Pharmaceuticals, LLC remained in operation without current licensure until March 7, 2008.

VIOLATIONS

The information contained in the fact assertions herein indicate that APP Pharmaceuticals, LLC has committed unprofessional conduct.

Violation of Mont. Code Ann. §37-1-141:

(6)(b) A licensee who practices after a license has expired is considered to be practicing without a license.

Violation of Mont. Code Ann. §37-1-316:

The following is unprofessional conduct for a licensee or license applicant governed by this chapter:

(18) conduct that does not meet the generally accepted standards of practice.

Violation of Mont. Code Ann. §37-7-604:

(1) A person or distribution outlet may not act as a wholesale drug distributor without first obtaining a license from the board and paying the license fee.

Violation of Mont. Code Ann. §37-7-605:

(1) An out-of-state wholesale drug distributor may not conduct business in this state without first obtaining a license from the board and paying the license fee established by the board.

Violation of ARM 24.101.408 RENEWED, LAPSED, EXPIRED, OR TERMINATED LICENSES

(5) A licensee who practices after a license has expired is considered to be practicing without a license and is subject to discipline provided by statute or rule.

Alleged violation of 24.174.1201:

(1) Every person engaged in manufacturing, wholesale distribution, or selling of drugs, medicines, chemicals, poisons for medicinal purposes, medical gases, or legend devices other than to the consuming public or patient, in the state of Montana, shall be licensed annually by the board.

Alleged violation of ARM 24.174.2301:

(1) The board defines "unprofessional conduct" as follows:

(a) engaging in any activity which violates state and federal statutes and rules governing the practice of pharmacy.

UNIFORM PROFESSIONAL LICENSING AND REGULATION PROCEDURE

You are advised that the law provides:

37-1-309. Notice -- request for hearing. (1) If a reasonable cause determination is made pursuant to 37-1-307 that a violation of this part has occurred, a notice must be prepared by department legal staff and served on the alleged violator. The notice may be served by certified mail to the current address on file with the board or by other means authorized by the Montana Rules of Civil Procedure. The notice may not allege a violation of a particular statute, rule, or standard unless the board or the board's screening panel, if one has been established, has made a written determination that

there are reasonable grounds to believe that the particular statute, rule or standard has been violated.

(2) A licensee or license applicant shall give the board the licensee's or applicant's current address and any change of address within 30 days of the change.

(3) The notice must state that the licensee or license applicant may request a hearing to contest the charge or charges. **A request for a hearing must be in writing and received in the offices of the department within 20 days after the licensee's receipt of the notice.** Failure to request a hearing constitutes a default on the charge or charges, and the board may enter a decision on the basis of the facts available to it.

37-1-312. Sanctions -- stay --costs --stipulations. (1) Upon a decision that a licensee or license applicant has violated this part or is unable to practice with reasonable skill and safety due to a physical or mental condition or upon stipulation of the parties as provided in subsection (3), the board may issue an order providing for one or any combination of the following sanctions:

(a) revocation of the license;

(b) suspension of the license for a fixed or indefinite term;

(c) restriction or limitation of the practice;

(d) satisfactory completion of a specific program of remedial education or treatment;

(e) monitoring of the practice by a supervisor approved by the disciplining authority;

(f) censure or reprimand, either public or private;

(g) compliance with conditions of probation for a designated period of time;

(h) payment of a fine not to exceed $1,000 for each violation. Fines must be deposited in the state general fund.

(i) denial of a license application;

(j) refund of costs and fees billed to and collected from a consumer.

(2) A sanction may be totally or partly stayed by the board. To determine which sanctions are appropriate, the board shall first consider the sanctions that are necessary to protect or compensate the public. Only after the determination has been made may the board consider and include in the order any requirements designed to rehabilitate the licensee or license applicant.

(3) The licensee or license applicant may enter into a stipulated agreement resolving potential or pending charges that includes one or more of the sanctions in this section. The stipulation is an informal disposition for the purposes of 2-4-603.

(4) A licensee shall surrender a suspended or revoked license to the board within 24 hours after receiving notification of the suspension or revocation by mailing it or delivering it personally to the board.

2-4-631(3). Licenses. Whenever notice is required, no revocation, suspension, annulment, withdrawal, or amendment of any license is lawful unless the agency gave notice by mail to the licensee of facts or conduct which warrant the intended action. If the agency finds that public health, safety, or welfare imperatively requires emergency action and incorporates a finding to that effect in its order, summary suspension of a license may be ordered pending proceedings for revocation or other action. These proceedings shall be promptly instituted and determined.

STATEMENT OF RIGHTS

APP Pharmaceuticals, LLC is entitled to a hearing on the proposed discipline against the license of APP Pharmaceuticals, LLC before an impartial and independent

Hearing Examiner appointed by the Department of Labor and Industry as provided in the Montana Administrative Procedure Act. Mont. Code Ann. § 2-4-601, et seq., and § 37-1-121. APP Pharmaceuticals, LLC has a right to be represented by an attorney at such hearing and during related proceedings.

If APP Pharmaceuticals, LLC wants to have a hearing and the opportunity to contest the proposed action, a **written request for hearing** must be sent advising Becky Carter, Compliance Supervisor, Business Standards Division, Department of Labor and Industry, 301 South Park, P.O. Box 200513, Helena, Montana 59620-0513. This request must be received in the offices of the Department within twenty (20) days after receipt of this notice.

DATED this 19th day of September, 2008.

Anjeanette C. Lindle

Anjeanette C. Lindle
Department Counsel
Montana Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that on the 19th day of September 2008, I served a true and accurate copy of the foregoing NOTICE OF PROPOSED BOARD ACTION AND OPPORTUNITY FOR HEARING by certified U.S. mail, certified number 70071490 0005 0568 5311, postage prepaid, upon the Licensee addressed as follows:

Christina McGahan
Regulatory Affairs - Labeling
Licensing and Registration
APP Pharmaceutical LLC
1501 East Woodfield Road
Suite 300 East
Schaumburg IL 60173

Susan C. Peters

STATE OF COLORADO

STATE BOARD OF PHARMACY
Wendy L. Anderson, Program Director

1560 Broadway, Suite 1300
Denver, Colorado 80202-5146
Phone (303) 894-7800
Fax (303) 894-7692
V/TDD: Dial 711 for Relay Colorado
www.dora.state.co.us/pharmacy

Department of Regulatory Agencies
D. Rico Munn
Executive Director

Division of Registrations
Rosemary McCool
Director

Bill Ritter, Jr.
Governor

December 22, 2008

APP Pharmaceuticals, LLC
Attn: Michael Bean, Designated Representative
600 Supreme Drive
Bensenville, IL 60106

RE: Stipulation and Final Agency Order
Case # 2009-1735

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE LICENSE TO PRACTICE AS AN OUT-OF-STATE PRESCRIPTION DRUG WHOLESALER IN THE STATE OF COLORADO OF APP PHARMACEUTICALS,

Dear Mr. Bean:

Enclosed you will find a copy of the fully executed Stipulation and Final Agency Order in the above-mentioned matter, which became effective December 19, 2008.

Accordingly, and pursuant to Item 8 – Conditional Registration, APP Pharmaceuticals, LLC, at the above listed location, has been issued out-of-state prescription drug wholesaler registration #7467, effective December 19, 2008.

If you have any questions, or require additional information, please contact the Board's office.

Respectfully,

FOR THE COLORADO STATE BOARD OF PHARMACY

Tia Johnson
Complaint/Licensing Analyst

Enclosure

cc: Leslii Lewis, Office of Expedited Settlement
Lisa E. Davis, Esq.
File

G:\Healthcare\Pharmacy\JOHNSON\Complaints\Monitoring\2008 corresp\STIP FAO LETTER.doc

BEFORE THE STATE BOARD OF PHARMACY
STATE OF COLORADO

Case No. 2009-001737

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE LICENSE TO PRACTICE AS AN OUT-OF-STATE PRESCRIPTION DRUG WHOLESALER IN THE STATE OF COLORADO OF APP PHARMACEUTICALS,

Wholesaler Applicant.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and APP Pharmaceuticals ("Wholesaler Applicant") to resolve all matters pertaining to Board Case Number 2009-001737 as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Wholesaler Applicant, its application for registration as an out-of-state prescription drug wholesaler and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of the Pharmaceuticals and Pharmacists Act at Title 12, Article 22, C.R.S.

2. Wholesaler Applicant admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

3. On December 17, 2007, Wholesaler Applicant distributed prescription drugs to a pharmacy in Colorado without having first registered as an out-of-state prescription drug wholesaler in the State of Colorado.

4. Wholesaler Applicant's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes:

Colorado Revised Statutes

12-22-125. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in

accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(I) Any of the provisions of this part 1, including but not limited to any acts in section 12-22-126;

(II) The lawful rules of the board; or

(III) Any state or federal law pertaining to drugs.

12-22-125.2. Disciplinary actions. (1) The board may deny or discipline an applicant, licensee, or registrant when the board determines that such applicant, licensee, or registrant has engaged in activities that are grounds for discipline.

* * *

12-22-802. Wholesaler license requirements. (1) A wholesaler that resides in this state shall be licensed by the board. A wholesaler that does not reside in this state shall be licensed in this state prior to engaging in the wholesale distribution of prescription drugs in this state...

* * *

5. On October 6, 2008, Wholesaler Applicant submitted an out-of-state prescription drug wholesaler application, which application was denied by the Board.

6. On December 3, 2008, Wholesaler Applicant submitted a written request asking that the Board accept its application by granting a conditional registration.

7. The Board finds and concludes, and Wholesaler Applicant agrees, that based upon Wholesaler Applicant's above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances as a condition of its registration as an out-of-state prescription drug wholesaler.

DISPOSITION

Conditional Registration;
$5,000.00 Fine and Terms

8. **Conditional Registration.** Wholesaler Applicant shall be granted a registration as an out-of-state prescription drug wholesaler upon execution of this Final Agency Order and satisfaction of the terms and conditions set forth herein.

9. **Fine with Surcharge.** Wholesaler Applicant accepts the following discipline: Pursuant to §12-22-125.2(5), C.R.S., Wholesaler Applicant shall pay a fine of Five Thousand Dollars and No Cents ($5,000.00). Wholesaler Applicant understands and acknowledges, pursuant to §24-34-108, C.R.S., that the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 15% of this fine. Wholesaler Applicant shall therefore pay a total amount of Five Thousand, Seven Hundred Fifty Dollars and No Cents ($5,750.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Wholesaler Applicant submits this signed Final Agency Order to the Board.

10. **Compliance.** Wholesaler Applicant shall at all times remain in compliance with §§12-22-801, *et seq.* C.R.S. and shall not at any time distribute prescription drugs into Colorado without being registered as an out-of-state prescription drug wholesaler in the State of Colorado at the time of distribution.

11. **Advisements and Waivers.** Wholesaler Applicant enters into this Final Agency Order freely and voluntarily, whether or not Wholesaler Applicant has consulted with legal counsel. Wholesaler Applicant acknowledges its understanding that it has the following rights:

    a. To have a formal notice of hearing and charges served upon it;
    b. To respond to said formal notice of charges;
    c. To have a formal disciplinary hearing pursuant to §12-22-125, C.R.S.; and
    d. To appeal this Board order.

    Wholesaler Applicant freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for Board's limiting the action taken against it to the sanctions imposed herein.

12. **Acknowledgments.** The undersigned authorized agent of Wholesaler Applicant has read this Final Agency Order in its entirety and acknowledges, whether or not Wholesaler Applicant has consulted with legal counsel, that Wholesaler Applicant understands the legal consequences and agrees that none of the terms or conditions herein are unconscionable.

13. **Violations.** Time is of the essence to this Final Agency Order. It is the responsibility of Wholesaler Applicant to take all appropriate steps to comply fully with this Final Agency Order. Wholesaler Applicant acknowledges and agrees that any violation of this Final Agency Order may be sanctioned as provided under §12-

22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Wholesaler Applicant to comply with all terms and conditions of this Final Agency Order.

14. **Integration and Severability**. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

15. **Public Record**. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

16. **Effective Date**. This Final Agency Order shall become effective upon signature of a Board member or representative.

ACCEPTED AND AGREED BY

Scott W Meach Dated: 12-15-08

Authorized Agent of Wholesaler Applicant

Subscribed and sworn to by SCOTT W MEACHAM, in his/her capacity as an authorized agent of APP PHARMACEUTICALS LLC, before me in the County of COOK, State of ILLINOIS, this 15TH day of DECEMBER, 2008.

"OFFICIAL SEAL"
DIANE M. SKRZYPINSKI
NOTARY PUBLIC, STATE OF ILLINOIS
MY COMMISSION EXPIRES 8/24/2011

Diane M. Skrzypinski
Notary Public

My commission expires: August 24, 2011

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 19th day of December, 2008.

State Board of Pharmacy

BY: Wendy Anderson
Wendy Anderson
Program Director

APPROVED AS TO FORM

Attorneys for Respondent:
Quarles & Brady LLP*

D.B
12/15/08

Lisa E. Davis

Quarles & Brady LLP
One Renaissance Square
Two North Central Avenue
Phoenix, AZ 85004-2391
Telephone: 602-229-5200
Fax: 602-229-5690

*Counsel of Record

APP Pharmaceuticals, LLC

Donna Bobrowicz

Donna Bobrowicz, Esq.

APP Pharmaceuticals
Sr. Patent Attorney
1501 E. Woodfield Road
Suite 300 East
Schaumburg, IL 60173
Telephone: 847-330-1248
Fax: 847-413-2670

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 22nd day of December 2008, addressed as follows:

APP Pharmaceuticals
600 Supreme Drive
Bensenville Ill 60106

Lisa E. Davis
Quarles & Brady LLP
One Renaissance Square
Two North Central Avenue
Phoenix, Az 85004-2391

To Remove Document Fold and Tear Along This Perforation

STATE OF COLORADO
Department of Regulatory Agencies
Division of Registrations

ACTIVE
WHOLESALER OUT-OF-STATE

PRINTED ON SECURE PAPER

7467	12/19/2008	10/31/2010
Number	Issue Date	Expires

APP Pharmaceuticals, LLC
Bensenville, IL 60106
United States

Director

Signature

APP Pharmaceuticals, LLC

BRD 76 TYPE WHO NUMBER 7467

MAIL CORRESPONDENCE TO ☐ HOME ☐ BUSINESS

HOME PHONE	BUSINESS PHONE
AREA — —	AREA — —

Name Change

Home Address - Include City State Zip Code

Business Name / Address - Include City State Zip Code

▲ Use the area above for any ADDRESS or NAME CHANGE ▲

◀ THIS IS YOUR WALLET CARD

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Smithfield Bioscience, Inc.
Address: 12150 Best Place City: Cincinnati State: OH Zip: 45241
Name: West Pharmaceutical Services, Inc.
Address: 530 Herman O West Drive City: Exton State: PA Zip: 19341
Name: Gerresheimer Glass
Address: 537 Crystal Avenue City: Vineland State: NJ Zip: 08360
Name: Teva API, Inc.
Address: 400 Interpace Parkway Morris City: Parsippany State: NJ Zip: 07054

Section 4: Publicly Traded Corporation

State of Incorporation: N/a
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): Fresenius Kabi Pharmaceuticals Holding, LLC
Corporation/Organization Name: Fresenius SE & Co. KGaA
Mailing Address: Else-Kröner-Str. 1 61352
City: Bad Homburg, Germany State: Zip:
Telephone: +49 6172 608-0 Email: licensure@cardinalhealth.com
Contact Person Name: LaToyia Martin

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Fresenius Kabi USA, LLC

Facility Name

Keegan Chamberlain

Print Name of Authorized Person Submitting Application

K Chmbl

Original signature of Authorized Person (copies or stamps not accepted)

9/12/24

Date

Board Use Only	Date Received: _____	Amount: _____

LIMITED POWER OF ATTORNEY

I, Sean Moriarty, Officer of Fresenius Kabi USA, LLC, a corporation organized and existing under the laws of Delaware, having a place of business at Three Corporate Drive, Lake Zurich, IL 60047, do hereby grant and empower Keegan Chamberlain and LaToyia Martin each in their capacity as an employee of Cardinal Health 200, LLC ("CAH") to act jointly or separately exercising rights on our behalf and to act as out true and lawful attorney-in-fact, with the power to execute any and all documents and any amendments thereto, on behalf of Fresenius Kabi USA, LLC upon review and approval from a member of the Fresenius Kabi USA, LLC Legal Department with respect to maintaining certain state agency licenses in accordance with the terms of that certain Master License Management Agreement between Fresenius Kabi USA, LLC and Cardinal Health 200, LLC dated January 1, 2022 and the Statement of Work fully executed on February 2, 2022.

This Limited Power of Attorney shall expire at the end of the day on December 31, 2024, unless earlier revoked by written instrument that is delivered to CAH.

The undersigned has caused this Limited Power of Attorney to be signed this 22nd day of March, 2024.

By: _____
Sean Moriarty

By: _____
Witness

FDA

FDA Home[1] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
Fresenius Kabi USA, LLC
3159 STALEY RD.
GRAND ISLAND, NY 14072
Registration Number: 1321116
FEI Number*: 3001833549
Status: Active
Date Of Registration Status: 2024

Owner/Operator:
Fresenius Kabi USA, LLC[6]
3 Corporate Drive
Lake Zurich, IL US 60047
Owner/Operator Number: 9034064[7]

Official Correspondent:
Molly Ventrelli
3 Corporate Drive
Lake Zurich, IL 60047
Phone: 847-5502014

Verified M.H 9/9/24

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9034064&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9034064&OwnerOperator

Page Last Updated: 02/12/2024

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsc | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of Health & Human Services

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9034064&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9034064&OwnerOperator

CardinalHealth

3159 Staley Road
Grand Island, New York 14072-2028

Officer Name	Title
Sean Moriarty	EVP, General Counsel and Secretary
Arunesh Verma	President and CEO
Alexandre Garini	EVP, CFO, Regional Finance Officer

Copyright © 2024 Cardinal Health. All Rights Reserved
The above information is confidential and to be used for licensing purposes only. Any other use is strictly prohibited without prior consent of Cardinal Health.

FRESENIUS KABI

Fresenius Kabi USA, LLC

Three Corporate Drive
Lake Zurich, IL 60047
T 847-550-2300
T 888-391-6300
www.fresenius-kabi.us

Top Shareholders

The Else Kröner-Fresenius-Stiftung (EKFS) – 27%

Harris Associates LP - 2.992%

Amundi Asset Management SA (Investment Management) - 0.5056

Sparinvest SA (Denmark) - 0.3286 %

Department of State: Division of Corporations

Allowable Characters

HOME

View Search Results

Entity Details

File Number:	4373141	Incorporation Date / Formation Date:	6/18/2007 (mm/dd/yyyy)
Entity Name:	FRESENIUS KABI USA, LLC		
Entity Kind:	Limited Liability Company	Entity Type:	General
Residency:	Domestic	State:	State:
Status:	Good Standing	Status Date:	6/18/2007

REGISTERED AGENT INFORMATION

Name:	CORPORATION SERVICE COMPANY		
Address:	251 LITTLE FALLS DRIVE		
City:	WILMINGTON	County:	New Castle
State:	DE	Postal Code:	19808
Phone:	302-636-5401		

Back to Entity Search | Email Status

For help on a particular field click on the Field Tag to take you to the help area.

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2023-26

NAME OF SUPERVISOR
SHANNON PELLERITE

THIS IS TO CERTIFY

FRESENIUS KABI USA, LLC
3159 STALEY RD
GRAND ISLAND, NY 14072

is duly recorded as a

REGISTERED MANUFACTURER OF DRUGS AND/OR DEVICES

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE FIRST DAY OF NOVEMBER, 2023.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF OCTOBER, 2026.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER
029146

Dina Joyce
EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

0877

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 09/26/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
MARSH USA LLC.
155 N. WACKER, SUITE 1200
CHICAGO, IL 60661

CN101377545-FKUSA-STD-24-25

CONTACT NAME: Marsh | U.S. Operations
PHONE (A/C, No, Ext): 866-966-4664 **FAX (A/C, No):**
E-MAIL ADDRESS: Chicago.CertRequest@marsh.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Federal Insurance Company	20281
INSURER B : Travelers Property Casualty Co. of America	25674
INSURER C : ACE Property and Casualty Insurance Company	20699
INSURER D : The Charter Oak Fire Insurance Company	25615
INSURER E : Westchester Surplus Lines Insurance Company	10172
INSURER F :	

INSURED
Fresenius Kabi USA, LLC
3 Corporate Drive
Lake Zurich, IL 60047

COVERAGES **CERTIFICATE NUMBER:** CHI-010748753-00 **REVISION NUMBER:** 0

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			36031526	01/01/2024	01/01/2025	EACH OCCURRENCE	$	2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	2,000,000
							MED EXP (Any one person)	$	10,000
							PERSONAL & ADV INJURY	$	2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	4,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$	EXCLUDED
	OTHER:							$	
B	AUTOMOBILE LIABILITY			HC2JCAP-9P529954-TIL-24	01/01/2024	01/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$	2,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
C	X UMBRELLA LIAB X OCCUR			XEUG71773954 005	01/01/2024	01/01/2025	EACH OCCURRENCE	$	10,000,000
	EXCESS LIAB CLAIMS-MADE			Excludes Products Liability			AGGREGATE	$	10,000,000
	DED RETENTION $							$	
D	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			UB-1L613255-24-I2-K (Ded) (AOS)	01/01/2024	01/01/2025	X PER STATUTE OTH-ER		
B	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: N	N/A		UB-1L610831-24-I2-R (Retro)	01/01/2024	01/01/2025	E.L. EACH ACCIDENT	$	1,000,000
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			(AZ, MA, NE, WI)			E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000
E	PRODUCTS LIABILITY			G46848408 007	01/01/2024	01/01/2025	EACH OCCURRENCE		10,000,000
	SIR: $2M each claim-$10M Aggr.			See Attached for Retroactive Dates			AGGREGATE		10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
State of Nevada Manufacturing License.
Fresenius Kabi Plants
3159 Staley Road, Grand Island, New York 14072
2020 Ruby Street, Melrose Park, Illinois 60160
5200 Corporate Parkway, Wilson, North Carolina 2789

CERTIFICATE HOLDER

State of Nevada
c/o Fresenius-Kabi USA LLC.
Three Corporate Drive
Lake Zurich, IL 60047

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
of Marsh USA LLC

Marsh USA LLC

© 1988-2016 ACORD CORPORATION. All rights reserved.

AGENCY CUSTOMER ID: CN101377545

LOC #: Chicago

ACORD®

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA LLC.	Fresenius Kabi USA, LLC 3 Corporate Drive Lake Zurich, IL 60047
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Claims Made - Retroactive dates:
11/13/2007- All Other Operations
06/01/1998 - Clinical Trails excluding Abraxane
01/01/2012 - Errors or Omissions Liability Coverage
01/07/2016 - Fresenius Kabi Rx, Inc.
01/07/2016 - Metoclopramide
05/04/2022 - Ivenix, Inc.

© 2008 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

VERIFICATION CERTIFICATE FOR INDEFINITE TERM SURETY BOND

THIS IS TO CERTIFY that Bond Number CMS0336703 issued by RLI Insurance Company, as Surety, dated the 14th day of November, 2019, in the amount of One Hundred Thousand & 00/100 ($ 100,000.00), on behalf of Fresenius Kabi, LLC, as Principal, and in favor of Nevada State Board of Pharmacy, as Obligee, covers a term which began on the 14th day of November, 2019, and ends only with the cancellation of said bond or other legal termination thereof; and that the said bond remains in effect, subject to all its agreements, conditions and limitations.

Current Renewal Term: 11/14/2023 to 11/14/2024.

Signed, sealed and dated this 10th day of September, 2024.

RLI Insurance Company
Surety

By: Andrea Allman
Andrea Allman, Attorney-in-Fact

RLI INSURANCE COMPANY CORPORATE SEAL ILLINOIS

POWER OF ATTORNEY

RLI Insurance Company
Contractors Bonding and Insurance Company

9025 N. Lindbergh Dr. Peoria, IL 61615
Phone: 800-645-2402

Know All Men by These Presents:

That this Power of Attorney is not valid or in effect unless attached to the bond which it authorizes executed, but may be detached by the approving officer if desired.

That **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, each an Illinois corporation, (separately and together, the "Company") do hereby make, constitute and appoint:

Carolyn E. Wheeler, Sandra G. King, Vicki Nobinger, Rachel A. Chaveriat, Bonnie Rice, Andrea Allman, Loretta M. Jones, Amanda L. Mills, Lisa M. Frye, Leslie Patterson, Sarah Major, Meri Damron, Carrie Wright, Lara Liparoto, jointly or severally

in the City of Knoxville, State of Tennessee its true and lawful Agent(s) and Attorney(s) in Fact, with full power and authority hereby conferred, to sign, execute, acknowledge and deliver for and on its behalf as Surety, in general, any and all bonds and undertakings in an amount not to exceed **Seventy Five Million** Dollars (**$75,000,000.00**) for any single obligation.

The acknowledgment and execution of such bond by the said Attorney in Fact shall be as binding upon the Company as if such bond had been executed and acknowledged by the regularly elected officers of the Company.

RLI Insurance Company and/or **Contractors Bonding and Insurance Company**, as applicable, have each further certified that the following is a true and exact copy of a Resolution adopted by the Board of Directors of each such corporation, and is now in force, to-wit:

> "All bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, any Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys in Fact or Agents who shall have authority to issue bonds, policies or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile."

IN WITNESS WHEREOF, the **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, as applicable, have caused these presents to be executed by its respective Sr. Vice President with its corporate seal affixed this 23rd day of August, 2024.

CONTRACTORS BONDING AND INSURANCE COMPANY CORPORATE SEAL ILLINOIS

RLI INSURANCE COMPANY CORPORATE SEAL ILLINOIS

RLI Insurance Company
Contractors Bonding and Insurance Company

By: _____
Eric Raudins — Sr. Vice President

State of Illinois }
County of Peoria } SS

On this 23rd day of August, 2024, before me, a Notary Public, personally appeared Eric Raudins, who being by me duly sworn, acknowledged that he signed the above Power of Attorney as the aforesaid officer of the **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company** and acknowledged said instrument to be the voluntary act and deed of said corporation.

By: _____
Jill A. Scott — Notary Public

NOTARY PUBLIC STATE OF OHIO

JILL A SCOTT
Notary Public
State of Ohio
My Comm. Expires
September 22, 2025

CERTIFICATE

I, the undersigned officer of **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, do hereby certify that the attached Power of Attorney is in full force and effect and is irrevocable; and furthermore, that the Resolution of the Company as set forth in the Power of Attorney, is now in force. In testimony whereof, I have hereunto set my hand and the seal of the **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company** this 10th day of September, 2024.

RLI Insurance Company
Contractors Bonding and Insurance Company

By: _____
Jeffrey D. Fick — Corporate Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Fresenius Kabi USA, LLC — MDEG License # (if applicable): N/A

Physical Address: 3159 Staley Rd

City: Grand Island — State: NY — Zip: 14072

Mailing Address (if different from physical address): 7000 cardinal place, QRA

City: Dublin — State: OH — Zip: 43215

Telephone: 716-773-0800 — Website: https://www.fresenius-kabi.com/us/

Licensing Company Email: licensure@cardinalhealth.com

Section 2: Personal Information

First: Shannon — Middle: Lee — Last: Pellerite

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☐ M ■ F ☐ X

Mailing Address: 3159 Staley Rd

City: Grand Island — State: NY — Zip: 14072

Telephone: 716-773-0800 ext. 2521 — Email: shannon.pellerite@fresenius-kabi.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Buffalo School of Pharmacy and Pharmaceutical Sciences		01/1984 - 05/1988	
Address	**City**	**State**	**Zip**
285 Pharmacy Building	Buffalo	NY	14214
Diploma/Degree obtained, if any			
BS in Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Daemen College		09/1982 - 12/1984	
Address	**City**	**State**	**Zip**
4380 Main Street	Amherst	NY	14226
Diploma/Degree obtained, if any			
N/A - Transferred to another college			

School Name		From - To (MM/YY – MM/YY)	
Kenmore West High School		09/1980 - 06/1982	
Address	**City**	**State**	**Zip**
33 Highland Parkway	Buffalo	NY	14223
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
N			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
			A

School Name		From - To (MM/YY – MM/YY	
N			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
			A

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/96 to present	[redacted]	Amherst	NY	14228
N	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
				A

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Fresenius Kabi USA, LLC			04/2019 to present	
Business Address		**City**	**State**	**Zip**
3159 Staley Rd		Grand Island	NY	14072
Phone	**Title**		**Number of Employed Hours**	
716-773-0800	Sr. Manager, Controlled Substances		over 5 years	

Description of Duties

Controlled Substance (CS) inventory management, ensures effective security controls, shipping/receiving of CS, coordinates import/export of CS, CS waste management, ARCOS reporting, Quota applications, and YERS Reporting

Business Name			From - To (MM/YY – MM/YY)	
N				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

A

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N				
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				A

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Shannon Pellerite, **certify that as the MDEG Administrator for**

Fresenius Kabi USA, LLC,

that I (initial that you have read and meet the following requirements):

1. SP Have a high school diploma or its equivalent;
2. SP Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SP Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. SP Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shannon Pellerite

Print Name (First, Last)

Shannon Pellerite

Original Signature (electronic, copies or stamps not accepted)

07-17-2024

Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Fresnius Kabi USA, LLC
Pharmacy/Wholesaler License # (if applicable): N/A
Physical Address: 3159 Staley Rd
City: Grand Island State: NY Zip: 14072
Mailing Address (if different from physical address): 7000 Cardinal Place, QRA
City: Dublin State: OH Zip: 43215
Telephone: 716-773-0800 Website: https://www.fresenius-kabi.com/us/
Licensing Company Email: licensure@cardinalhealth.com

Section 2: Personal Information

First: Shannon Middle: Lee Last: Pellerite
Alias(es, nicknames, name changes, etc.): N/A
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X
Mailing Address: 3159 Staley Rd
City: Grand Island State: NY Zip: 14072
Telephone: 716-773-0800 ext. 2521 Email: shannon.pellerite@fresenius-kabi.com
Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Buffalo School of Pharmacy and Pharmaceutical Sciences		01/1984 - 05/1988	
Address	**City**	**State**	**Zip**
285 Pharmacy Building	Buffalo	NY	14214
Diploma/Degree obtained, if any			
BS in Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Daemen College		09/1982 - 2/1984	
Address	**City**	**State**	**Zip**
4380 Main Street	Amherst	NY	14226
Diploma/Degree obtained, if any			
N/A - Transferred to another college			

School Name		From - To (MM/YY – MM/YY)	
Kenmore West High School		09/1980 - 06-1982	
Address	**City**	**State**	**Zip**
33 Highland Parkway	Buffalo	NY	14223
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

A

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/96 to present	[redacted]	Amherst	NY	14228
N				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

A

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Fresenius Kabi USA, LLC			04/2019 to present	
Business Address		**City**	**State**	**Zip**
3159 Staley Rd		Grand Island	NY	14072
Phone	**Title**		**Number of Employed Hours**	
716-773-0800	Sr. Manager, Controlled Substances		over 5 years	
Description of Duties				
Controlled Substance (CS) inventory management, ensures effective security controls, shipping/receiving of CS, coordinates import/export of CS, CS waste management, ARCOS reporting, Quota applications, and YERS reporting				

Business Name			From - To (MM/YY – MM/YY)	
N				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				
A				

Continue on next page if additional space is needed.

Business Name N			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties A				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N				
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				A

Provide explanation below: N/A

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Shannon Pellerite, **certify that as the designated representative for**

Fresenius Kabi USA, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SP I am at least 21 years of age;
3. SP I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SP I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SP I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SP I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SP I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Shannon Pellerite

Print Name (First, Last)

Shannon Pellerite

Original Signature (electronic, copies or stamps not accepted)

07-17-2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shannon Pellerite

Print Name (First, Last)

Shannon Pellerite — 07-17-2024

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Erie

I, Shannon Pellerite, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Shannon Pellerite — 07.25.2024

Original Signature — **Date**

Subscribed and Sworn to before me this 25 day of July 2024.

Lyn A. Davey

Notary Public Signature

Lyn A. Davey
Notary Public, State of New York
Qualified in Niagara County
My Commission Expires ~~March 22~~ 05 21, 20 28

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Fresenius Kabi USA, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 3159 Staley Rd

City: Grand Island State: NY Zip: 14072-2028

Mailing Address (if different from physical address): 7000 cardinal place, QRA

City: Dublin State: OH Zip: 43215

Telephone: 716-773-0800 Website: https://www.fresenius-kabi.com/us/

Licensing Company Email: licensure@cardinalhealth.com

Section 2: Personal Information

First: Shannon Middle: Lee Last: Pellerite

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: 3159 Staley Rd

City: Grand Island State: NY Zip: 14072-2028

Telephone: 716-773-0800 ext. 2521 Email: shannon.pellerite@fresenius-kabi.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Buffalo School of Pharmacy and Pharmaceutical Sciences		01/1984 - 05/1988	
Address	**City**	**State**	**Zip**
285 Pharmacy Building	Buffalo	NY	14214
Diploma/Degree obtained, if any			
BS in Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Daemen College		09/1982 - 12-1984	
Address	**City**	**State**	**Zip**
4380 Main Street	Amherst	NY	14226
Diploma/Degree obtained, if any			
N/A - Transferred to another college			

School Name		From - To (MM/YY – MM/YY)	
Kenmore West High School		06/1980 - 06/1982	
Address	**City**	**State**	**Zip**
33 Highland Parkway	Buffalo	NY	14223
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
N			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
			A

School Name		From - To (MM/YY – MM/YY	
N			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
			A

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/96 to present	[redacted]	Amherst	NY	14228
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
				A

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
N/A			
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			
			A

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

A

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N				
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				A

Provide explanation below: N/A

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shannon Pellerite
Print Name (First, Last)

Shannon Pellerite — 07-25-2024
Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Erie

I, Shannon Pellerite, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Shannon Pellerite — 07-25-2024
Original Signature — **Date**

Subscribed and Sworn to before me this 25 day of July 2024.

Lyn A. Davey
Notary Public Signature

Lyn A. Davey
Notary Public, State of New York
Qualified in Niagara County
My Commission Expires 5/21/2028

(Seal)

CardinalHealth

3159 Staley Road
Grand Island, New York 14072-2028

Employee List

Officer Name	Title
Sean Moriarty	EVP, General Counsel and Secretary
Arunesh Verma	President and CEO
Alexandre Garini	EVP, CFO, Regional Finance Officer
Shannon Pellerite	Sr. Manager, Controlled Substances
Anthony Pavell	Plant Manager

Copyright © 2024 Cardinal Health. All Rights Reserved
The above information is confidential and to be used for licensing purposes only. Any other use is strictly prohibited without prior consent of Cardinal Health.

4U

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☑ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☑ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Genentech USA , Inc.

Physical Address: 1 DNA Way, Building 25

City: South San Francisco State: CA Zip: 94080

Mailing Address (if different from physical address): Genentech USA, Inc., Attn: Jill JewelMS 245D, 1 DNA Way

City: South San Francisco State: CA Zip: 94080

Telephone: 650-225-1000 Website: www.gene.com

Name of Designated Representative (DR): Martha Greene

Licensing Company Email: US_State_Licensing-d@gene.com DR Email: US_State_Licensing-d@gene.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☑ Dangerous Drugs	☑ Manufacturer
☑ Practitioners	☐ Controlled Substances	☐ Repacker
☑ Hospitals	☑ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☑ Others: Prescription human drugs	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☑ Others: Specialty Distributors / Clinics		☑ Others: Virtual manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	☐	☑
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?	☐	☑
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	☑	☐
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?	☐	☑
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?	☐	☑

Nevada

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/7/2023	12/22/2023	AZ	Phoenix	
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
23-0666		Arizona State Board of Pharmacy		
Reason/Charge				
non-disciplinary civil penalty for failing to provide notice of a prior disciplinary action				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Genentech, Inc.		non-disciplinary civil penalty		
Name of Business/Industry/Entity				
Genentech, Inc				

Provide explanation below:

Genentech, Inc. received a non-disciplinary civil penalty from the Arizona Board of Pharmacy for failing to provide notice of a prior disciplinary action (a settlement with the Colorado Board of Pharmacy). Genentech, Inc. promptly paid the required penalty which resolved the matter.

Martha Gruer

Original Signature (electronic, copies or stamps not accepted)

9/4/24

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
5/12/2021		TX	Austin	
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2536		Texas Department of State Health Services		
Reason/Charge				
delinquency notice for operating under an expired license				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Genentech, Inc.		delinquency notice		
Name of Business/Industry/Entity				
Genentech, Inc				

Provide explanation below:

Genentech, Inc. received a delinquency notice from the State of TX for operating under an expired license. License was promptly renewed and is presently in good standing.

Original Signature (electronic, copies or stamps not accepted)

9/4/24
Date

Nevada

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
5/10/2019	5/22/2019	CO	Denver	
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2019-1831		Colorado State Board of Pharmacy		
Reason/Charge				
Disciplinary Action for failing to notify the Board of a Designated Representative change.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Genentech, Inc.			Disciplinary Action	
Name of Business/Industry/Entity				
Genentech, Inc				

Provide explanation below:

Genentech, Inc. received a Disciplinary Action from the State of CO for failing to notify the Board of a Designated Representative change.

Mantra Green
Original Signature (electronic, copies or stamps not accepted)

9/4/24
Date

Nevada

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
11/09/2021		TX	Austin	
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2019		Texas Department of State Health Services		
Reason/Charge				
delinquency notice for operating under an expired license				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Genentech USA, Inc.		delinquency notice		
Name of Business/Industry/Entity				
Genentech USA, Inc				

Provide explanation below:

Genentech USA, Inc. received a delinquency notice from the State of TX for operating under an expired license. License was promptly renewed and is presently in good standing.

Original Signature (electronic, copies or stamps not accepted)

9/4/24
Date

Genentech

Genentech Inc. Disciplinary / Administrative Actions

NV History of Company Question #3

- 12/2023 Genentech, Inc. received a non-disciplinary civil penalty from the Arizona Board of Pharmacy for failing to provide notice of a prior disciplinary action (a settlement with the Colorado Board of Pharmacy). Genentech, Inc. promptly paid the required penalty which resolved the matter.
- 05/2021 Genentech, Inc. received a delinquency notice from the State of TX for operating under an expired license. License was promptly renewed and is presently in good standing.
- 05/2019 – Genentech, Inc. received a Disciplinary Action from the State of CO for failing to notify the Board of a Designated Representative change.

Genentech

Genentech USA, Inc Disciplinary / Administrative Action

NV History of Company Question #3

- 11/2021 Genentech USA, Inc. received a delinquency notice from the State of TX for operating under an expired license. License was promptly renewed and is presently in good standing.

Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington, Suite 260, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
Phone: 602-771-2727 Fax: 602-771-2749 pharmacy.az.gov

Order for Non-Disciplinary Civil Penalty

In the Matter of:

Respondent Name	Genentech, Inc.
License/Permit No.	M002234 (Applicant)
Board Case No.	23-0666

	Check all that apply:			Fine(s)
☐	Failing to submit a remodel application before remodeling a permitted facility.			$250
☐	Failing to provide notice before a business is relocated.			$500
☐	Failing to update contact information within 10 days.			$50
☐	Failing to update change of employment information within 10 days.			$50
☐	Failing to complete required continuing education for pharmacist. (First offense)	Deficient CEs:		$100/CE
☐	Failing to complete required continuing education for pharmacist. (Second offense)	Deficient CEs:		$150/CE
☐	Failing to complete required continuing education for technician. (First offense)	Deficient CEs:		$25/CE
☐	Failing to complete required continuing education for technician. (Second offense)	Deficient CEs:		$37.50/CE
☐	Failing to provide notice of a new pharmacist in charge within 14 days.			$100
☐	Failing to provide notice of a new designated representative within 10 days.			$100
☐	Failing to provide notice of a new criminal charge, arrest, or conviction in any jurisdiction.			$250
☒	Failing to provide notice of disciplinary action taken against the licensee or permittee in any jurisdiction.			$250
☐	Failing to renew a pharmacist license timely within 60 days and continuing to work with an expired license.*	Days worked:		$100/day
☐	Failing to renew a technician license timely within 60 days and continuing to work with an expired license. **	Days worked:		$50/day
☐	Failing to conduct a controlled substance inventory when there is a new pharmacist in charge within 10 days.			$250
☐	Failing to obtain a permit before shipping into Arizona anything for which a permit is required.	Items:		$100/Item
☐	Failing to respond timely to a subpoena.			$50
☐	Failing to provide notice before there is a change in ownership.			$250
☐	Failing to conduct required controlled substance inventories.			$250
☐	Failing to provide written notice to the Board at least 14 days before discontinuing operation of the pharmacy.			$250
☐				
			TOTAL:	**$250**
*Max $1,000				
**Max $500				
For Office Use Only				
Comment:				

The non-disciplinary civil penalty shall be paid within 90 days from the date of issuance of this order. Failure to pay the non-disciplinary civil penalty within 90 days from date of issuance of this order shall result in this case being presented to the Board and may be subject to disciplinary action. If the licensee/permittee wishes to request a rehearing/review of the Order, the request shall be filed within 35 days of the issuance of the Order under the Board's Statutes and rule.

Payment can be made using check or money order to: Arizona State Board of Pharmacy
P.O. Box 18520
Phoenix, AZ 85005

Executive Director's Signature: Kam Gandhi **Issue Date:** December 7, 2023

TEXAS
Health and Human Services

Texas Department of State Health Services,

John Hellerstedt, M.D.
Commissioner

YOU ARE OPERATING IN VIOLATION OF TEXAS HEALTH & SAFETY CODE. YOU MUST COMPLY WITH THE LAW AND OBTAIN A VALID LICENSE.

May 12, 2021

Delinquent Notice

Budget: ZZ114 Fund: 183
OOS Prescription Drugs Distributor License
Client Code: 2501
License #: 0037598
File #: 2536
Application #: 19204

GENENTECH INC / CHRISTINA OATES
1 DNA WAY MS 241A
S SAN FRANCISCO, CA 94080

RE: GENENTECH INC 1 DNA WAY S SAN FRANCISCO, CA 94080

Your license expired on 03/25/2021 and is no longer valid. If you are operating, you are in violation of the law and must obtain a valid license immediately to avoid enforcement action.

The Department has sent you written notice informing you that you must obtain a current license. To date, the Department has not received your application and licensure fee or written notice that your business has closed or is not required to license with the Department.

If you do not obtain a valid license within 30 days from the date of this letter, the Department will refer your case for enforcement action. Operating without a license is punishable by a penalty of up to $25,000 per day, per violation, or referral to the Attorney General for an injunction, which will be an order from the court prohibiting you from operating without a license, plus assessing civil penalties, attorney's fees, and costs.

You may obtain a renewal application at www.dshs.texas.gov/fdlicense/default.aspx. You must submit all license fees and late fees before the Department will issue a license.

If you are no longer in business or are not required to hold a license with the Department, please fax (512) 834-6741, email Drugs-foodsafety@dshs.texas.gov or mail: Texas Department of State Health Services, Food and Drug Licensing Group - MC 2835, PO Box 149347, Austin TX 78714-9347: a written statement on this delinquent notice (see next page), informing the Department you are no longer in business. After the Department receives your written notice stating that you are out of business, your record will be updated, and no further action will be necessary.

If you need additional information, you may contact the Drugs and Food Safety Licensing Group at (512) 834-6727.

Sincerely,

Liane El-Sheikh

Liane El-Sheikh, Manager
Business Filing and Verification Section
Drug & Device Licensing Unit, DSHS

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2019-1831

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE OUT-OF-STATE PRESCRIPTION DRUG WHOLESALER REGISTRATION IN THE STATE OF COLORADO OF GENENTECH INC., REGISTRATION NO. WHO 7079,

Respondent Outlet.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Genentech Inc., ("Respondent Outlet") to resolve all matters pertaining to Board Case Number 2019-1831, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Outlet, its registration as an out-of-state prescription drug wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2018).

2. Respondent Outlet was originally registered in the State of Colorado on or about December 22, 2006, being issued registration #WHO 7079, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Outlet's address of record with the Board and current location is 1 DNA Way MS 241A in South San Francisco, California.

4. Respondent Outlet admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

5. Respondent Outlet failed to timely submit to the Board an application detailing a change in designated representative and fee. In this case, 182 days transpired between August 15, 2018, the date the previous designated representative ceased the position, and February 13, 2019, the date the application and fee were received.

6. On or about March 14, 2019, the Board initiated a complaint against Respondent Outlet because of the delay of 182 days in submitting an application detailing a change in designated representative and fee.

7. Respondent Outlet's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

Colorado Revised Statutes

12-42.5-123. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(II) The lawful rules of the board.

* * *

Pharmacy Board Rules and Regulations

15.01.14 Change of name, location, or ownership, or designated representative.

c. Any change in the designated representative of a wholesaler shall be reported to the Board on a form supplied by the Board within thirty calendar days of such change. The incoming designated representative must undergo the required background check.

TERMS OF DISCIPLINE

8. **Fine with Surcharge**. Pursuant to section 12-42.5-124(5)(a)(I), C.R.S., Respondent Outlet shall pay a fine of One Thousand Dollars and No Cents ($1,000.00). Respondent Outlet understands and acknowledges that, pursuant to section 24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies may impose an additional surcharge of 15% of this fine. Respondent Outlet shall therefore pay a total amount of **One Thousand One Hundred Fifty Dollars and No Cents ($1,150.00)**. The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Outlet submits this signed Final Agency Order to the Board.

9. **Compliance**. Respondent Outlet shall submit all future applications and appropriate fees to the Board detailing changes in designated representative

within the required time frame specified by Board rule or statute in effect at the time of such designated representative change.

10. **Other Requirements.** Respondent Outlet acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Outlet shall:

    a. promptly pay all Respondent Outlet's own fees and costs associated with this Final Agency Order;

    b. comply fully with this Final Agency Order; and

    c. comply fully with the Pharmacists, Pharmacy Businesses and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

11. **Advisements and Waivers.** Through its undersigned Authorized Representative, Respondent Outlet enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Outlet acknowledges its understanding that it has the following rights:

    a. to have formal notice of hearing and charges served upon it;

    b. to respond to said formal notice of charges;

    c. to have a formal disciplinary hearing pursuant to sections 12-42.5-123 and 12-42.5-124, C.R.S.; and

    d. to appeal this Final Agency Order.

    Respondent Outlet freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Outlet to the sanctions imposed herein.

12. **Acknowledgments.** The undersigned Authorized Representative of Respondent Outlet has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Outlet understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Outlet is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Outlet further acknowledges that it is not entering into this Final Agency Order under any duress.

13. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Outlet to take all appropriate steps to comply fully with this Final Agency Order. Respondent Outlet acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful

Board order, may be sanctioned as provided under section 12-42.5-124(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Outlet's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Outlet to comply with all terms and conditions of this Final Agency Order.

14. **Integration and Severability**. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

15. **Public Record**. Upon execution by all parties, this Stipulation and Final Agency Order shall be a public record, maintained in the custody of the Board.

16. **Effective Date**. This Final Agency Order shall become effective upon (a) mailing by first-class mail to Respondent Outlet at Respondent Outlet's address of record with the Board, or (b) service by electronic means on Respondent Outlet at Respondent Outlet's electronic address of record. Respondent Outlet hereby consents to service by electronic means if Respondent Outlet has an electronic address on file with the Board.

ACCEPTED AND AGREED BY

Respondent Outlet

Authorized Representative — Dated: 5/10/19

Jonathan Witt
Name / Title
Sr VP/ Genentech Business Operations

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 22 day of May, 2019.

State Board of Pharmacy

BY: _____
Dmitry Kunin
Program Director

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by electronic means or by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 22 day of May 2019, addressed as follows:

By electronic mail:

Genentech Inc.
1 DNA Way MS 241A
South San Francisco, CA 94080-4918

Email: heather.desper@iqvia.com and coates@gene.com

Agent of the Board

TEXAS Health and Human Services

Texas Department of State Health Services

John Hellerstedt, M.D.
Commissioner

YOU ARE OPERATING IN VIOLATION OF TEXAS HEALTH & SAFETY CODE. YOU MUST COMPLY WITH THE LAW AND OBTAIN A VALID LICENSE.

November 09, 2021 **Delinquent Notice** Budget: ZZ114 Fund: 183
OOS Prescription Drugs Distributor License

CHRISTINA OATES / GENENTECH USA INC
1 DNA WAY, MS 241A
S SAN FRANCISCO, CA 94080

Client Code: 2501
License #: 0099943
File #: 2019
Application #: 19938

RE: GENENTECH USA INC 1 DNA WAY BUILDING 25 S SAN FRANCISCO, CA 94080

Your license expired on 09/30/2021 and is no longer valid. If you are operating, you are in violation of the law and must obtain a valid license immediately to avoid enforcement action.

The Department has sent you written notice informing you that you must obtain a current license. To date, the Department has not received your application and licensure fee or written notice that your business has closed or is not required to license with the Department.

If you do not obtain a valid license within 30 days from the date of this letter, the Department will refer your case for enforcement action. Operating without a license is punishable by a penalty of up to $25,000 per day, per violation, or referral to the Attorney General for an injunction, which will be an order from the court prohibiting you from operating without a license, plus assessing civil penalties, attorney's fees, and costs.

You may obtain a renewal application at www.dshs.texas.gov/fdlicense/default.aspx. You must submit all license fees and late fees before the Department will issue a license.

If you are no longer in business or are not required to hold a license with the Department, please fax (512) 834-6741, email Drugs-foodsafety@dshs.texas.gov or mail: Texas Department of State Health Services, Food and Drug Licensing Group - MC 2835, PO Box 149347, Austin TX 78714-9347: a written statement on this delinquent notice (see next page), informing the Department you are no longer in business. After the Department receives your written notice stating that you are out of business, your record will be updated, and no further action will be necessary.

If you need additional information, you may contact the Drugs and Food Safety Licensing Group at (512) 834-6727.

Sincerely,

Liane El-Sheikh

Liane El-Sheikh, Manager
Business Filing and Verification Section
Drug & Device Licensing Unit, DSHS

IF YOUR BUSINESS HAS CLOSED OR IS NO LONGER REQUIRED TO LICENSE. PLEASE COMPLETE ONE OF THE FOLLOWING STATEMENTS AND RETURN A COPY OF THE STATEMENT TO THE DEPARTMENT.

Client Code:2501 License #:0099943 File #: 2019 Application #: 19938

☐ **My business closed on (date):**

_____

☐ **My business is not required to license because (please provide reason):**

_____

_____ _____

Owner/Representative Signature Date Signed

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Genentech USA, Inc

Address: 7100 Riverport Drive City: Louisville State: KY Zip: 40258

Name: Genentech USA Inc

Address: 4625 NE Brookwood Pkwy City: Hillsboro State: OR Zip: 97124

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Genentech, Inc.

Corporation/Organization Name: Genentech USA, Inc.

Mailing Address: Genentech USA, Inc., Attn: Jill Jewell, MS 245D, 1 DNA Way,

City: South San Francisco, State: CA Zip: 94080

Telephone: 650-225-1000 Email: US_State_Licensing-d@gene.com

Contact Person Name: Jill Jewell

Section 6: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	☐	✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	☐	✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

Nevada

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

GENENTECH USA , INC.

Facility Name

MARTHA GREENE

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

9/4/24

Date

Board Use Only	Date Received: 9/11/24	Amount: $1000-ck 0658089

An official website of the United States government Here's how you know

FDA

Search FDA.gov

Home ▶ Drug Databases ▶ DECRS ▶ Search Result

Share Tweet Linkedin Email Print

Drug Establishments Current Registration Site

New Search

Search Results for *Genentech*

Showing 1 to 3 of 3 entries Show 50 entries

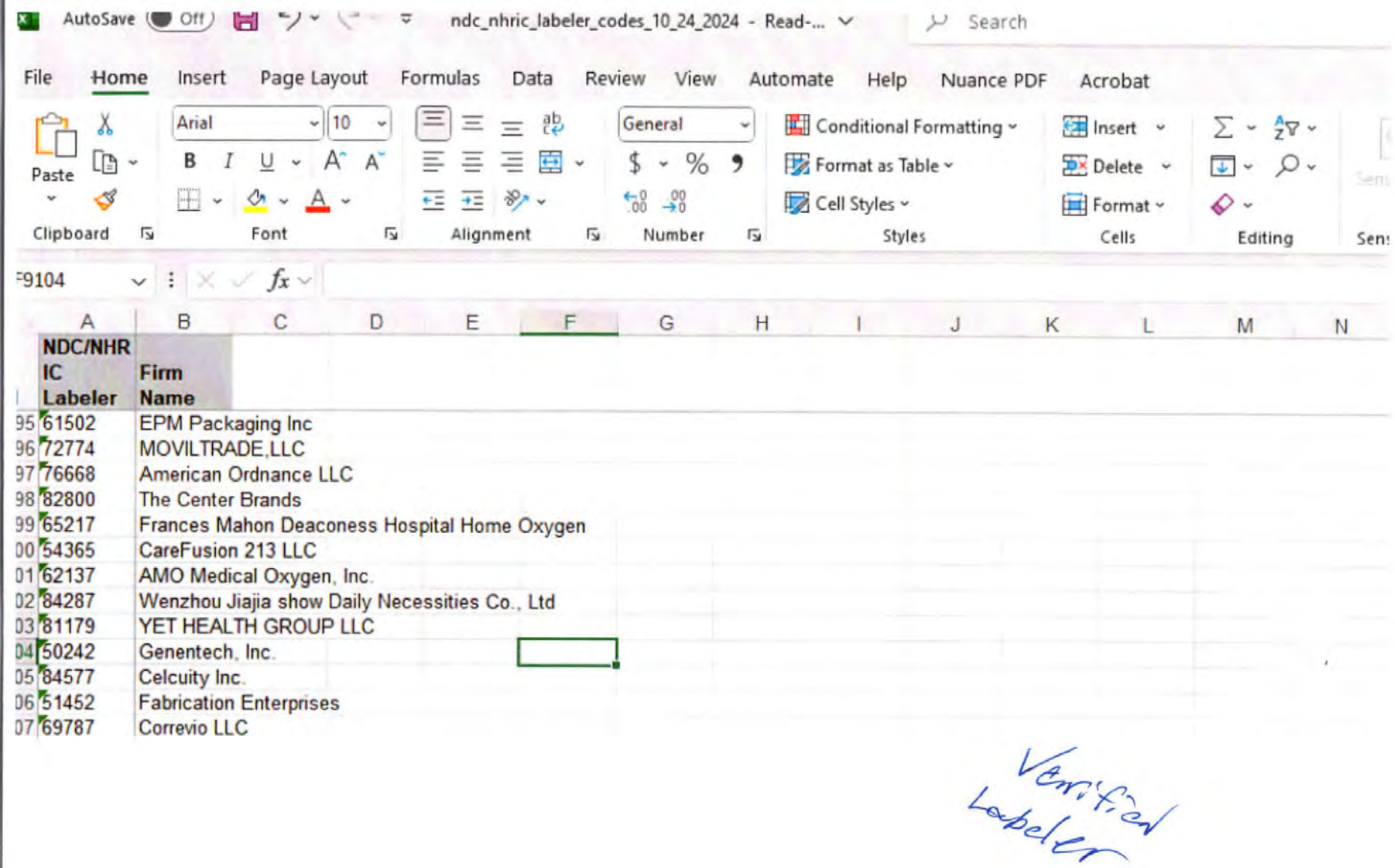
Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Genentech, Inc.	2917293	080129000	ANALYSIS; API MANUFACTURE; LABEL; MANUFACTURE; PACK	1 DNA Way, South San Francisco, California (CA) 94080, United States (USA)	12/31/2025
Genentech, Inc.	3006129086	146373191	ANALYSIS; API MANUFACTURE	1 Antibody Way, Oceanside, California (CA) 92056, United States (USA)	12/31/2025
Genentech, Inc.	3007232634	833220176	ANALYSIS; LABEL; MANUFACTURE; PACK	4625 NE Brookwood Pkwy, Hillsboro, Oregon (OR) 97124, United States (USA)	12/31/2025

Previous 1 Next

0925

Data Current Through: Tuesday, Nov 05, 2024

New Search


AutoSave Off ndc_nhric_labeler_codes_10_24_2024 - Read-... Search

File Home Insert Page Layout Formulas Data Review View Automate Help Nuance PDF Acrobat

Paste Clipboard Arial 10 Font Alignment General Number Conditional Formatting Format as Table Cell Styles Styles Insert Delete Format Cells Editing

9104

	A	B
	NDC/NHRIC Labeler	Firm Name
95	61502	EPM Packaging Inc
96	72774	MOVILTRADE,LLC
97	76668	American Ordnance LLC
98	82800	The Center Brands
99	65217	Frances Mahon Deaconess Hospital Home Oxygen
00	54365	CareFusion 213 LLC
01	62137	AMO Medical Oxygen, Inc.
02	84287	Wenzhou Jiajia show Daily Necessities Co., Ltd
03	81179	YET HEALTH GROUP LLC
04	50242	Genentech, Inc.
05	84577	Celcuity Inc.
06	51452	Fabrication Enterprises
07	69787	Correvio LLC

Verified Labeler

Proprietary Name	Strength	Dosage Form	Product NDC	Package Description
ACTEMRA	80mg/4mL	INJECTION, SOLUTION, CONCENTRATE	50242-135	1 VIAL, SINGLE-USE in 1 BOX (50242-135-01) / 4 mL in 1 VIAL, SINGLE-USE
ACTEMRA	200mg/10mL	INJECTION, SOLUTION, CONCENTRATE	50242-136	1 VIAL, SINGLE-USE in 1 BOX (50242-136-01) / 10 mL in 1 VIAL, SINGLE-USE
ACTEMRA	400mg/20mL	INJECTION, SOLUTION, CONCENTRATE	50242-137	1 VIAL, SINGLE-USE in 1 BOX (50242-137-01) / 20 mL in 1 VIAL, SINGLE-USE
Actemra	162mg/.9mL	INJECTION, SOLUTION	50242-138	1 SYRINGE, GLASS in 1 BOX (50242-138-01) / .9 mL in 1 SYRINGE, GLASS
Actemra	162mg/.9mL	INJECTION, SOLUTION	50242-138	1 SYRINGE, GLASS in 1 BOX (50242-138-86) / .9 mL in 1 SYRINGE, GLASS
Actemra ACTPen	162mg/.9mL	INJECTION, SOLUTION	50242-143	1 SYRINGE, GLASS in 1 BOX (50242-143-01) / .9 mL in 1 SYRINGE, GLASS
Actemra ACTPen	162mg/.9mL	INJECTION, SOLUTION	50242-143	1 SYRINGE, GLASS in 1 BOX (50242-143-86) / .9 mL in 1 SYRINGE, GLASS
Activase	N/A	KIT	50242-044	1 KIT in 1 CARTON (50242-044-13) * 50 mL in 1 VIAL, SINGLE-USE * 50 mL in 1 VIAL, SINGLE-USE
Activase	N/A	KIT	50242-085	1 KIT in 1 CARTON (50242-085-27) * 100 mL in 1 VIAL, SINGLE-USE * 100 mL in 1 VIAL, SINGLE-USE
ALECENSA	150mg/1	CAPSULE	50242-130	1 BOTTLE, PLASTIC in 1 CARTON (50242-130-01) / 240 CAPSULE in 1 BOTTLE, PLASTIC
ALECENSA	150mg/1	CAPSULE	50242-130	1 BOTTLE, PLASTIC in 1 CARTON (50242-130-86) / 240 CAPSULE in 1 BOTTLE, PLASTIC
Avastin	100mg/4mL	INJECTION, SOLUTION	50242-060	1 VIAL, SINGLE-USE in 1 CARTON (50242-060-01) / 4 mL in 1 VIAL, SINGLE-USE
Avastin	400mg/16mL	INJECTION, SOLUTION	50242-061	1 VIAL, SINGLE-USE in 1 CARTON (50242-061-01) / 16 mL in 1 VIAL, SINGLE-USE
Cathflo Activase	2.2mg/2mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	50242-041	10 VIAL in 1 CARTON (50242-041-10) / 2 mL in 1 VIAL
Cathflo Activase	2.2mg/2mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	50242-041	1 VIAL in 1 CARTON (50242-041-64) / 2 mL in 1 VIAL

CellCept	250mg/1	CAPSULE	0004-0259	1 BOTTLE, PLASTIC in 1 CARTON (0004-0259-01) / 100 CAPSULE in 1 BOTTLE, PLASTIC
CellCept	250mg/1	CAPSULE	0004-0259	1 BOTTLE, PLASTIC in 1 CARTON (0004-0259-43) / 500 CAPSULE in 1 BOTTLE, PLASTIC
CellCept	500mg/1	TABLET, FILM COATED	0004-0260	1 BOTTLE, PLASTIC in 1 CARTON (0004-0260-01) / 100 TABLET, FILM COATED in 1 BOTTLE, PLASTIC
CellCept	500mg/1	TABLET, FILM COATED	0004-0260	1 BOTTLE, PLASTIC in 1 CARTON (0004-0260-43) / 500 TABLET, FILM COATED in 1 BOTTLE, PLASTIC
CellCept	200mg/mL	POWDER, FOR SUSPENSION	0004-0261	1 BOTTLE, PLASTIC in 1 CARTON (0004-0261-29) / 225 mL in 1 BOTTLE, PLASTIC
CellCept	500mg/20mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	0004-0298	4 VIAL in 1 CARTON (0004-0298-09) / 20 mL in 1 VIAL
Columvi	2.5mg/2.5mL	SOLUTION, CONCENTRATE	50242-125	1 VIAL, SINGLE-DOSE in 1 CARTON (50242-125-01) / 2.5 mL in 1 VIAL, SINGLE-DOSE
Columvi	10mg/10mL	CONCENTRATE	50242-127	1 VIAL, SINGLE-DOSE in 1 CARTON (50242-127-01) / 10 mL in 1 VIAL, SINGLE-DOSE
Cotellic	20mg/1	TABLET, FILM COATED	50242-717	63 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (50242-717-01)
Cotellic	20mg/1	TABLET, FILM COATED	50242-717	63 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (50242-717-86)
Enspryng	120mg/mL	INJECTION, SOLUTION	50242-007	1 SYRINGE, PLASTIC in 1 CARTON (50242-007-01) / 1 mL in 1 SYRINGE, PLASTIC
Enspryng	120mg/mL	INJECTION, SOLUTION	50242-007	1 SYRINGE, PLASTIC in 1 CARTON (50242-007-86) / 1 mL in 1 SYRINGE, PLASTIC
ERIVEDGE	150mg/1	CAPSULE	50242-140	1 BOTTLE, PLASTIC in 1 CARTON (50242-140-01) / 28 CAPSULE in 1 BOTTLE, PLASTIC
ERIVEDGE	150mg/1	CAPSULE	50242-140	1 BOTTLE, PLASTIC in 1 CARTON (50242-140-86) / 28 CAPSULE in 1 BOTTLE, PLASTIC
ESBRIET	801mg/1	TABLET, COATED	50242-123	1 BOTTLE, PLASTIC in 1 CARTON (50242-123-01) / 90 TABLET, COATED in 1 BOTTLE, PLASTIC

ESBRIET	267mg/1	CAPSULE	50242-121	1 BOTTLE, PLASTIC in 1 CARTON (50242-121-01) / 270 CAPSULE in 1 BOTTLE, PLASTIC
ESBRIET	267mg/1	TABLET, COATED	50242-122	1 BOTTLE, PLASTIC in 1 CARTON (50242-122-06) / 270 TABLET, COATED in 1 BOTTLE, PLASTIC
ESBRIET	267mg/1	TABLET, COATED	50242-122	1 BOTTLE, PLASTIC in 1 CARTON (50242-122-86) / 189 TABLET, COATED in 1 BOTTLE, PLASTIC
EVRYSDI	.75mg/mL	POWDER, FOR SOLUTION	50242-175	1 BOTTLE, GLASS in 1 CARTON (50242-175-07) / 80 mL in 1 BOTTLE, GLASS
FUZEON	N/A	KIT	0004-0381	1 KIT in 1 CARTON (0004-0381-40) * 1 mL in 1 VIAL, SINGLE-USE * 1 mL in 1 VIAL, SINGLE-DOSE
Gavreto	100mg/1	CAPSULE	50242-210	1 BOTTLE in 1 CARTON (50242-210-12) / 120 CAPSULE in 1 BOTTLE
Gavreto	100mg/1	CAPSULE	50242-210	1 BOTTLE in 1 CARTON (50242-210-60) / 60 CAPSULE in 1 BOTTLE
Gavreto	100mg/1	CAPSULE	50242-210	1 BOTTLE in 1 CARTON (50242-210-83) / 60 CAPSULE in 1 BOTTLE
Gavreto	100mg/1	CAPSULE	50242-210	1 BOTTLE in 1 CARTON (50242-210-90) / 90 CAPSULE in 1 BOTTLE
Gazyva	1000mg/40mL	INJECTION, SOLUTION, CONCENTRATE	50242-070	1 VIAL, SINGLE-USE in 1 CARTON (50242-070-01) / 40 mL in 1 VIAL, SINGLE-USE
Gazyva	1000mg/40mL	INJECTION, SOLUTION, CONCENTRATE	50242-070	1 VIAL, SINGLE-USE in 1 CARTON (50242-070-86) / 40 mL in 1 VIAL, SINGLE-USE
Hemlibra	105mg/.7mL	INJECTION, SOLUTION	50242-922	1 VIAL, SINGLE-USE in 1 CARTON (50242-922-01) / .7 mL in 1 VIAL, SINGLE-USE
Hemlibra	150mg/mL	INJECTION, SOLUTION	50242-923	1 VIAL, SINGLE-USE in 1 CARTON (50242-923-01) / 1 mL in 1 VIAL, SINGLE-USE
Hemlibra	12mg/.4mL	INJECTION, SOLUTION	50242-927	1 VIAL, SINGLE-USE in 1 CARTON (50242-927-01) / .4 mL in 1 VIAL, SINGLE-USE
Hemlibra	300mg/2mL	INJECTION, SOLUTION	50242-930	1 VIAL, SINGLE-USE in 1 CARTON (50242-930-01) / 2 mL in 1 VIAL, SINGLE-USE
Hemlibra	30mg/mL	INJECTION, SOLUTION	50242-920	1 VIAL, SINGLE-USE in 1 CARTON (50242-920-01) / 1 mL in 1 VIAL, SINGLE-USE

Hemlibra	60mg/.4mL	INJECTION, SOLUTION	50242-921	1 VIAL, SINGLE-USE in 1 CARTON (50242-921-01) / .4 mL in 1 VIAL, SINGLE-USE
Herceptin	150mg/7.4mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	50242-132	1 VIAL, SINGLE-DOSE in 1 CARTON (50242-132-01) / 15 mL in 1 VIAL, SINGLE-DOSE
Herceptin Hylecta	10000U/5mL, 600 mg/5mL	INJECTION, SOLUTION	50242-077	1 VIAL, SINGLE-DOSE in 1 CARTON (50242-077-01) / 6 mL in 1 VIAL, SINGLE-DOSE
KADCYLA	20mg/mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	50242-087	1 VIAL, SINGLE-USE in 1 CARTON (50242-087-01) / 8 mL in 1 VIAL, SINGLE-USE
KADCYLA	20mg/mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	50242-088	1 VIAL, SINGLE-USE in 1 CARTON (50242-088-01) / 5 mL in 1 VIAL, SINGLE-USE
LUCENTIS	10mg/mL	INJECTION, SOLUTION	50242-080	1 SYRINGE, GLASS in 1 CARTON (50242-080-03) / .05 mL in 1 SYRINGE, GLASS
LUCENTIS	10mg/mL	INJECTION, SOLUTION	50242-080	1 SYRINGE, GLASS in 1 CARTON (50242-080-88) / .05 mL in 1 SYRINGE, GLASS
LUCENTIS	6mg/mL	INJECTION, SOLUTION	50242-082	1 SYRINGE, GLASS in 1 CARTON (50242-082-03) / .05 mL in 1 SYRINGE, GLASS
LUCENTIS	6mg/mL	INJECTION, SOLUTION	50242-082	1 SYRINGE, GLASS in 1 CARTON (50242-082-88) / .05 mL in 1 SYRINGE, GLASS
Lunsumio	30mg/30mL	CONCENTRATE	50242-142	1 VIAL in 1 CARTON (50242-142-01) / 30 mL in 1 VIAL
Lunsumio	1mg/mL	CONCENTRATE	50242-159	1 VIAL in 1 CARTON (50242-159-01) / 1 mL in 1 VIAL
Nutropin AQ NuSpin 10	10mg/2mL	INJECTION, SOLUTION	50242-074	1 CARTRIDGE in 1 CARTON (50242-074-01) / 2 mL in 1 CARTRIDGE
Nutropin AQ NuSpin 20	20mg/2mL	INJECTION, SOLUTION	50242-076	1 CARTRIDGE in 1 CARTON (50242-076-01) / 2 mL in 1 CARTRIDGE
Nutropin AQ NuSpin 5	5mg/2mL	INJECTION, SOLUTION	50242-075	1 CARTRIDGE in 1 CARTON (50242-075-01) / 2 mL in 1 CARTRIDGE
OCREVUS	300mg/10mL	INJECTION	50242-150	1 VIAL, SINGLE-USE in 1 CARTON (50242-150-01) / 10 mL in 1 VIAL, SINGLE-USE
Pegasys	180ug/mL	INJECTION, SOLUTION	0004-0350	1 VIAL, SINGLE-USE in 1 BOX (0004-0350-09) / 1 mL in 1 VIAL, SINGLE-USE

PERJETA	30mg/mL	INJECTION, SOLUTION, CONCENTRATE	50242-145	1 VIAL, SINGLE-USE in 1 CARTON (50242-145-01) / 14 mL in 1 VIAL, SINGLE-USE
Phesgo	30000U/15mL, 1200 mg/15mL, 600 mg/15mL	INJECTION, SOLUTION	50242-245	1 VIAL, SINGLE-DOSE in 1 CARTON (50242-245-01) / 15 mL in 1 VIAL, SINGLE-DOSE
Phesgo	30000U/15mL, 1200 mg/15mL, 600 mg/15mL	INJECTION, SOLUTION	50242-245	1 VIAL, SINGLE-DOSE in 1 CARTON (50242-245-86) / 15 mL in 1 VIAL, SINGLE-DOSE
Phesgo	20000U/10mL, 600 mg/10mL, 600 mg/10mL	INJECTION, SOLUTION	50242-260	1 VIAL, SINGLE-DOSE in 1 CARTON (50242-260-01) / 10 mL in 1 VIAL, SINGLE-DOSE
Phesgo	20000U/10mL, 600 mg/10mL, 600 mg/10mL	INJECTION, SOLUTION	50242-260	1 VIAL, SINGLE-DOSE in 1 CARTON (50242-260-86) / 10 mL in 1 VIAL, SINGLE-DOSE
Piasky	340mg/2mL	INJECTION, SOLUTION	50242-115	1 VIAL, SINGLE-USE in 1 CARTON (50242-115-01) / 2 mL in 1 VIAL, SINGLE-USE
POLIVY	30mg/1.88mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	50242-103	1 VIAL in 1 CARTON (50242-103-01) / 6 mL in 1 VIAL
POLIVY	140mg/7.52mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	50242-105	1 VIAL, SINGLE-DOSE in 1 CARTON (50242-105-01) / 20 mL in 1 VIAL, SINGLE-DOSE
Pulmozyme	1mg/mL	SOLUTION	50242-100	5 POUCH in 1 CARTON (50242-100-40) / 6 AMPULE in 1 POUCH (50242-100-39) / 2.5 mL in 1 AMPULE
Rituxan	10mg/mL	INJECTION, SOLUTION	50242-051	10 VIAL, SINGLE-USE in 1 CARTON (50242-051-10) / 10 mL in 1 VIAL, SINGLE-USE
Rituxan	10mg/mL	INJECTION, SOLUTION	50242-051	1 VIAL, SINGLE-USE in 1 CARTON (50242-051-21) / 10 mL in 1 VIAL, SINGLE-USE
Rituxan	10mg/mL	INJECTION, SOLUTION	50242-053	1 VIAL, SINGLE-USE in 1 CARTON (50242-053-06) / 50 mL in 1 VIAL, SINGLE-USE
Rituxan Hycela	2000U/mL, 120 mg/mL	INJECTION, SOLUTION	50242-108	1 VIAL, SINGLE-DOSE in 1 CARTON (50242-108-01) / 11.7 mL in 1 VIAL, SINGLE-DOSE

Rituxan Hycela	2000U/mL, 120 mg/mL	INJECTION, SOLUTION	50242-108	1 VIAL, SINGLE-DOSE in 1 CARTON (50242-108-86) / 11.7 mL in 1 VIAL, SINGLE-DOSE
Rituxan Hycela	2000U/mL, 120 mg/mL	INJECTION, SOLUTION	50242-109	1 VIAL, SINGLE-DOSE in 1 CARTON (50242-109-01) / 13.4 mL in 1 VIAL, SINGLE-DOSE
Rozlytrek	100mg/1	CAPSULE	50242-091	1 BOTTLE in 1 CARTON (50242-091-30) / 30 CAPSULE in 1 BOTTLE
Rozlytrek	100mg/1	CAPSULE	50242-091	1 BOTTLE in 1 CARTON (50242-091-86) / 30 CAPSULE in 1 BOTTLE
Rozlytrek	200mg/1	CAPSULE	50242-094	1 BOTTLE in 1 CARTON (50242-094-47) / 90 CAPSULE in 1 BOTTLE
Rozlytrek	200mg/1	CAPSULE	50242-094	1 BOTTLE in 1 CARTON (50242-094-90) / 90 CAPSULE in 1 BOTTLE
Rozlytrek	50mg/201	PELLET	50242-623	42 DOSE PACK in 1 CARTON (50242-623-42) / 20 PELLET in 1 DOSE PACK (50242-623-01)
Susvimo	100mg/mL	INJECTION, SOLUTION	50242-078	1 VIAL in 1 CARTON (50242-078-12) / 1 mL in 1 VIAL
Susvimo	100mg/mL	INJECTION, SOLUTION	50242-078	1 VIAL in 1 CARTON (50242-078-55) / 1 mL in 1 VIAL
Tamiflu	6mg/mL	POWDER, FOR SUSPENSION	0004-0822	1 BOTTLE, GLASS in 1 CARTON (0004-0822-05) / 60 mL in 1 BOTTLE, GLASS
TARCEVA	25mg/1	TABLET	50242-062	30 TABLET in 1 BOTTLE (50242-062-01)
TARCEVA	100mg/1	TABLET	50242-063	30 TABLET in 1 BOTTLE (50242-063-01)
TARCEVA	150mg/1	TABLET	50242-064	30 TABLET in 1 BOTTLE (50242-064-01)
TECENTRIQ	1200mg/20mL	INJECTION, SOLUTION	50242-917	1 VIAL, SINGLE-USE in 1 CARTON (50242-917-01) / 20 mL in 1 VIAL, SINGLE-USE
TECENTRIQ	1200mg/20mL	INJECTION, SOLUTION	50242-917	1 VIAL, SINGLE-USE in 1 CARTON (50242-917-86) / 20 mL in 1 VIAL, SINGLE-USE
TECENTRIQ	840mg/14mL	INJECTION, SOLUTION	50242-918	1 VIAL, SINGLE-USE in 1 CARTON (50242-918-01) / 14 mL in 1 VIAL, SINGLE-USE
TNKase	N/A	KIT	50242-176	1 KIT in 1 CARTON (50242-176-01) * 1 VIAL, SINGLE-USE in 1 CARTON (50242-037-06) / 50 mg in 1 VIAL, SINGLE-USE * 1 VIAL, SINGLE-USE in 1 CARTON (50242-901-09) / 10 mL in 1 VIAL, SINGLE-USE

TNKase	N/A	KIT	50242-120	1 KIT in 1 CARTON (50242-120-47) * 1 VIAL, SINGLE-USE in 1 CARTON (50242-901-09) / 10 mL in 1 VIAL, SINGLE-USE * 1 VIAL, SINGLE-USE in 1 CARTON (50242-037-06) / 50 mg in 1 VIAL, SINGLE-USE
VABYSMO	6mg/.05mL	INJECTION, SOLUTION	50242-096	1 VIAL in 1 CARTON (50242-096-01) / .05 mL in 1 VIAL (50242-096-03)
VABYSMO	6mg/.05mL	INJECTION, SOLUTION	50242-096	1 SYRINGE in 1 CARTON (50242-096-06) / .05 mL in 1 SYRINGE
VABYSMO	6mg/.05mL	INJECTION, SOLUTION	50242-096	1 SYRINGE in 1 CARTON (50242-096-45) / .05 mL in 1 SYRINGE
VABYSMO	6mg/.05mL	INJECTION, SOLUTION	50242-096	1 VIAL in 1 CARTON (50242-096-86) / .05 mL in 1 VIAL (50242-096-77)
Valcyte	450mg/1	TABLET, FILM COATED	0004-0038	1 BOTTLE, PLASTIC in 1 CARTON (0004-0038-22) / 60 TABLET, FILM COATED in 1 BOTTLE, PLASTIC
Valcyte	50mg/mL	POWDER, FOR SOLUTION	0004-0039	1 BOTTLE, GLASS in 1 CARTON (0004-0039-09) / 100 mL in 1 BOTTLE, GLASS
Xeloda	150mg/1	TABLET, FILM COATED	0004-1100	60 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (0004-1100-20)
Xeloda	500mg/1	TABLET, FILM COATED	0004-1101	120 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (0004-1101-50)
Xofluza	40mg/20mL	GRANULE, FOR SOLUTION	50242-583	1 BOTTLE, GLASS in 1 CARTON (50242-583-01) / 20 mL in 1 BOTTLE, GLASS
Xofluza	40mg/1	TABLET, FILM COATED	50242-860	1 BLISTER PACK in 1 CARTON (50242-860-01) / 1 TABLET, FILM COATED in 1 BLISTER PACK
Xofluza	40mg/1	TABLET, FILM COATED	50242-860	1 BLISTER PACK in 1 CARTON (50242-860-86) / 1 TABLET, FILM COATED in 1 BLISTER PACK
Xofluza	80mg/1	TABLET, FILM COATED	50242-877	1 BLISTER PACK in 1 CARTON (50242-877-01) / 1 TABLET, FILM COATED in 1 BLISTER PACK
Xofluza	80mg/1	TABLET, FILM COATED	50242-877	1 BLISTER PACK in 1 CARTON (50242-877-86) / 1 TABLET, FILM COATED in 1 BLISTER PACK
Xolair	300mg/2mL	INJECTION, SOLUTION	50242-227	1 SYRINGE, GLASS in 1 CARTON (50242-227-01) / 2 mL in 1 SYRINGE, GLASS

Xolair	300mg/2mL	INJECTION, SOLUTION	50242-227	1 SYRINGE, GLASS in 1 CARTON (50242-227-55) / 2 mL in 1 SYRINGE, GLASS
Xolair	300mg/2mL	INJECTION, SOLUTION	50242-227	1 SYRINGE, GLASS in 1 CARTON (50242-227-86) / 2 mL in 1 SYRINGE, GLASS
Xolair	300mg/2mL	INJECTION, SOLUTION	50242-227	1 SYRINGE, GLASS in 1 CARTON (50242-227-99) / 2 mL in 1 SYRINGE, GLASS
XOLAIR	150mg/1.2mL	INJECTION, SOLUTION	50242-040	1 VIAL, SINGLE-USE in 1 CARTON (50242-040-62) / 1.2 mL in 1 VIAL, SINGLE-USE
XOLAIR	150mg/1.2mL	INJECTION, SOLUTION	50242-040	1 VIAL, SINGLE-USE in 1 CARTON (50242-040-86) / 1.2 mL in 1 VIAL, SINGLE-USE
Xolair PFS	75mg/.5mL	INJECTION, SOLUTION	50242-214	1 SYRINGE, GLASS in 1 CARTON (50242-214-01) / .5 mL in 1 SYRINGE, GLASS
Xolair PFS	75mg/.5mL	INJECTION, SOLUTION	50242-214	1 SYRINGE, GLASS in 1 CARTON (50242-214-03) / .5 mL in 1 SYRINGE, GLASS
Xolair PFS	75mg/.5mL	INJECTION, SOLUTION	50242-214	1 SYRINGE, GLASS in 1 CARTON (50242-214-55) / .5 mL in 1 SYRINGE, GLASS
Xolair PFS	75mg/.5mL	INJECTION, SOLUTION	50242-214	1 SYRINGE, GLASS in 1 CARTON (50242-214-83) / .5 mL in 1 SYRINGE, GLASS
Xolair PFS	75mg/.5mL	INJECTION, SOLUTION	50242-214	1 SYRINGE, GLASS in 1 CARTON (50242-214-86) / .5 mL in 1 SYRINGE, GLASS
Xolair PFS	75mg/.5mL	INJECTION, SOLUTION	50242-214	1 SYRINGE, GLASS in 1 CARTON (50242-214-99) / .5 mL in 1 SYRINGE, GLASS
Xolair PFS	150mg/mL	INJECTION, SOLUTION	50242-215	1 SYRINGE, GLASS in 1 CARTON (50242-215-01) / 1 mL in 1 SYRINGE, GLASS
Xolair PFS	150mg/mL	INJECTION, SOLUTION	50242-215	1 SYRINGE, GLASS in 1 CARTON (50242-215-03) / 1 mL in 1 SYRINGE, GLASS
Xolair PFS	150mg/mL	INJECTION, SOLUTION	50242-215	1 SYRINGE, GLASS in 1 CARTON (50242-215-55) / 1 mL in 1 SYRINGE, GLASS
Xolair PFS	150mg/mL	INJECTION, SOLUTION	50242-215	1 SYRINGE, GLASS in 1 CARTON (50242-215-83) / 1 mL in 1 SYRINGE, GLASS
Xolair PFS	150mg/mL	INJECTION, SOLUTION	50242-215	1 SYRINGE, GLASS in 1 CARTON (50242-215-86) / 1 mL in 1 SYRINGE, GLASS
Xolair PFS	150mg/mL	INJECTION, SOLUTION	50242-215	1 SYRINGE, GLASS in 1 CARTON (50242-215-99) / 1 mL in 1 SYRINGE, GLASS

ZELBORAF	240mg/1	TABLET, FILM COATED	50242-090	1 BOTTLE, PLASTIC in 1 CARTON (50242-090-02) / 112 TABLET, FILM COATED in 1 BOTTLE, PLASTIC

Genentech
A Member of the Roche Group

OWNERSHIP ATTACHMENT
CORPORATE OFFICERS

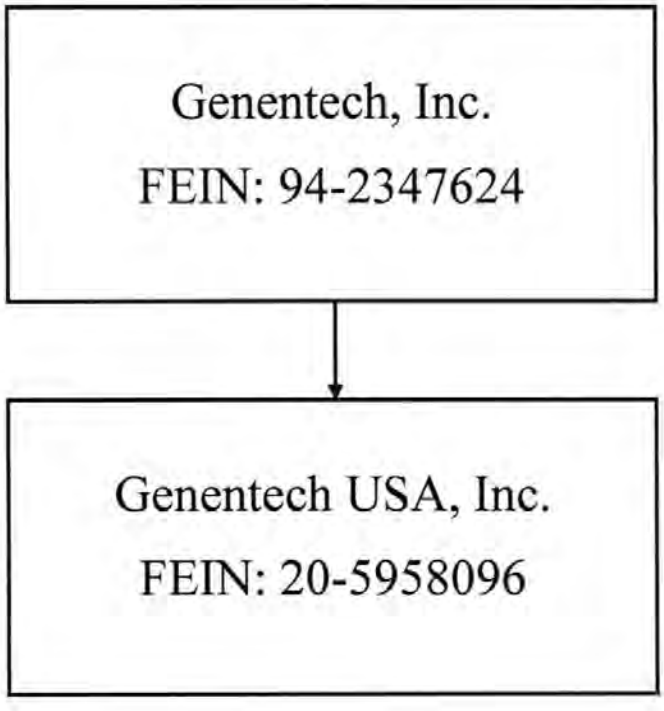
Genentech USA, Inc.

Name: Matteo Pietra
Title: Chief Financial Officer
Business Address: 1 DNA Way, South San Francisco, CA 94080
Business Phone: (650) 225-1000
Fax #: (650) 952-9881
Ownership: 0%

Name: Jonathan Witt
Title: Sr. Vice President, Genentech Business Operations
Business Address: 1 DNA Way, South San Francisco, CA 94080
Business Phone: (650) 225-1000
Fax #: (650) 952-9881
Ownership: 0%

Genentech, Inc. Organizational Structure

Genentech, Inc. directly owns Genentech USA, Inc. Both are non-publicly trading entities.



Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "GENENTECH USA, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTEENTH DAY OF MARCH, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "GENENTECH USA, INC." WAS INCORPORATED ON THE FOURTH DAY OF OCTOBER, A.D. 2006.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4230521 8300

SR# 20240986162

Authentication: 203012333

Date: 03-13-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

23

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	GENENTECH USA, INC.
Entity No.:	3009399
Registration Date:	07/31/2007
Entity Type:	Stock Corporation - Out of State - Stock
Formed In:	DELAWARE
Status:	Active

The above referenced entity is active on the Secretary of State's records and is qualified to transact intrastate business in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of March 13, 2024.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 190883839

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

CALIFORNIA STATE BOARD OF PHARMACY
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

Renewal License

Wholesale Drug Permit

License No. WLS 5122
Receipt No. 00193807

Valid Until: 9/1/2025

GENENTECH USA INC
BUILDING 25 1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080-4918

In accordance with the provisions of section 4160 of the Business and Professions Code, the firm name hereon is issued a Wholesale Drug Permit.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) manager, vice president of operations, or designated representative-in-charge.

This permit is valid only at the address shown.

The official status of this license can be verified at www.pharmacy.ca.gov

---- NON-TRANSFERABLE ----- POST IN PUBLIC VIEW -----

FORM WPHWLS (09/30/19) WLS

CALIC100.RENWALR.08082024.23082.SEQID1047

GENENTECH USA INC
BUILDING 25 1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080-4918[1047]

BOARD OF PHARMACY
2720 GATEWAY OAKS DR, SUITE 100
SACRAMENTO, CA 95833

BOARD OF PHARMACY

LICENSING DETAILS FOR: WLS 5122

NAME: GENENTECH USA INC

LICENSE TYPE: WHOLESALER

LICENSE STATUS: CLEAR

ADDRESS

BUILDING 25 1 DNA WAY
SOUTH SAN FRANCISCO CA 94080
SAN MATEO COUNTY

ISSUANCE DATE

SEPTEMBER 21, 2007

EXPIRATION DATE

SEPTEMBER 1, 2024

CURRENT DATE / TIME

JULY 12, 2024
5:53:36 AM

LICENSE RELATIONSHIPS

NAME: GREENE, MARTHA M

ADDRESS NOT DISCLOSED

LICENSE/REGISTRATION TYPE: DESIGNATED REPRESENTATIVE (WHOLESALER)

LICENSE NUMBER: 20644 **PRIMARY STATUS:** CLEAR

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 107937251

Application/License No. _____

Genentech USA, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1 DNA Way, Building 25, South San Francisco, CA 94080 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty and Surety Company of America (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Tower Square, Hartford, CT 06183 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on March 20, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 20th day of March, 2024.

Genentech USA, Inc.
APPLICANT/PRINCIPAL

COMPANY

Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

Travelers Casualty and Surety Company of America
SURETY

Surety Company's Representative

April D. Perez, Attorney-in-fact
print name
NV Non-Resident License #722132

SIGNED and SEALED in the presence of:

Witness Annette Audinot

Witness Jessica Iannotta

Countersigned by:

n/a
Nevada Resident Agent

Posted February 20, 2020

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint April D. Perez of Morristown, New Jersey, their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **21st** day of **April, 2021.**

HARTFORD, CONN. HARTFORD, CONN. CORPORATE SEAL

State of Connecticut

By: _____
Robert L. Raney, Senior Vice President

City of Hartford ss.

On this the **21st** day of **April, 2021**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June, 2026**

NOTARY PUBLIC

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this 20th day of March, 2024.

HARTFORD, CONN. HARTFORD, CONN. CORPORATE SEAL

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.

TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA

HARTFORD, CONNECTICUT 06183

FINANCIAL STATEMENT AS OF JUNE 30, 2023

CAPITAL STOCK $ 6,480,000

ASSETS		LIABILITIES & SURPLUS	
BONDS	$ 5,150,661,933	LOSSES	$ 1,536,742,249
STOCKS	115,760,594	LOSS ADJUSTMENT EXPENSES	136,032,224
CASH AND INVESTED CASH	83,310,786	COMMISSIONS	38,298,447
OTHER INVESTED ASSETS	6,561,822	OTHER EXPENSES	36,588,002
SECURITIES LENDING REINVESTED COLLATERAL ASSETS	25,993,585	TAXES, LICENSES AND FEES	11,726,720
INVESTMENT INCOME DUE AND ACCRUED	43,143,069	UNEARNED PREMIUMS	1,453,378,390
PREMIUM BALANCES	347,718,526	ADVANCE PREMIUM	2,435,053
REINSURANCE RECOVERABLE	43,481,728	POLICYHOLDER DIVIDENDS	18,990,836
NET DEFERRED TAX ASSET	70,753,315	CEDED REINSURANCE NET PREMIUMS PAYABLE	97,783,193
CURRENT FEDERAL AND FOREIGN INCOME TAXES RECOVERABLE	4,319,605	AMOUNTS WITHHELD / RETAINED BY COMPANY FOR OTHERS	21,267,968
GUARANTY FUNDS RECEIVABLE OR ON DEPOSIT	1,369,093	REMITTANCES AND ITEMS NOT ALLOCATED	5,152,800
RECEIVABLE FROM PARENTS, SUBSIDIARIES AND AFFILIATES	26,863,847	PROVISION FOR REINSURANCE	6,464,384
OTHER ASSETS	1,590,021	PAYABLE FOR SECURITIES LENDING	25,993,585
		OTHER ACCRUED EXPENSES AND LIABILITIES	317,899
		TOTAL LIABILITIES	$ 3,391,171,631
		CAPITAL STOCK	$ 6,480,000
		PAID IN SURPLUS	433,803,760
		OTHER SURPLUS	2,090,072,333
		TOTAL SURPLUS TO POLICYHOLDERS	$ 2,530,356,093
TOTAL ASSETS	$ 5,921,527,924	TOTAL LIABILITIES & SURPLUS	$ 5,921,527,924

STATE OF CONNECTICUT)

COUNTY OF HARTFORD) SS.

CITY OF HARTFORD)

MICHAEL J. DOODY, BEING DULY SWORN, SAYS THAT HE IS VICE PRESIDENT – FINANCE, OF TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA, AND THAT TO THE BEST OF HIS KNOWLEDGE AND BELIEF, THE FOREGOING IS A TRUE AND CORRECT STATEMENT OF THE FINANCIAL CONDITION OF SAID COMPANY AS OF THE 30TH DAY OF JUNE, 2023.

Michael J Doody

VICE PRESIDENT – FINANCE

NOTARY PUBLIC

SUBSCRIBED AND SWORN TO BEFORE ME THIS
16TH DAY OF AUGUST, 2023

SUSAN M. WEISSLEDER
Notary Public
My Commission Expires November 30, 2027



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Genentech USA, Inc. MDEG License # (if applicable): N/A

Physical Address: 1 DNA Way, Bldg. 25

City: South San Francisco State: CA Zip: 94080

Mailing Address (if different from physical address): Genentech USA, Inc. ATTN: Jill Jewell MS 245D, 1 DNA Way

City: South San Francisco State: CA Zip: 94080

Telephone: 650-225-1000 Website: www.gene.com

Licensing Company Email: US_State_Licensing-d@gene.com

Section 2: Personal Information

First: Martha Middle: Marella Last: Greene

Alias(es, nicknames, name changes, etc.): n/a

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: Genentech USA, Inc. ATTN: Jill Jewell MS 245D, 1 DNA Way

City: South San Francisco State: CA Zip: 94080

Telephone: 650-225-1000 Email: US_State_Licensing-d@gene.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
California State University East Bay		1995-1997	
Address	**City**	**State**	**Zip**
25800 Carlos Bee Blvd.	Hayward	CA	94542
Diploma/Degree obtained, if any			
Bachelor of Science: Business, Marketing			

School Name		From - To (MM/YY – MM/YY)	
Notre Dame High School			
Address	**City**	**State**	**Zip**
1540 Ralston Ave.	Belmont	CA	94002
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
9/2003- Present	[redacted]	Redwood City	CA	94061
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Genentech USA, Inc.			3/2000- present	
Business Address		**City**	**State**	**Zip**
1 DNA Way		South San Francisco	CA	94080
Phone	**Title**		**Number of Employed Hours**	
650-467-0055	Executive Director Channel Operations		> 6000 hours	
Description of Duties				
- ensure product gets to the right customer, at the right time with the right price - ensure channel success; -product protection initiatives				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Martha Greene — Original Signature (electronic, copies or stamps not accepted)

10/23/24 — Date

I, Martha Greene, **certify that as the MDEG Administrator for**

Genentech USA, Inc. facility located at 1 DNA Way, Bldg. 25, South San Francisco, CA 94080,

that I (initial that you have read and meet the following requirements):

1. MG Have a high school diploma or its equivalent;
2. MG Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MG Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MG Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Martha Greene
Print Name (First, Last)

Martha Greene
Original Signature (electronic, copies or stamps not accepted)

10/23/24
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Genentech USA , Inc.

Pharmacy/Wholesaler License # (if applicable) Applying

Physical Address 1 DNA Way, Building 25

City South San Francisco State CA Zip 94080

Mailing Address (if different from physical address) Genentech USA, Inc., Attn: Jill Jewll MS 245D, 1 DNA Way,

City South San Francisco State CA Zip 94080

Telephone 650-225-1000 Website www.gene.com

Licensing Company Email US_State_Licensing-d@gene.com

Section 2: Personal Information

First Martha Middle Marella Last Greene

Alias(es, nicknames, name changes, etc.) n/a

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address Genentech USA, Inc., Attn: Jill Jewel MS 245D, 1 DNA Way,

City South San Francisco, State CA Zip 94080

Telephone 650-225-1000 Email US_State_Licensing-d@gene.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	☐	☑
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	☐	☑
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	☐	☑

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	☐	☑
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	☐	☑

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
California State University East Bay		1995-1997	
Address	**City**	**State**	**Zip**
25800 Carlos Bee Boulevard	Hayward	CA	94542
Diploma/Degree obtained, if any	Bachelor of Science: Business, Marketing		

School Name		From - To (MM/YY – MM/YY)	
Notre Dame High School		1984-1989	
Address	**City**	**State**	**Zip**
1540 Ralston Ave	Belmont	CA	94002
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
9/2003-Present	[redacted]	Redwood City,	CA	94061
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Genentech USA, Inc.			From - To (MM/YY – MM/YY): 3/2000-Present	
Business Address: 1 DNA Way,	City: South San Francisco,		State: CA	Zip: 94080
Phone: 650-467-0055	Title: Executive Director Channel Operations		Number of Employed Hours: > 6000 hours	
Description of Duties: - Ensure product gets to the right customer, at the right time with the right price -Ensure channel access -Product protection initiatives				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	☐	☑
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	☐	☑
3. Have you ever had a civil or criminal record expunged or sealed by a court order?	☐	☑
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	☐	☑
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	☐	☑
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	☐	☑
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?	☐	☑
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.	☐	☑
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	☐	☑
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	☐	☑

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Mandra Grund
Original Signature (electronic, copies or stamps not accepted)

9/4/2024
Date

I, Martha Greene, **certify that as the designated representative for**

Genentech USA , Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MG I am at least 21 years of age;
3. MG I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MG I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MG I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MG I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MG I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Martha Greene

Print Name (First, Last)

Martha Greene

Original Signature (electronic, copies or stamps not accepted)

9/4/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Martha Greene

Print Name (First, Last)

Martha Greene

Original Signature (electronic, copies or stamps not accepted)

9/4/24

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of please see attached San Mateo

I, Martha Greene, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Martha Greene

Original Signature

9/4/24

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

please see attached

(Seal)

ACKNOWLEDGMENT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of San Mateo)

On September 4, 2024 before me, Deborah Hong Moy, Notary Public
(insert name and title of the officer)

personally appeared Martha Greene,
who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

DEBORAH HONG MOY
Notary Public - California
San Mateo County
Commission # 2475255
My Comm. Expires Dec 5, 2027

Signature Deborah Hong Moy (Seal)

Genentech USA, Inc. Employee List

Facility Address: 1 DNA Way, Bldg. 25, South San Francisco, CA 94080

Martha Greene - Executive Director Channel Operations

Mary Zapantis - Sr. Director Product Life Cycle and Protection

4V

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☒ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Gramercy Extremity Orthopedics

Physical Address: 1239 N. Glenville Dr

City: Richardson State: TX Zip: 75081

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Website: _____

Name of Designated Representative (DR): _____

Licensing Company Email: _____ DR Email: _____

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: Gramercy Extremity Orthopedics

Mailing Address: 1239 N. Glenville Dr

City: Richardson State: TX Zip: 75081

Telephone: 214-435-3078 Email: msimpson@gramercyortho.com

Contact Person Name: Michael Simpson

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Gramercy Extremity Orthopedics

Facility Name

Michael Simpson

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

6/24/24

Date

Board Use Only	Date Received: 7/22/24	Amount: $1000-ck 10775

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
GRAMERCY EXTREMITY ORTHOPEDICS, LLC.
1239 N Glenville Dr
Richardson, TX 75081
Registration Number: 3012478585
FEI Number*: 3012478585
Status: Active
Date Of Registration Status: 2024

Owner/Operator:
Gramercy Extremity Orthopedics, LLC.[6]
1239 N. Glenville Drive
Richardson, TX US 75081
Owner/Operator Number: 10053967[7]

Official Correspondent:
John A Rigol
1239 N. Glenville Drive
Richardson, TX 75081
Phone: 855-4362278

Verified MJT 7/26/24

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

---

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10053967&OwnerOperatc
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10053967&OwnerOperatc

Page Last Updated: 07/22/2024

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsc | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of **Health & Human Services**

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10053967&OwnerOperatc
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10053967&OwnerOperatc

List of Officers/Directors	
Name	Title
Michael Simpson	Chief Exective Officer
Paul Vasta	Chief Technology Officer

Help (./help/index.html)

DRLM Home (mainMenu.htm)

✔ Facility

✔ Products Listing

Annual Registration Successful

Facility: GRAMERCY EXTREMITY ORTHOPEDICS, LLC., Richardson, Texas, UNITED STATES

You have successfully updated your registration and listing information for 2024.

Your registration will be valid through Dec 31, 2024.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2024.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 10053967.

Facility Information

Registration Number:
3012478585

Initial Importer:
N

Facility Name:
GRAMERCY EXTREMITY ORTHOPEDICS, LLC.

Legal Name:

Address:
1239 N Glenville Dr
Richardson, Texas, 75081, UNITED STATES

DUNS Number:

Foreign Trade Zone:
N

Facility URL:

Other Business Trade Name(s):

Establishment located on a campus:
N

Owner/Operator Information

Owner/Operator Number:
10053967

Contact Name:
John A Rigol

Company:
GRAMERCY EXTREMITY ORTHOPEDICS, LLC.

Address: 1239 N. Glenville Drive
Richardson, TEXAS, 75081, UNITED STATES

Telephone:
855 - 4362278

Fax:
-

E-mail: jrigol@gramercyortho.com

DUNS Number:

Official Correspondent Information

Contact Name:
John A Rigol

Company:
GRAMERCY EXTREMITY ORTHOPEDICS, LLC.

Address: 1239 N. Glenville Drive
Richardson, TEXAS, 75081, UNITED STATES

Telephone:
855 - 4362278

Fax:
-

E-mail: jrigol@gramercyortho.com

DUNS Number:

Device Listings

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities
D320854	K170571		HWC	Screw, fixation, bone	Repackager/Relabeler
D451827	K212334		HRS	Plate, fixation, bone	Manufacturer Complaint File Establishment Specification Developer

D442085	K210534		HWC	Screw, fixation, bone	Specification Developer Manufacturer Complaint File Establishment
			HRS	Plate, fixation, bone	
D348007	K182212		JDR	Staple, fixation, bone	Specification Developer Manufacturer Complaint File Establishment
D435111	K200108		HWC	Screw, fixation, bone	Manufacturer Complaint File Establishment Specification Developer
			HRS	Plate, fixation, bone	
D287735	K161904		HTN	WASHER, BOLT NUT	Specification Developer Manufacturer Complaint File Establishment
			HWC	Screw, fixation, bone	
D435403	K202817		HTN	WASHER, BOLT NUT	Manufacturer Specification Developer Complaint File Establishment
			HWC	Screw, fixation, bone	

Date of Initial Registration: 2017-01-26 21:35:01.0

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for Gramercy Extremity Orthopedics LLC (file number 802111466), a Domestic Limited Liability Company (LLC), was filed in this office on December 03, 2014.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on February 06, 2024.

Jane Nelson
Secretary of State

- Please contact this office immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **www.dshs.texas.gov**.
- Please submit written notice if you close or sell your business.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drug and Device Business Filing and Verification Unit at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

GRAMERCY EXTREMITY ORTHOPEDICS
1239 N GLENVILLE DR
RICHARDSON TX 75081

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

GRAMERCY EXTREMITY ORTHOPEDICS LLC DBA
GRAMERCY EXTREMITY ORTHOPEDICS
1239 N GLENVILLE DR
RICHARDSON, TX 75081

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

DEVICE MANUFACTURER

License # 1002060
Expires: November 29, 2025

NON-TRANSFERABLE

J. A. Shuld, MD
Commissioner

513741

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 10/24/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Insureon, Division of Specialty Program Group LLC / DBA SPG Insurance Solutions LLC in CA 203 N. LaSalle St., 20th Floor, Chicago, IL 60601	**CONTACT NAME:** **PHONE (A/C, No, Ext):** (844) 387-3240 **FAX (A/C, No):** 312-690-4123 **E-MAIL ADDRESS:**

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A :	Transportation Insurance Company	20494
INSURER B :	CNA Insurance Companies	20443
INSURER C :	American Casualty Company	20427
INSURER D :	CHUBB	12777
INSURER E :	Standard Security Life Ins. Co. of NY	69078
INSURER F :	Travelers	25674

INSURED
Gramercy Extremity Orthopedics LLC
1239 N GLENVILLE DR, RICHARDSON, TX, 75081-2412

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	✔ COMMERCIAL GENERAL LIABILITY ☐ CLAIMS-MADE ✔ OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: ✔ POLICY ☐ PRO-JECT ☐ LOC OTHER:			6074606685	4/20/2024	4/20/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ Excluded
A	AUTOMOBILE LIABILITY ☐ ANY AUTO ☐ ALL OWNED AUTOS ☐ SCHEDULED AUTOS ✔ HIRED AUTOS ✔ NON-OWNED AUTOS			6074606685	4/20/2024	4/20/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $
B	✔ UMBRELLA LIAB ✔ OCCUR EXCESS LIAB ☐ CLAIMS-MADE ☐ DED ✔ RETENTION $ 10,000			6074606699	4/20/2024	4/20/2025	EACH OCCURRENCE AGGREGATE	$ 1,000,000 $ 1,000,000
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: No / N/A If yes, describe under DESCRIPTION OF OPERATIONS below			6076298317	4/20/2024	4/20/2025	✔ PER STATUTE ☐ OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ 500,000 $ 500,000 $ 500,000
D	Directors and Officers Liability			J06589790	6/28/2024	6/28/2025	Occurrence/Aggregate	$ / $
F	Professional Liability (Errors and Omissions)			ZPP 61N17891	8/23/2024	8/23/2025	Occurrence/Aggregate	$5,000,000 / $5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

State of Nevada

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

© 1988-2014 ACORD CORPORATION. All rights reserved.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 100896545

Application/License No. _____

GRAMERCY EXTREMITY ORTHOPEDICS LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1239 N GLENVILLE DR RICHARDSON, TX, 75081 (Address of Applicant/Principal), as PRINCIPAL, and AMERICAN CONTRACTORS INDEMNITY COMPANY (Surety Company), a corporation organized under the laws of the state of California (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 801 S. Figueroa Street, Suite 700, Los Angeles, CA 90017 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 10/25/2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 16th day of October, 2024.

APPLICANT/PRINCIPAL

GRAMERCY EXTREMITY ORTHOPEDICS LLC

Authorized Representative

SURETY

AMERICAN CONTRACTORS INDEMNITY COMPANY

Surety Company's Representative

JOSHUA KAYSER, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A Retaliatory
Nevada Resident Agent

TOKIO MARINE HCC

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS:

That American Contractors Indemnity Company of the State of California, a California corporation, does hereby appoint,

JOSHUA KAYSER

its true and lawful Attorney-in-Fact, with full authority to execute on its behalf bond number 100896545 issued in the course of its business and to bind the Company thereby, in an amount not to exceed Twenty-five thousand and 00/100 ($25,000.00).

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following resolutions adopted by the Board of Directors of AMERICAN CONTRACTORS INDEMNITY COMPANY at a meeting duly called and held on the 1st day of September, 2011.

"*Be it Resolved*, that the President, any Vice-President, any Assistant Vice-President, any Secretary or any Assistant Secretary shall be and is hereby vested with full power and authority to appoint any one or more suitable persons as Attorney(s)-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

Attorney-in-Fact may be given full power and authority for and in the name of and on behalf of the Company, to execute, acknowledge and deliver, any and all bonds, recognizances, contracts, agreements or indemnity and other conditional or obligatory undertakings, including any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts, and any and all notices and documents canceling or terminating the Company's liability thereunder, and any such instruments so executed by any such Attorney-in-Fact shall be binding upon the Company as if signed by the President and sealed and effected by the Corporate Secretary.

Be it Resolved, that the signature of any authorized officer and seal of the Company heretofore or hereafter affixed to any power of attorney or any certificate relating thereto by facsimile, and any power of attorney or certificate bearing facsimile signature or facsimile seal shall be valid and binding upon the Company with respect to any bond or undertaking to which it is attached."

The Attorney-in-Fact named above may be an agent or a broker of the Company. The granting of this Power of Attorney is specific to this bond and does not indicate whether the Attorney-in-Fact is or is not an appointed agent of the Company.

IN WITNESS WHEREOF, American Contractors Indemnity Company has caused its seal to be affixed hereto and executed by its President on this 18th day of April, 2022.

AMERICAN CONTRACTORS INDEMNITY COMPANY

By: _____
Adam S. Pessin, President

A Notary Public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles

On this 18th day of April, 2022, before me, Sonia O. Carrejo, a notary public, personally appeared Adam S. Pessin, President of American Contractors Indemnity Company, who proved to me on the basis of satisfactory evidence to be the person whose name is subscribed to the within instrument and acknowledged to me that he executed the same in his authorized capacity, and that by his signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of CALIFORNIA that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Signature _____ (seal)

SONIA O. CARREJO
Notary Public - California
Los Angeles County
Commission # 2398710
My Comm. Expires Apr 23, 2026

I, Kio Lo, Assistant Secretary of American Contractors Indemnity Company, do hereby certify that the Power of Attorney and the resolution adopted by the Board of Directors of said Company as set forth above, are true and correct transcripts thereof and that neither the said Power of Attorney nor the resolution have been revoked and they are now in full force and effect.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seals of said Companies at Los Angeles, California this 16th day of October, 2024.

Bond No. 100896545
Agency No. 13266

Kio Lo, Assistant Secretary

Visit tmhcc.com/surety for more information

HCCSOZZPOAACIC07/2023

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Gramercy Extremity Orthopedics MDEG License # (if applicable) _____

Physical Address 1239 N. Glenville Dr

City Richardson State TX Zip 75081

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Michael Middle _____ Last Simpson

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Richardson State TX Zip 75081

Telephone [redacted] Email MSimpson@gramercyortho.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Texas at Dallas		1983 - 1985	
Address	**City**	**State**	**Zip**
800 W. Campbell Rd.	Richardson	TX	75080
Diploma/Degree obtained, if any			
BS. - Business / MIS			

School Name		From - To (MM/YY – MM/YY)	
Lake Highlands High School		78 - 80	
Address	**City**	**State**	**Zip**
9449 Church Rd.	Dallas	TX	75238
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/18 - 02/24	[redacted]	Carrollton	TX	75010
01/14 - 12/17		The Colony	TX	75056
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Gramercy Extremity Orthopedics LLC			01/15	05/24
Business Address	**City**		**State**	**Zip**
1239 N. Glenville DR.	Richardson		TX	75081
Phone	**Title**		**Number of Employed Hours**	
855-436-2278	C.E.O			
Description of Duties	MANAGE ALL ASPECTS of Company			

Business Name			From - To (MM/YY – MM/YY)	
Small Bone Innovations			04/12	06/14
Business Address	**City**		**State**	**Zip**
No longer in Business - Acq.	Morristown		PA	
Phone	**Title**		**Number of Employed Hours**	
N/A	C.E.O.			
Description of Duties	MANAGE ALL ASPECTS of Company			

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. **Provide all the following *<u>where applicable</u>*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Michael Simpson, **certify that as the MDEG Administrator for** Gramercy Extremity Orthopedics, LLC,

that I (initial that you have read and meet the following requirements):

1. MS Have a high school diploma or its equivalent;
2. MS Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MS Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MS Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Simpson
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/21/2024
Date

Board Use Only	Date Received: 7/22/24

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Gramercy Extremity Orthopedics, LLC
Pharmacy/Wholesaler License # (if applicable) N/A
Physical Address 1239 N. Glenville DR.
City Richardson State TX Zip 75081
Mailing Address (if different from physical address) _____
City _____ State _____ Zip _____
Telephone 855-436-2278 x100 Website www.GramercyOrtho.com
Licensing Company Email GEOSUPPORTCENTER@GramercyOrtho.com

Section 2: Personal Information

First Michael Middle Patrick Last Simpson
Alias(es, nicknames, name changes, etc.) _____
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X
Mailing Address [redacted]
City Carrollton State TX Zip 75010
Telephone [redacted] Email MSimpson@GramercyOrtho.com
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY of TEXAS AT DALLAS		08/82 – 12/85	
Address	**City**	**State**	**Zip**
800 W. CAMPBELL RD.	RICHARDSON	TX	75080
Diploma/Degree obtained, if any			
B.S. IN BUSINESS			

School Name		From - To (MM/YY – MM/YY)	
LAKE HIGH ~~SCHOOL~~ LAND High school		8/78 5/80	
Address	**City**	**State**	**Zip**
9449 Church Rd.	DALLAS	TX	75238
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/17 – 10-24	[redacted]	CARROLLTON	TX	75010
From - To (MM/YY – MM/YY)		City	State	Zip
10/14 9/17		The Colony	TX	75056
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
GrAmercy Extremity Orthopedics			1/15-Current	
Business Address		City	State	Zip
1239 N. Glenville DR.		Richardson	TX	75081
Phone	Title		Number of Employed Hours	
855-436-2278	C.E.O.		18,000 +	
Description of Duties				
Manage all aspects of company				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		N/A
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✗
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Michael Simpson, **certify that as the designated representative for**

Gramercy Extremity Orthopedics LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MS I am at least 21 years of age;
3. MS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Michael Simpson
Print Name (First, Last)

Michael Simpson
Original Signature (electronic, copies or stamps not accepted)

10/8/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Simpson
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/8/24
Date

Please have this section completed in the presence of a Notary Public.

State of TEXAS, ss. County of Dallas

I, Michael Simpson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/8/24
Date

Subscribed and Sworn to before me this 11th day of October.

Bradley Simpson
Notary Public Signature

BRADLEY TRAVIS SIMPSON
Notary Public, State of Texas
Comm. Expires 01-12-2027
Notary ID 134143513

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Gramercy Extremity Orthopedics, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) N/A

Physical Address 1239 N. Glenville Dr.

City Richardson State TX Zip 75081

Mailing Address (if different from physical address)

City State Zip

Telephone 214-435-3078 Website www.gramercyortho.com

Licensing Company Email

Section 2: Personal Information

First Michael Middle Patrick Last Simpson

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Carrollton State TX Zip 75010

Telephone [redacted] Email MSimpson@Gramercyortho.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
University of Texas at Dallas			1983 - 1985	
Address: 800 W. Campbell Rd., ~~Richardson~~	City: Richardson		State: TX	Zip: 75080
Diploma/Degree obtained, if any: B.S. - Business				
School Name: Lake Highlands High School			From - To (MM/YY – MM/YY): 78-80	
Address: 9449 Church Rd.	City: Dallas		State: TX	Zip: 75238
Diploma/Degree obtained, if any:				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/18 - 02-24	[redacted]	Carrollton	TX	75010
01/14 12/17	[redacted]	The Colony	TX	75056
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Gramercy Extremity Orthopedics			From - To (MM/YY – MM/YY): 01/15 03/24
Business Address: 1239 N. Glenville Dr.	City: Richardson	State: TX	Zip: 75081
Phone: 855-436-2278	Title: Chief Executive Officer		
Description of Duties: Management of company			

Business Name: Small Bone Innovations			From - To (MM/YY – MM/YY): 04/12 06/14
Business Address: No longer in business	City: Morristown	State: PA	Zip:
Phone: N/A	Title: Chief Executive officer		
Description of Duties: Management of company			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	N/A	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Simpson
Print Name (First, Last)

Michael Simpson — 3/13/24
Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Dallas

I, Michael Simpson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Michael Simpson — 3/13/24
Original Signature — **Date**

Subscribed and Sworn to before me this 13th day of March.

Bradley Simpson
Notary Public Signature

BRADLEY TRAVIS SIMPSON
Notary Public, State of Texas
Comm. Expires 01-12-2027
Notary ID 134143513

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Gramercy Extremity Orthopedics

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 1239 N. Glenville Dr

City Richardson State TX Zip 75081

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First PAUL Middle JOSEPH Last VASSA

Alias(es, nicknames, name changes, etc.) —

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City McKinney State TX Zip 7557[redacted]

Telephone [redacted] Email PVASSA@GRAMERCYORTHO.COM

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIV TEXAS AT ARLINGTON / UNIV TEXAS SOUTHWESTERN MEDICAL		1/93 – 12/95	
Address	City	State	Zip
701 S. NEDDERMAN DR	ARLINGTON	TX	76019
Diplomа/Degree obtained, if any			
Ph.D. BME			

School Name		From - To (MM/YY – MM/YY)	
UNIV TEXAS AT ARLINGTON		1/91 – 12/92	
Address	City	State	Zip
701 S. NEDDERMAN DR	ARLINGTON	TX	76019
Diplomа/Degree obtained, if any			
MS BME			

School Name		From - To (MM/YY – MM/YY)	
FLORIDA ATLANTIC UNIV		1/84 – 5/86	
Address	City	State	Zip
777 GLADES RD	BOCA RATON	FL	33431
Diplomа/Degree obtained, if any			
BSEE			

School Name		From - To (MM/YY – MM/YY)	
GEORGIA INST TECHNOLOGY		9/81 – 12/83	
Address	City	State	Zip
	ATLANTA	GA	30332
Diplomа/Degree obtained, if any			
—			

School Name		From - To (MM/YY – MM/YY	
SOUTH BROWARD HIGH		8/74 – 5/81	
Address	City	State	Zip
1901 N FEDERAL HWY	HOLLYWOOD	FL	33020
Diplomа/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1/17 – PRES	[redacted]	MCKINNEY	TX	75070
4/16 – 12/17		MCKINNEY	TX	75071
3/09 – 3/16		MCKINNEY	TX	75070
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)
GRAMERCY EXTREMITY ORTHOPEDICS		3/15 – PRES
Business Address	**City**	**State** / **Zip**
1239 N GLENVILLE DR	RICHARDSON	TX 75081
Phone	**Title**	
855 - 436-2276	CFO	
Description of Duties		
ENGINEERING + TECHNOLOGY		

Business Name		From - To (MM/YY – MM/YY)
ALALIA RESEARCH GROUP		3/12 - 3/15
Business Address	**City**	**State** / **Zip**
4 PARK PLAZA	IRVINE	CA 92614
Phone	**Title**	
332 236-8484	VP	
Description of Duties		
MEDICAL PATENT ANALYSIS		

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State** / **Zip**
Phone	**Title**	
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State** / **Zip**
Phone	**Title**	
Description of Duties		

Business Name		From - To (MM/YY – MM/YY)
Business Address	**City**	**State** / **Zip**
Phone	**Title**	
Description of Duties		

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

PAUL VASTA

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/13/2024

Date

Please have this section completed in the presence of a Notary Public.

State of TEXAS, ss. County of DALLAS

I, PAUL VASTA, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

03/13/2024

Date

Subscribed and Sworn to before me this 13th day of March.

Bradley Simpson

Notary Public Signature

BRADLEY TRAVIS SIMPSON
Notary Public, State of Texas
Comm. Expires 01-12-2027
Notary ID 134143513

(Seal)

List of Employees	
Name	Title
Bradley Simpson	Logistics Analyst
Karen Vasta	Office Manager
Roger Hill	Quality Director
Cedrick Grayson	QC Technician
Craig Youngman	Operations Assistant
James Guilas	Northeast Regional Sales Director
Alex Ochoa	Midwest Regional Sales Director

4W

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☐ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH02480	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Innogenix LLC

Physical Address: 8200 New Horizon Blvd

City: Amityville State: NY Zip: 11701

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 6314504704 Website: http://www.innogenix.com

Name of Designated Representative (DR): Pankaj Gupta

Licensing Company Email: info@innogenix.com DR Email: pgupta@innogenix.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): _____

Corporation/Organization Name: Innogenix, LLC

Mailing Address: 8200 New Horizons Blvd

City: Amityville State: NY Zip: 11701

Telephone: (631) 450-4704 Email: pgupta@innogenix.com

Contact Person Name: Pankaj Gupta

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Innogenix, LLC

Facility Name

Pankaj Gupta

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

3/28/24

Date

Board Use Only	Date Received: 4/2/24	Amount: $1000 - Check 5349

UNANIMOUS RESOLUTION
OF
BOARD OF MANGERS
OF
INNOGENIX, LLC

August 23, 2023

The UNDERSIGNED, being all of the members of the Board of Managers (the Managers) of Innogenix, LLC, a limited liability company duly organized under the laws of the State of Delaware (the "**COMPANY**"), DO HEREBY CONSENT to the following resolution without a meeting as the duly authorized resolution of the Managers of the Company and to the taking of the action authorized below:

BE IT RESOLVED, that the Company approves the redemption of all the unit equity interests owned by Messrs. Ram Potti. RSMB Investments, LLC; Manish Potti, Scotland Parkway, LLC and Bharath Potti by the Company per the terms and conditions of the Redemption Agreement.

RESOLVED, that the Company approves the purchase of the above cited equity unit interests by A&K Holding, LLC, RSL Associates, LLC and JAAA Holdings, LLC per the Redemption Agreement.

RESOLVED, that the Managers are hereby authorized to perform and execute this action in conformance with all the necessary documents and resolutions of the Company.

RESOLVED, that this written consent may be executed in one or more counterparts and shall be deemed to constitute one and the same instrument.

IN WITNESS WHEREOF, the undersigned have executed this Unanimous Written Consent of the Managers as of the date set forth above.

Shirish Valsangikar, President

Pankaj Gupta, Executive Vice President & COO

Randy (Jai) Narine, Vice President

Joe Jairam, Vice President

Robert A. Stanczuk, Vice President

An official website of the United States government Here's how you know

U.S. FOOD & DRUG ADMINISTRATION

Search FDA.gov Menu

Home Drug Databases DECRS Search Result

Share Tweet Linkedin Email Print

Drug Establishments Current Registration Site

New Search

Search Results for *Innogenix*

Showing 1 to 1 of 1 entries Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Innogenix, LLC.	3013326213	044649124	ANALYSIS; LABEL; MANUFACTURE; PACK	8200 New Horizons Blvd, Amityville, New York (NY) 11701, United States (USA)	12/31/2024

Previous 1 Next

Data Current Through: Wednesday, Mar 27, 2024

New Search

Verified 3/28/24

P: 631-450-4704
F: 631-450-4707
8200 New Horizons Blvd Amityville, NY 11701

Current List of Members / Officers

Name	Title	Date of Birth	Address	% Ownership
Jeenarine Narine	Member	[redacted]		
RSL Associates, LLC (Jai R Narine)	Member			
JAAA Holding Company, LLC. (Neatram Joe Jairam)	Member			
A & K Holding, LLC (Kileshwar Mathura)	Member			
Shirish Valsangikar	President			
Pankaj Gupta	COO			

INNOGENIX, LLC. - PRINCIPAL OWNERS

S. No.	Member/Group	% Ownership (2016)	% Ownership (2023)
1	Jeenarine Narine	15%	27%
2	Potti Family, LLC. (Ram Potti)	15%	0%
3	Scottland Parkway, LLC. (Manish Potti)	15%	0%
4	Bharath Potti	10%	0%
5	JAAA Holding Company, LLC. (Neatram Joe Jairam)	15%	23%
6	RSL Associates, LLC. (Jai R Narine)	15%	23%
7	A&K Family Holding, LLC. (Kileshwar Mathura)	15%	18%

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "INNOGENIX, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-THIRD DAY OF FEBRUARY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "INNOGENIX, LLC" WAS FORMED ON THE EIGHTEENTH DAY OF JULY, A.D. 2016.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

6100672 8300

SR# 20240647388

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202870402

Date: 02-23-24

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2023-26

NAME OF SUPERVISOR
PANKAJ GUPTA

THIS IS TO CERTIFY

INNOGENIX, LLC
8200 NEW HORIZONS BLVD.
AMITYVILLE, NY 11701

is duly recorded as a

REGISTERED MANUFACTURER OF DRUGS AND/OR DEVICES

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE FIRST DAY OF SEPTEMBER, 2023.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF AUGUST, 2026.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER

035716

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

Hudson Insurance Company
1035 Greenwood Blvd Ste 265
Lake Mary, FL 32746-5422
Telephone 888-400-5505

STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521

Bond Rider

To be attached to and form part of:

Bond Number 809031
issued to Innogenix, LLC
in favor of STATE BOARD OF PHARMACY
described as NV - Pharmaceutical Wholesaler $25,000

Effective date of Rider: August 8, 2023

It is understood and agreed that the bond is changed or revised as described below:

✓ Address changed to:
___ Name changed to:
___ Bond term changed to:
___ Other change:

Address change

From: 1800 NEW HORIZONS BLVD, AMITYVILLE, NY 11701

To: 8200 New Horizons Blvd, Amityville, NY 11701

Said bond shall be subject to all its terms, conditions and limitations, except as herein expressly modified.

In witness whereof, Hudson Insurance Company has caused its corporate seal to be hereunto affixed this 8th day of August 2023.

Hudson Insurance Company Corporate SEAL 1918 Delaware B503

Hudson Insurance Company

By: _____
Eric Fauerbach, Attorney-in-Fact

809031

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That HUDSON INSURANCE COMPANY, a corporation of the State of Delaware, with offices at 100 William Street, New York, New York, 10038, has made, constituted and appointed, and by these presents, does make, constitute and appoint

Eric Fauerbach

of the State of South Carolina

its true and lawful Attorney(s)-in-Fact, at New York, New York, each of them alone to have full power to act without the other or others, to make, execute and deliver on its behalf, as Surety, bonds and undertakings given for any and all purposes, also to execute and deliver on its behalf as aforesaid renewals, extensions, agreements, waivers, consents or stipulations relating to such bonds or undertakings provided, however, that no single bond or undertaking shall obligate said Company for any portion of the penal sum thereof in excess of the sum of

Twenty-Five Thousand Dollars and Zero Cents

Such bonds and undertakings when duly executed by said Attorney(s)-in-Fact, shall be binding upon said Company as fully and to the same extent as if signed by the President of said Company under its corporate seal attested by its Secretary.

In Witness Whereof, HUDSON INSURANCE COMPANY has caused these presents to be of its Senior Vice President thereunto duly :d, on this 2nd day of June, 20 22 at New York, New York.

e seal)

HUDSON INSURANCE COMPANY

Attest.....
Dina Daskalakis No. 01MU6067553
Corporate Secretary

By.....
Michael P. Cifone
Senior Vice President

STATE OF NEW YORK
COUNTY OF NEW YORK, SS.

On the 2nd day of June, 20 22 before me personally came Michael P. Cifone to me known, who being by me duly sworn did depose and say that he is a Senior Vice President of **HUDSON INSURANCE COMPANY**, the corporation described herein and which executed the above instrument, that he knows the seal of said Corporation, that the seal affixed to said instrument is such corporate seal, that it was so affixed by order of the Board of Directors of said Corporation, and that he signed his name thereto by like order.

(Notarial Seal)

ANN M. MURPHY
NOTARY PUBLIC
STATE OF NEW YORK

.....
ANN M. MURPHY
Notary Public, State of New York
No. 01MU6067553
Qualified in Nassau County
Commission Expires December 10, 2025

CERTIFICATION

STATE OF NEW YORK
COUNTY OF NEW YORK SS.

The undersigned **Dina Daskalakis** hereby certifies:

That the original resolution, of which the following is a true and correct copy, was duly adopted by unanimous written consent of the Board of Directors of Hudson Insurance Company dated July 27th, 2007, and has not since been revoked, amended or modified:

"RESOLVED, that the President, the Executive Vice Presidents, the Senior Vice Presidents and the Vice Presidents shall have the authority and discretion, to appoint such agent or agents, or attorney or attorneys-in-fact, for the purpose of carrying on this Company's surety business, and to empower such agent or agents, or attorney or attorneys-in-fact, to execute and deliver, under this Company's seal or otherwise, bonds obligations, and recognizances, whether made by this Company as surety thereon or otherwise, indemnity contracts, contracts and certificates, and any and all other contracts and undertakings made in the course of this Company's surety business, and renewals, extensions, agreements, waivers, consents or stipulations regarding undertakings so made; and

FURTHER RESOVLED, that the signature of any such Officer of the Company and the Company's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seal when so used whether heretofore or hereafter, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed."

THAT the above and foregoing is a full, true and correct copy of Power of Attorney issued by said Company, and of the whole of the original and that the said Power of Attorney is still in full force and effect and has not been revoked, and furthermore that the Resolution of the Board of Directors, set forth in the said Power of Attorney is now in force.

Witness the hand of the undersigned and the seal of said Corporation this 8th day of August, 20 23.

seal)

By.....
Dina Daskalakis, Corporate Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 809031

Application/License No. _____

INNOGENIX, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1800 NEW HORIZONS BLVD AMITYVILLE, NY 11701 (Address of Applicant/Principal), as PRINCIPAL, and HUDSON INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of DELAWARE (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1035 GREENWOOD BLVD STE 265 LAKE MARY, FL 32746 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on JULY 29, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 1ST day of AUGUST, 2023.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

ERIC FAUERBACH, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Taylor Branum

Witness Jason O'Leary

Countersigned by:

Not Needed
Nevada Resident Agent

Hudson Insurance Company CORPORATE SEAL 1918 DELAWARE B503

Posted February 20, 2020

HUDSON INSURANCE GROUP

Bond Number: 809031

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That HUDSON INSURANCE COMPANY, a corporation of the State of Delaware, with offices at 100 William Street, New York, New York, 10038, has made, constituted and appointed, and by these presents, does make, constitute and appoint

Eric Fauerbach

of the State of South Carolina

its true and lawful Attorney(s)-in-Fact, at New York, New York, each of them alone to have full power to act without the other or others, to make, execute and deliver on its behalf, as Surety, bonds and undertakings given for any and all purposes, also to execute and deliver on its behalf as aforesaid renewals, extensions, agreements, waivers, consents or stipulations relating to such bonds or undertakings provided, however, that no single bond or undertaking shall obligate said Company for any portion of the penal sum thereof in excess of the sum of

Twenty Five Thousand And 00/100 Dollars ($25,000.00)

Such bonds and undertakings when duly executed by said Attorney(s)-in-Fact, shall be binding upon said Company as fully and to the same extent as if signed by the President of said Company under its corporate seal attested by its Secretary.

In Witness Whereof, HUDSON INSURANCE COMPANY has caused these presents to be of its Senior Vice President thereunto duly
d, on this 2nd day of June, 20 22 at New York, New York.
seal)

HUDSON INSURANCE COMPANY

Attest.....
Dina Daskalakis No. 01MU6067553
Corporate Secretary

By.....
Michael P. Cifone
Senior Vice President

STATE OF NEW YORK
COUNTY OF NEW YORK. SS.

On the 2nd day of June, 20 22 before me personally came Michael P. Cifone to me known, who being by me duly sworn did depose and say that he is a Senior Vice President of **HUDSON INSURANCE COMPANY**, the corporation described herein and which executed the above instrument, that he knows the seal of said Corporation, that the seal affixed to said instrument is such corporate seal, that it was so affixed by order of the Board of Directors of said Corporation, and that he signed his name thereto by like order.

(Notarial Seal)

ANN M. MURPHY
NOTARY PUBLIC
STATE OF NEW YORK

.....
ANN M. MURPHY
Notary Public, State of New York
No. 01MU6067553
Qualified in Nassau County
Commission Expires December 10, 2025

CERTIFICATION

STATE OF NEW YORK
COUNTY OF NEW YORK SS.

The undersigned **Dina Daskalakis** hereby certifies:

That the original resolution, of which the following is a true and correct copy, was duly adopted by unanimous written consent of the Board of Directors of Hudson Insurance Company dated July 27th, 2007, and has not since been revoked, amended or modified:

"RESOLVED, that the President, the Executive Vice Presidents, the Senior Vice Presidents and the Vice Presidents shall have the authority and discretion, to appoint such agent or agents, or attorney or attorneys-in-fact, for the purpose of carrying on this Company's surety business, and to empower such agent or agents, or attorney or attorneys-in-fact, to execute and deliver, under this Company's seal or otherwise, bonds obligations, and recognizances, whether made by this Company as surety thereon or otherwise, indemnity contracts, contracts and certificates, and any and all other contracts and undertakings made in the course of this Company's surety business, and renewals, extensions, agreements, waivers, consents or stipulations regarding undertakings so made; and

FURTHER RESOVLED, that the signature of any such Officer of the Company and the Company's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seal when so used whether heretofore or hereafter, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed."

THAT the above and foregoing is a full, true and correct copy of Power of Attorney issued by said Company, and of the whole of the original and that the said Power of Attorney is still in full force and effect and has not been revoked, and furthermore that the Resolution of the Board of Directors, set forth in the said Power of Attorney is now in force.

Witness the hand of the undersigned and the seal of said Corporation this 1st day of August, 2023.
(Corporate seal)

By.....
Dina Daskalakis, Corporate Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Innogenix, LLC

Pharmacy/Wholesaler License # (if applicable): WH02480

Physical Address: 8200 New Horizons Blvd

City: Amityville State: NY Zip: 11701

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 631 450 4704 Website: http://www.innogenix.com

Licensing Company Email: info@innogenix.com

Section 2: Personal Information

First: Pankaj Middle: Last: Gupta

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: South Setauket State: NY Zip: 11720

Telephone: (631) 450-4704 Email: pgupta@innogenix.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		x

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Birla Institute of Technology and Sciences		1993 - 1994	
Address	**City**	**State**	**Zip**
Vidya Vihar	Pilani	Rajasthan	333031
Diploma/Degree obtained, if any			
Masters in Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Karnatak University		1988 - 1992	
Address	**City**	**State**	**Zip**
Pavate Nagar,	Dharwad	Karnataka	580003
Diploma/Degree obtained, if any			
Bachelor of Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Govt College		1985 - 1987	
Address	**City**	**State**	**Zip**
Trimmu Rd, Sant Nagar, Hemrajpur	Gurdaspur	Punjab	143521
Diploma/Degree obtained, if any			
Pre Medical (10+2)			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/18 - Till Date	[redacted]	South Setauket	NY	11720
07/10 to 05/18		South Setauket	NY	11720

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Innogenix, LLC			From - To (MM/YY – MM/YY): Jan 2017 to current	
Business Address: 8200 New Horizons Blvd	City: Amityville		State: NY	Zip: 11701
Phone: 631 450 4704	Title: COO		Number of Employed Hours: 20,000	
Description of Duties: Oversight of R&D, manufacturing, packaging and warehousing				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Pankaj Gupta, **certify that as the designated representative for** Innogenix LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Pankaj Gupta
PANKAJ GUPTA
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/25/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

PANKAJ GUPTA

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/25/2024

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Nassau

I, PANKAJ GUPTA, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5/25/2024

Date

Subscribed and Sworn to before me this 25th day of May, 2024.

Notary Public Signature

SUSAN E KURAU
NOTARY PUBLIC-STATE OF NEW YORK
No. 01KU6248573
Qualified in Nassau County
My Commission Expires 10-17-2024

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Innogenix, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable) WH02480

Physical Address 8200 New Horizons Blvd

City Amityville State NY Zip 11701

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 631 450 4704 Website http://www.innogenix.com

Licensing Company Email info@innogenix.com

Section 2: Personal Information

First Jeenarine Middle _____ Last Narine

Alias(es, nicknames, name changes, etc.) _____

Date of Birt [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Delray Beach State FL Zip 33446

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2018-Present	[redacted]	Delray Beach	FL	33446
2015-2018		Boca Raton	FL	33496
2004-2015		Dix Hills	NY	11746
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
EPIC Pharma			2008-2016
Business Address	**City**	**State**	**Zip**
227-15 N. Conduit Ave	Laurelton	NY	
Phone	**Title**		
	President/Owner		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5.23.24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeenarine Narine

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5.23.24

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Nassau

I, Jeenarine Narine, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5.23.24

Date

Subscribed and Sworn to before me this 23 day of May 2024.

Notary Public Signature

JODY GRUTER
Notary Public - State of New York
NO. 01GR6295637
Qualified in Nassau County
My Commission Expires Jan 6, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Innogenix, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable) WH02480

Physical Address 8200 New Horizons Blvd

City Amityville State NY Zip 11701

Mailing Address (if different from physical address)

City State Zip

Telephone 631 450 4704 Website http://www.innogenix.com

Licensing Company Email info@innogenix.com

Section 2: Personal Information

First Neatram Middle Joe Last Jairam

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Dix Hills State NY Zip 11746

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Magill Secondary School		1984-1991	
Address	**City**	**State**	**Zip**
Canal No 1 West bank Demerara Guyana			
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2013-8/2017	[redacted]	Farmingdale	NY	11735
082017-Present	[redacted]	Dix Hills	NY	11746

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Innogenix			From - To (MM/YY – MM/YY): 8/2017-Present
Business Address: 8200 New Horizons Blvd	City: Amityville	State: NY	Zip: 11701
Phone: 631-450-4704	Title: Member		
Description of Duties: Owner			

Business Name: Pharma Surplus Equipment			From - To (MM/YY – MM/YY): 8/2011-Present
Business Address: 240 N. Oak Street	City: Copiague	State: NY	Zip: 11726
Phone: 631-629-9129	Title: President		
Description of Duties: Owner			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Neatram Joe Jairam

Print Name (First, Last)

Neat

Original Signature (electronic, copies or stamps not accepted)

5/1/2024

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Suffolk

I, Neatram Joe Jairam, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Neat

Original Signature

5/1/2024

Date

Subscribed and Sworn to before me this 1st day of May 2024.

Notary Public Signature

TRINA RENEE JOHNSON
Notary Public - State of New York
NO. 01JO6111725
Qualified in Suffolk County
My Commission Expires Oct 9, 2024

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Innogenix, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable): WH02480

Physical Address: 8200 New Horizons Blvd

City: Amityville State: NY Zip: 11701

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 631 450 4704 Website: http://www.innogenix.com

Licensing Company Email: info@innogenix.com

Section 2: Personal Information

First: KIESHWAR Middle: Last: MATHURA

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Dix Hills State: NY Zip: 11746

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
BARUCH College			1990 - 1995	
Address	City		State	Zip
NYC			NY	
Diploma/Degree obtained, if any				
BBA				
School Name			From - To (MM/YY – MM/YY)	
James Monroe High			1986 - 1990	
Address	City		State	Zip
Bronx				
Diploma/Degree obtained, if any				
Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2014 - 2018	[redacted]	Farmingdale	NY	11735
From - To (MM/YY – MM/YY)		City	State	Zip
2010 - 2014		Dix Hills	NY	11746
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Kileshwar Mathura CPA PC				From - To (MM/YY – MM/YY): 2002 – current
Business Address: 565 Broadhollow RD		City: Farmingdale	State: NY	Zip: 11735
Phone	Title			
Description of Duties: CPA				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

KILESHWAR MATHURA

Print Name (First, Last)

Kileshwar Mathura — 5-3-2024

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Suffolk

I, Kileshwar Mathura, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Kileshwar Mathura — 5-3-2024

Original Signature — **Date**

Subscribed and Sworn to before me this 3rd day of May, 2024.

Notary Public Signature

KIM ANN VOLZ
NOTARY PUBLIC-STATE OF NEW YORK
No. 01VO5020890
Qualified in Suffolk County
My Commission Expires 11-29-2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Innogenix, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable): WH02480

Physical Address: 8200 New Horizons Blvd

City: Amityville State: NY Zip: 11701

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 631 450 4704 Website: http://www.innogenix.com

Licensing Company Email: info@innogenix.com

Section 2: Personal Information

First: JAI Middle: RANDY Last: NARINE

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: FARMINGDALE State: NY Zip: 11735

Telephone: [redacted] Email: BNARINE@INNOGENIX.COM

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
St John's University		09/00 – 05/05	
Address	**City**	**State**	**Zip**
8000 Utopia Pkwy	Queens	NY	11439
Diploma/Degree obtained, if any			
Finance			

School Name		From - To (MM/YY – MM/YY)	
Walt Whitman High School		09/96 – 06/00	
Address	**City**	**State**	**Zip**
301 W Hills Rd	Huntington Station	NY	11746
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2013 – 2024	[redacted]	Farmingdale	NY	11735
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
INNOGENIX LLC			05/17	– 04/24
Business Address	**City**		**State**	**Zip**
8200 NEW HORIZONS BLVD	Amityville		NY	11701
Phone	**Title**			
631-450-4706	VP SALES			
Description of Duties				
MARKETING AND SALES OF PRODUCTS				

Business Name			From - To (MM/YY – MM/YY)	
A & J MACHINE INC			04/00	– 05/16
Business Address	**City**		**State**	**Zip**
240 NORTH OAK ST	COPIAGUE		NY	11726
Phone	**Title**			
631-845-7586	VP SALES			
Description of Duties				
SALES OF EQUIPMENT				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date 5/8/24

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jai Narine

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/8/24

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Nassau

I, Jai Narine, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5/8/24

Date

Subscribed and Sworn to before me this 8th day of May 2024.

Notary Public Signature

JERRY W SIERRA
Notary Public - State of New York
NO. 01SI6225206
Qualified in Nassau County
My Commission Expires Aug 29, 2026

(Seal)

Innogenix Employees

Employee Name	Hire Date
Arshad, Hira	08/08/2022
Avila Cedillo, Henry R	04/15/2024
Bhurke, Priya A	09/26/2022
Bingi, Ramprasad	05/26/2020
Consiglio, Mario	06/10/2019
David, Alen Carlo Santos	02/27/2017
Fuentes, Danis R	12/08/2020
Gopi, Prasad	05/10/2021
Gopi, Radhakrishna	02/27/2017
Gross, Kaylee T	03/14/2022
Gupta, Pankaj	01/03/2017
Habiboodean, Ameer M	10/05/2022
Haridat, Ramkumar	04/11/2017
Hu, Diana	02/27/2017
Jairam, Neatram Joe	01/03/2017
Jampalli, Thriveni	12/13/2019
Kaur, Manjeet	12/05/2022
Libia, Humaira Khan	10/01/2019
Lituma, Edisson M	08/22/2022
Maareddy, Rajeshwara Reddy	06/08/2017
Marquez Salinas, Meybi J	09/26/2022
Martinez-Sanchez, Cristian D	07/02/2018
Momin, MD H	04/17/2023
Narine, Jai R	08/01/2016
Narine, Rabindra	11/06/2017
Narine-Jairam, Rupwattie	05/08/2017
Nath, Dabashis Kumar	01/07/2019
Nuti, Sita Ramam	11/02/2020
Orellana, Nelson E	09/29/2020
Paul, Marlyn	03/04/2019
Quintanilla, Silvia	09/28/2020
Regis, Roodland	05/21/2018
Salgado Zayas, Marlene E	05/11/2020
Sayas Quintanilla, Reina E	07/18/2022
Stanczuk, Robert A	07/06/2020
Torres, Omar	10/28/2019
Valsangikar, Shirish G	12/12/2016

4X

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH N/A	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Mycone Dental Supply Co., Inc. d/b/a Keystone Industries-Myerstown

Physical Address: 52 West King Street

City: Myerstown State: PA Zip: 17067

Mailing Address (if different from physical address): c/o State License Servicing, 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: www.keystoneind.com

Name of Designated Representative (DR): Debra Jean Tucker-Hansen

Licensing Company Email: KEY@slsny.com DR Email: dhansen@keystoneind.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☒ Others: Drugs (Human OTC)	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Distribution sites within organization, Manufacturers, Distributors		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

N/A **Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: GemChem Inc.
Address: 53 N. Cedar St City: Lititz State: PA Zip: 17543

Name: Brenntag Northeast, LLC
Address: 81 W Huller Lane City: Reading State: PA Zip: 19605

Name: Univar Solutions USA, Inc.
Address: 3075 Highland Pkwy Ste 200 City: Downers Grove State: IL Zip: 60515

Name: UPI Chem Inc.
Address: 2390 Park Center Drive City: Mebane State: NC Zip: 27302

N/A

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NY
Parent Company (if any): See attached Organizational Chart
Corporation/Organization Name: Mycone Dental Supply Co., Inc. d/b/a Keystone Industries-Myerstown
Mailing Address: c/o State License Servicing 1751 State Route 17A, Suite 3
City: Florida State: NY Zip: 10921
Telephone: (845) 544-2482 Email: KEY@slsny.com
Contact Person Name: Christine Cannon

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: FDA: 2523320	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019_Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

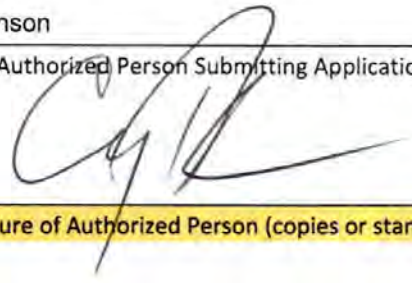
I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Mycone Dental Supply Co., Inc. d/b/a Keystone Industries-Myerstown

Facility Name

Cary B. Robinson

Print Name of Authorized Person Submitting Application



Original signature of Authorized Person (copies or stamps not accepted)

8-6-24

Date

Board Use Only	Date Received: 8/19/24	Amount: $1000-ck 7681

Proof of FDA

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
Keystone Industries - Gibbstown
Business Trade Names:
(1) Deepak Products Inc. (2) Keystone Industries (3) Mycone Dental Supply Co., Inc.

480 S Democrat Rd
Gibbstown, NJ 08027
Registration Number: 3010002722
FEI Number*: 3010002722
Status: Active
Date Of Registration Status: 2024

Owner/Operator:
Keystone Industries[6]
480 S. Democrat Road
Gibbstown, NJ US 08027
Owner/Operator Number: 9007845[7]

Official Correspondent:
Gloria Zuclich
480 S. Democrat Road
Gibbstown, NJ 08027
Phone: 856-6634700-7252

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

---

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9007845&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9007845&OwnerOperator

Page Last Updated: 06/17/2024

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyôl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

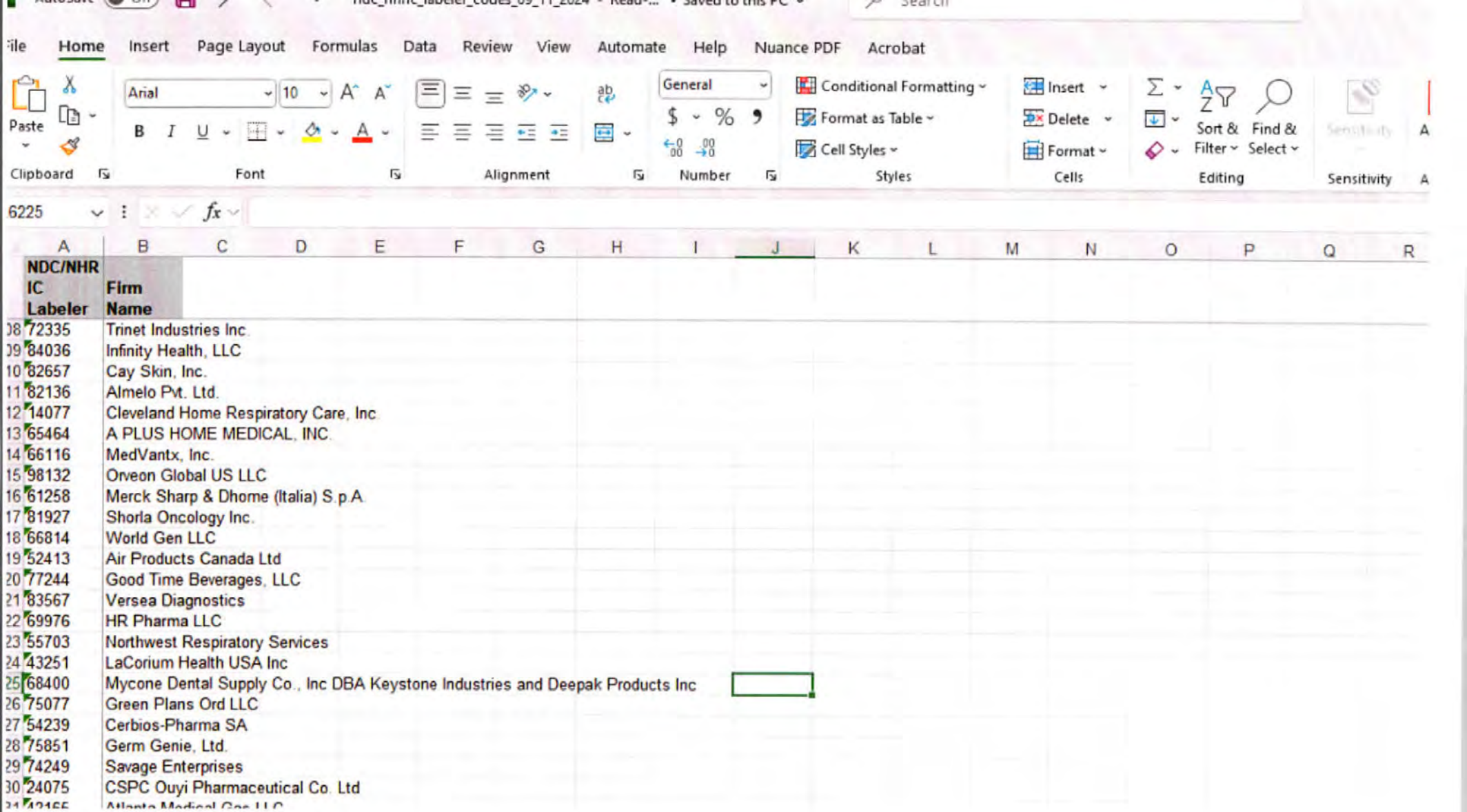
For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of **Health & Human Services**

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9007845&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9007845&OwnerOperator



NDC/NHRIC Labeler	Firm Name
72335	Trinet Industries Inc.
84036	Infinity Health, LLC
82657	Cay Skin, Inc.
82136	Almelo Pvt. Ltd.
14077	Cleveland Home Respiratory Care, Inc
65464	A PLUS HOME MEDICAL, INC.
66116	MedVantx, Inc.
98132	Orveon Global US LLC
61258	Merck Sharp & Dhome (Italia) S.p.A.
81927	Shorla Oncology Inc.
66814	World Gen LLC
52413	Air Products Canada Ltd
77244	Good Time Beverages, LLC
83567	Versea Diagnostics
69976	HR Pharma LLC
55703	Northwest Respiratory Services
43251	LaCorium Health USA Inc
68400	Mycone Dental Supply Co., Inc DBA Keystone Industries and Deepak Products Inc
75077	Green Plans Ord LLC
54239	Cerbios-Pharma SA
75851	Germ Genie, Ltd.
74249	Savage Enterprises
24075	CSPC Ouyi Pharmaceutical Co. Ltd

Mycone Dental Supply Co., Inc.
d/b/a Keystone Industries-Myerstown

Corporate Address: 480 South Democrat Rd., Gibbstown, NJ 08027 USA
FEIN: 13-1869682
www.keystoneind.com

Drug Labeler Code: 68400
Incorporation State: NY
Incorporation Date: 6/18/1958

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
MY	52 West King Street Myerstown, PA 17067 County: Lebanon	2523320 devices only			No	(717) 866-7571	(717) 866-5129

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Debra Jean Tucker-Hansen	[redacted]	Warehouse Manager	No	[redacted]		

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
Edward Robinson Mycone 2019 Trust for Cary Robinson % Cozen O'Connor Edward M Glickman Et Al	1650 Market St Ste 2800 Philadelphia , PA 19103	N/A	47.5	N/A	38-7222467	N/A	N/A
Edward Robinson Mycone 2019 Trust for Danielle Robinson % Cozen O'Connor Edward M Glickman Et Al	1650 Market St Ste 2800 GibbstownPhiladelphia, PA 19103	N/A	47.5	N/A	38-7222466	N/A	N/A
Cary Robinson and Edward Glickman, Trustees under Indenture of Fred I. Robinson	480 S Democrat Road Gibbstown, NJ 08027	N/A	5	N/A	23-7799136	N/A	N/A

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Cary B. Robinson	[redacted]	President	No	[redacted]		
Lawrence W. Steffier		EVP	No			

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
Incorp Services, Inc.			

3PLS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Sardo & Son's Warehouse, Inc	300 White Clay Center Newark, DE 19711					

For licensing issues, please contact State License Servicing, LLC (845) 544-2482 KEY@slsny.com

Company Particulars

Cert. of Good Standing

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, ROBERT J. RODRIGUEZ, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	MYCONE DENTAL SUPPLY CO., INC.
DOS ID Number:	111695
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	06/18/1958
Statement Status:	CURRENT
Statement Due Date:	06/30/2024

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on November 10, 2023 at 10:47 A.M.

ROBERT J. RODRIGUEZ, Secretary of State

Brendan C. Hughes

By Brendan C. Hughes
Executive Deputy Secretary of State

Authentication Number: 100004645884 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

Certificate of Licensure

Certificate No. 8000001932
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Drug & Device Registration
2525 North 7th Street
SUITE 210D
HARRISBURG, PA 17110
(717) 787-4779

Category:

Wholesaler/Distributor

KEYSTONE INDUSTRIES-MYERSTOWN
MYCONE DENTAL SUPPLY
52 W. KING STREET
MYERSTOWN, PA 17067

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Wholesale Prescription Drug License Act, Act #145, approved December 14, 1992.

Issuance Date: January 14, 2008
Expiration Date: The Last Day of March, 2025

Susan Coble
Acting Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

Debra L. Bogen, MD, FAAP
Acting Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

HS License

Home State (PA) VOL

Date: 8/5/2024

To: Nevada Licensing or Registering Board or Agency:
(Name of State or Agency)

Name of Facility: Keystone Industries - Myerstown dba Mycone Dental Supply

Facility Address : 52 W. King Street Myerstown, PA 17067

PA. Facility License, Registration, or Record number : 8000001932

The information below is to be completed only by a Pennsylvania state Licensing or Registering Agency. Must have State seal to be valid.

pennsylvania
DEPARTMENT OF HEALTH

www.health.pa.gov
www.health.state.pa.us/ddc

Drug Device and Cosmetic (DDC) Program
2525 N. 7th Street, Suite 210D
Harrisburg, PA 17110
Ph: 717-787-4779 Email: ra-ddc@pa.gov

Current Status: Active ☑ Yes ☐ No
Location: ☑ In state ☐ Out of State/Nonresident*
Type of Facility: wholesale Distributor / medical devices
Issue Date: 1/14/2008
Expiration Date: 3/31/2025

☑ The above facility is in good standing and has not had any formal disciplinary action under the above registration/license/record number administered or issued by the Commonwealth of Pennsylvania Department of Health DDC Program.

☐ The above facility has had any formal disciplinary action under the above registration/license record number administered or issued by the Commonwealth of Pennsylvania Department of Health DDC Program. Please explain:

Jessica Waller-Administrative Assistant
DDC Program Staff- Name

Jessica Waller
Signature

STATE SEAL:

*Interested parties are encouraged to verify status/standing with entity's home state or FDA if applicable.

Home State (PA) Verifications

Pennsylvania Department of Health

Drug, Device and Cosmetic Program

Public Lookup

Enter the 10-digit Certificate Number or Registrant's Name (or first few letters).

Lookup

Description of Certificate Categories

You may contact our office at (717) 787-4779 if the Certificate Number/Registrant you are researching is not found.

Keystone Industries-Myerstown Mycone Dental Supply 52 W. King Street; Myerstown, PA 17067
Certificate(s): **3000008261** issued: 01/14/2008 expires: 3/31/2025; **8000001932** issued: 01/14/2008 expires: 3/31/2025

The entity noted above holds an active registration and/or license with the Pennsylvania Department of Health Drug, Device, and Cosmetic (DDC) program.

No formal probation, suspension, revocation, or formal disciplinary action has been issued directly by the Pennsylvania Department of Health Drug, Device, and Cosmetic (DDC) program against the aforementioned specific registration and/or license. Contact the DDC program with any further questions at (717) 787-4779 or email: ra-ddc@pa.gov

Back to DD&C Home

Home : Press Releases : Office of the Secretary
Bureau of Community Program Licensure and Certification : Drug, Device and Cosmetic Program : Quality Assurance

Copyright © 2009-2018 Commonwealth of Pennsylvania, All Rights Reserved.

Assembly Version
4.0.18274.4
Database Version
Could not retrieve database version. Check that the database is registered as a Data-tier Application.

Certificate of Liability Insurance

MYCODEN-01 XIRTSHELLY

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 3/1/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER AP Benefit Advisors, LLC - Biddle 575 E Swedesford Rd, Suite 200 Wayne, PA 19087	CONTACT NAME: PHONE (A/C, No, Ext): (484) 427-8900 FAX (A/C, No): E-MAIL ADDRESS: thomas.shelly@assuredpartners.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : National Union Fire Insurance Co Pittsburgh PA	19445
INSURED Mycone Dental Supply Co. Inc. National Keystone Products Co., T&S Dental Plastics Co., Mizzy Syrjet, Dental Resources Co. 480 S. Democrat Road Gibbstown, NJ 08027	INSURER B : Continental Insurance Company	35289
	INSURER C : Great American E&S Insurance Co	37532
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			3960933	3/1/2024	3/1/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ $ $ $ $ $	1,000,000 300,000 25,000 1,000,000 2,000,000 2,000,000
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY SCHEDULED AUTOS X HIRED AUTOS ONLY X NON-OWNED AUTOS ONLY			6586172	3/1/2024	3/1/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $	1,000,000
B	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION $ 0			4031014511	3/1/2024	3/1/2025	EACH OCCURRENCE AGGREGATE	$ $	5,000,000 5,000,000
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N N If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		11957527/11957528	3/1/2024	3/1/2025	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $	1,000,000 1,000,000 1,000,000
C	Excess Liability			XS F171502	3/1/2024	3/1/2025	Per Occur/Aggregate		5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence of Insurance

CERTIFICATE HOLDER	CANCELLATION
Evidence of Insurance	SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS. AUTHORIZED REPRESENTATIVE Brendan Buchness

ACORD 25 (2016/03) © 1988-2015 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

The Cincinnati Insurance Companies
CHANGE RIDER

To be attached to and form a part of Bond No. CBE1045096

Executed by Mycone Dental Supply Co

as Principal and by The Cincinnati Insurance Company as Surety,

in favor of Nevada : State Board of Pharmacy

as Obligee for the term beginning 07/15/2024 .

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to revise the information contained in the original bond as follows:

Address has been changed to 52 West King Street, Myerstown PA 17067

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated. This rider is effective on the 15th day of July , 2024 .

Mycone Dental Supply Co
Principal

Executed by:

By The Cincinnati Insurance Company
Surety

CINCINNATI OHIO

James G Flatt Attorney-in-fact

F-650 (7/18)

THE CINCINNATI INSURANCE COMPANY
THE CINCINNATI CASUALTY COMPANY

Fairfield, Ohio CBE1045096

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That THE CINCINNATI INSURANCE COMPANY and THE CINCINNATI CASUALTY COMPANY, corporations organized under the laws of the State of Ohio, and having their principal offices in the City of Fairfield, Ohio (herein collectively called the "Companies"), do hereby constitute and appoint

James G Flatt

of WAYNE PA
their true and legal Attorney(s)-in-Fact, each in their separate capacity if more than one is named above, to sign, execute, seal and deliver on behalf of the Companies as Surety, any and all bonds, policies, undertakings or other like instruments, as follows:

Twenty-Five Thousand Dollars $ 25,000.00

This appointment is made under and by authority of the following resolutions adopted by the Boards of Directors of The Cincinnati Insurance Company and The Cincinnati Casualty Company, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the President or any Senior Vice President be hereby authorized, and empowered to appoint Attorneys-in-Fact of the Company to execute any and all bonds, policies, undertakings, or other like instruments on behalf of the Corporation, and may authorize any officer or any such Attorney-in-Fact to affix the corporate seal; and may with or without cause modify or revoke any such appointment or authority. Any such writings so executed by such Attorneys-in-Fact shall be binding upon the Company as if they had been duly executed and acknowledged by the regularly elected officers of the Company.

RESOLVED, that the signature of the President or any Senior Vice President and the seal of the Company may be affixed by facsimile on any power of attorney granted, and the signature of the Secretary or Assistant Vice-President and the Seal of the Company may be affixed by facsimile to any certificate of any such power and any such power of certificate bearing such facsimile signature and seal shall be valid and binding on the Company. Any such power so executed and sealed and certified by certificate so executed and sealed shall, with respect to any bond or undertaking to which it is attached, continue to be valid and binding on the Company.

IN WITNESS WHEREOF, the Companies have caused these presents to be sealed with their corporate seals, duly attested by their President or any Senior Vice President this 16th day of March, 2021.

THE CINCINNATI INSURANCE COMPANY
THE CINCINNATI CASUALTY COMPANY

Stephen A Ventre

STATE OF OHIO)SS:
COUNTY OF BUTLER)

On this 16th day of March, 2021 before me came the above-named President or Senior Vice President of The Cincinnati Insurance Company and The Cincinnati Casualty Company, to me personally known to be the officer described herein, and acknowledged that the seals affixed to the preceding instrument are the corporate seals of said Companies and the corporate seals and the signature of the officer were duly affixed and subscribed to said instrument by the authority and direction of said corporations.

Keith Collett, Attorney at Law
Notary Public – State of Ohio
My commission has no expiration date.
Section 147.03 O.R.C.

I, the undersigned Secretary or Assistant Vice-President of The Cincinnati Insurance Company and The Cincinnati Casualty Company, hereby certify that the above is the Original Power of Attorney issued by said Companies, and do hereby further certify that the said Power of Attorney is still in full force and effect.

Given under my hand and seal of said Companies at Fairfield, Ohio, this 16th day of July, 2024

BN-1457 (3/21)

Bond

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. CBE1045096

Application/License No. 000000

Mycone Dental Supply Co, doing or intending to do
Applicant/Principal
business as a pharmaceutical wholesaler, whose address for purposes of service is

480 S Democrat Rd, Gibbstown, NJ 08027-1239, as
Address of Applicant/Principal
PRINCIPAL, and The Cincinnati Insurance Company, a
Surety Company
corporation organized under the laws of the state of Ohio
State of Incorporation
and authorized to transact a general surety business in the State of Nevada, whose address

for purposes of service is

6200 S Gilmore Rd, Fairfield, OH 45014-5141 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ($ 25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on

July 15, 2024 .
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 15th day of July, 20 24.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

James G Flatt, Attorney-In-fact

print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

THE CINCINNATI INSURANCE COMPANY
THE CINCINNATI CASUALTY COMPANY

Fairfield, Ohio CBE1045096

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That THE CINCINNATI INSURANCE COMPANY and THE CINCINNATI CASUALTY COMPANY, corporations organized under the laws of the State of Ohio, and having their principal offices in the City of Fairfield, Ohio (herein collectively called the "Companies"), do hereby constitute and appoint

James G Platt

of WAYNE PA
their true and legal Attorney(s)-in-Fact, each in their separate capacity if more than one is named above, to sign, execute, seal and deliver on behalf of the Companies as Surety, any and all bonds, policies, undertakings or other like instruments, as follows:

Twenty-Five Thousand Dollars $ 25,000.00

This appointment is made under and by authority of the following resolutions adopted by the Boards of Directors of The Cincinnati Insurance Company and The Cincinnati Casualty Company, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the President or any Senior Vice President be hereby authorized, and empowered to appoint Attorneys-in-Fact of the Company to execute any and all bonds, policies, undertakings, or other like instruments on behalf of the Corporation, and may authorize any officer or any such Attorney-in-Fact to affix the corporate seal; and may with or without cause modify or revoke any such appointment or authority. Any such writings so executed by such Attorneys-in-Fact shall be binding upon the Company as if they had been duly executed and acknowledged by the regularly elected officers of the Company.

RESOLVED, that the signature of the President or any Senior Vice President and the seal of the Company may be affixed by facsimile on any power of attorney granted, and the signature of the Secretary or Assistant Vice-President and the Seal of the Company may be affixed by facsimile to any certificate of any such power and any such power of certificate bearing such facsimile signature and seal shall be valid and binding on the Company. Any such power so executed and sealed and certified by certificate so executed and sealed shall, with respect to any bond or undertaking to which it is attached, continue to be valid and binding on the Company.

IN WITNESS WHEREOF, the Companies have caused these presents to be sealed with their corporate seals, duly attested by their President or any Senior Vice President this 16th day of March, 2021.

THE CINCINNATI INSURANCE COMPANY
THE CINCINNATI CASUALTY COMPANY

Stephen A. Jantra

STATE OF OHIO)SS:
COUNTY OF BUTLER)

On this 16th day of March, 2021 before me came the above-named President or Senior Vice President of The Cincinnati Insurance Company and The Cincinnati Casualty Company, to me personally known to be the officer described herein, and acknowledged that the seals affixed to the preceding instrument are the corporate seals of said Companies and the corporate seals and the signature of the officer were duly affixed and subscribed to said instrument by the authority and direction of said corporations.

Keith Collett, Attorney at Law
Notary Public – State of Ohio
My commission has no expiration date.
Section 147.03 O.R.C.

I, the undersigned Secretary or Assistant Vice-President of The Cincinnati Insurance Company and The Cincinnati Casualty Company, hereby certify that the above is the Original Power of Attorney issued by said Companies, and do hereby further certify that the said Power of Attorney is still in full force and effect.

Given under my hand and seal of said Companies at Fairfield, Ohio, this 15th day of July, 2024

BN-1457 (3/21)

The Cincinnati Insurance Companies

CINCIBOND ®

Surety Made Simple ®

Report of Execution

Bond No. CBE1045096

Agency: AP Benefit Advisors, LLC
575 E SWEDESFORD RD STE 200, , WAYNE, PA 19087-1613
Code: 37113

Principal: Mycone Dental Supply Co

Address: 480 S Democrat Rd

City: Gibbstown **State:** NJ **Zip:** 08027-1239

Obligee: Nevada : State Board of Pharmacy

Attn: State Board Of Pharmacy

Address: 431 W Plumb Ln

City: Reno **State:** NV **Zip:** 89509

Bond Amount: $ 25,000.00 **Description:** Pharmaceutical Wholesaler Bond

Effective Date: 07/15/2024 **Expiration Date:** 07/15/2025

Premium: $ 500.00 **Current Term Billing Type:** Agency Billed

*** Total:** $ 500.00

* Includes applicable surcharge and premium taxes:

Surcharge: $ 0.00
Municipal Tax: $ 0.00
County Tax: $ 0.00

Commission Amount: $ 150.00

Commission Rate: 30%

The first annual premium is earned on upon the issuance of this bond.

For Surety Department:

email: commericalsurety@cinfin.com

phone: 1-844-880-BOND

For Direct Billing Questions:

email: cincibill@cinfin.com

phone: 1-877-942-2455

HEADQUARTERS USE
Class Codes: 66 - 579 **Terr Code:** 1000056

BN-1400 (2/19)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Mycone Dental Supply Co., Inc. d/b/a Keystone Industries-Myerstown — MDEG License # (if applicable): N/A

Physical Address: 52 West King Street

City: Myerstown — State: PA — Zip: 17067

Mailing Address (if different from physical address): c/o State License Servicing 1751 State Route 17A, Suite 3

City: Florida — State: NY — Zip: 10921

Telephone: (845) 544-2482 — Website: www.keystoneind.com

Licensing Company Email: KEY@slsny.com

Section 2: Personal Information

First: Debra — Middle: Jean — Last: Tucker-Hansen

Alias(es, nicknames, name changes, etc.): DEB HANSEN

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☐ M ☒ F ☐ X

Mailing Address: c/o State License Servicing 1751 State Route 17A, Suite 3

City: Florida — State: NY — Zip: 10921

Telephone: [redacted] — Email: dhansen@keystoneind.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
George Brown College		2003 - 2005	
Address	**City**	**State**	**Zip**
341 King St E 6th Fl	Toronto	ON	Canada
Diploma/Degree obtained, if any			
Logistics Management Certificate			
School Name		**From - To (MM/YY – MM/YY)**	
Gloucester City Jr./Sr. High School		09/1982 - 06/1986	
Address	**City**	**State**	**Zip**
1300 Market St	Gloucester City	NJ	08030
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2/2007 – Curre	[redacted]	Lebanon	PA	17046
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Keystone Industries			1997 - Present	
Business Address		**City**	**State**	**Zip**
52 West King Street		Myerstown	PA	17067
Phone	**Title**		**Number of Employed Hours**	
(717) 866-7571	Warehouse Manager		~ 57,000 hrs	
Description of Duties				
Responsible for all aspects of warehousing including; receiving, inventory control, returns/credits, storage and distribution. Including pharmaceutical products.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

N/A

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Debra Jean Tucker-Hansen, **certify that as the MDEG Administrator for**

Mycone Dental Supply Co., Inc.,

that I (initial that you have read and meet the following requirements):

1. DH Have a high school diploma or its equivalent;
2. DH Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. DH Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. DH Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Debra Jean Tucker-Hansen
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/24/2024
Date

Board Use Only	Date Received: 8/19/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Mycone Dental Supply Co., Inc. d/b/a Keystone Industries-Myerstown

Pharmacy/Wholesaler License # (if applicable): Applying

Physical Address: 52 West King Street

City: Myerstown State: PA Zip: 17067

Mailing Address (if different from physical address): c/o State License Servicing 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: www.keystoneind.com

Licensing Company Email: KEY@slsny.com

Section 2: Personal Information

First: Debra Middle: Jean Last: Tucker-Hansen

Alias(es, nicknames, name changes, etc.): DEB HANSEN

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]

City: Lebanon State: PA Zip: 17046

Telephone: [redacted] Email: dhansen@keystoneind.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
George Brown College		2003 2005	
Address	City	State	Zip
341 King St E 6th Fl	Toronto	ON	Canada
Diploma/Degree obtained, if any			
Logistics Management Certificate			

School Name		From - To (MM/YY – MM/YY)	
Gloucester City Jr./Sr. High School		09/1982 - 06/1986	
Address	City	State	Zip
1300 Market St	Gloucester City	NJ	08030
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2/2007 - Current	[redacted]	Lebanon	PA	17046
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Keystone Industries			1997 - Present	
Business Address		**City**	**State**	**Zip**
52 West King Street		Myerstown	PA	17067
Phone	**Title**		**Number of Employed Hours**	
(717) 866-7571	Warehouse Manager		~ 57,000 hrs	
Description of Duties				
Responsible for all aspects of warehousing including; receiving, inventory control, returns/credits, storage and distribution. Including pharmaceutical products.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

N/A

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Debra Jean Tucker-Hansen, **certify that as the designated representative for**

Mycone Dental Supply Co., Inc. d/b/a Keystone Industries-Myerstown,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. DH I am at least 21 years of age;
3. DH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Debra Jean Tucker-Hansen
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/24/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Debra Jean Tucker-Hansen

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/24/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Lebanon

I, Debra Jean Tucker-Hansen, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature Debra Jean Tucker-Hansen

7/24/2024

Date

Subscribed and Sworn to before me this 24th day of July.

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
COURTNEY BISH - Notary Public
Lebanon County
My Commission Expires April 15, 2027
Commission Number 1289962

(Seal)

Employee List

Employee Name	Dept.
Alleman, JoAnne	A Shift- Extrusion
Allwein, Margaret	Pk-shear-HS-Lam
Arnick, Michael	Inventory
Artley, Pamela	Prophy
Bainbridge, Angela	Bosworth
Bair, Jaysean	Distribution
Beamesderfer, Tina	Prophy
Behm, Patti	Office
Betz, Jenny	Pk-shear-HS-Lam
Billman, Penny	Prophy
Bish, Courtney	Office
Bollinger, Corey	Warehouse/Receiving
Boyer, Linda	Pk-shear-HS-Lam
Brannen, Judy	B Shift-Mizzy-Prophy
Breneman, Matthew	Distribution
Brown, Clint	Inventory
Buser, Brian	Maintenance
Devitz, Joseph	Bosworth
Dissinger, Doreen	Pk-shear-HS-Lam
Dobi, Lynn	Prophy
Ernfield, Scott	Electrical Assembly
Feliciano, Melanie	A Shift- Extrusion
Fox, Celeste T.	QA
Fox, Kayla	Office
Franco Rosa, Bryan	Distribution
Franzone, Joyce	Bosworth
Gettle, Todd	R&D
Greenly, Tracey	Pk-shear-HS-Lam
Groft, David	B Shift- Pk-Shear-Lam
Gromis, Jennifer	B Shift- Extrusion
Grove, Diana	B Shift- Extrusion
Hank, Jodi	Manufacturing
Hansen, Deb	Distribution
Hansen, Tim	QA
Harris, Dorene	Electrical Assembly
Hartman, Teresa	Prophy
Hassler, Alexander	Distribution
Heist, Corey	Warehouse/Receiving

Employee Name	Dept.
Heist, Stacie	Distribution
Helsel, Cindy	Bosworth
Hernandez, Arleen	A Shift- Extrusion
Hibshman, Nicole	Purchasing
Jones, Donald	A Shift- Extrusion
Jones, Pamela	Pk-shear-HS-Lam
Keller, Daniel	Prophy
Kirby, Maggie	Distribution
Kononchuk, David	B Shift- Extrusion
Koyste, Jeffrey	A Shift- Extrusion
Krall, Denise	Prophy
Kreiser, Crystal	Pk-shear-HS-Lam
Little, James	R&D
Maldonado, Carmen	Distribution
Markel, Dustin	Distribution
Messner, Amanda	B Shift- Lamination
Miller, Christopher	B Shift- Extrusion
Miller, Sarah	QA
Mongkon, Bell	Shop
Nelson, Dave	MGMT
Nicolas Castro, Vasti	Distribution
Peoples, Mario	B Shift- Extrusion
Ramberger, Brian	Maintenance
Rivera, Malik	Pk-shear-HS-Lam
Robinson, Kelly	Pk-shear-HS-Lam
Rohrbach, Carrie	Pk-shear-HS-Lam
Rohrbach, Kathleen	B Shift- Pk-Shear-Lam
Roman, Ismael	Shop
Schaffner, Cathy	Pk-shear-HS-Lam
Schickel, Tim	Pk-shear-HS-Lam
Schneck, Debbie	B Shift- Pk-Shear-Lam
Schwear, Tracey	QA
Shober, Bradley	QA
Smith, Cindy	Pk-shear-HS-Lam
Smith, Nicole	Office
Smith, Vicky	Pk-shear-HS-Lam
Sonnon, Dawn	Distribution
Stegman, Victoria	Distribution

Employee Name	Dept.
Stoner, Malinda	Distribution
Umbenhauer, Jean - PT	Distribution
Velez-Rivera, Wilson	A Shift- Extrusion
Walsh, Thomas	Purchasing
Wehr, Amber	Pk-shear-HS-Lam
Wehr, Brandon	Mizzy
Wehr, Julie	A Shift- Extrusion
Weiant, Gerald	Inventory
Wenrich, John	Manufacturing
Witmer, Lori	B Shift-Mizzy-Prophy
Yeyna, Simon	Pk-shear-HS-Lam
Zombro, Tyler	Maintenance

4Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Mylan Institutional, Inc.

Physical Address: 2898 Manufacturers Rd, Office 116

City: Greensboro State: NC Zip: 27406

Mailing Address (if different from physical address): 3711 Collins Ferry Rd

City: Morgantown State: WV Zip: 26505

Telephone: 815-282-1201 Website: www.viatris.com

Name of Designated Representative (DR): Matthew Dildy

Licensing Company Email: compliance.mylan@gmail.com DR Email: marie.kidder@viatris.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☑ Pharmacies	☑ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☑ Controlled Substances	☐ Repacker
☑ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☑ Others: Opioids	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☑ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

08/13/24
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Mylan Pharmaceuticals Inc.

Address: 2898 Manufacturers Road City: Greensboro State: NC Zip: 27406

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Illinios

Parent Company (if any): Mylan Inc

Corporation/Organization Name: Mylan Institutional, Inc.

Mailing Address: 3711 Collins Ferry Road

City: Morgantown State: WV Zip: 26505

Telephone: 304-554-4758 Email: marie.kidder@viatris.com

Contact Person Name: Marie Kidder

Section 6: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

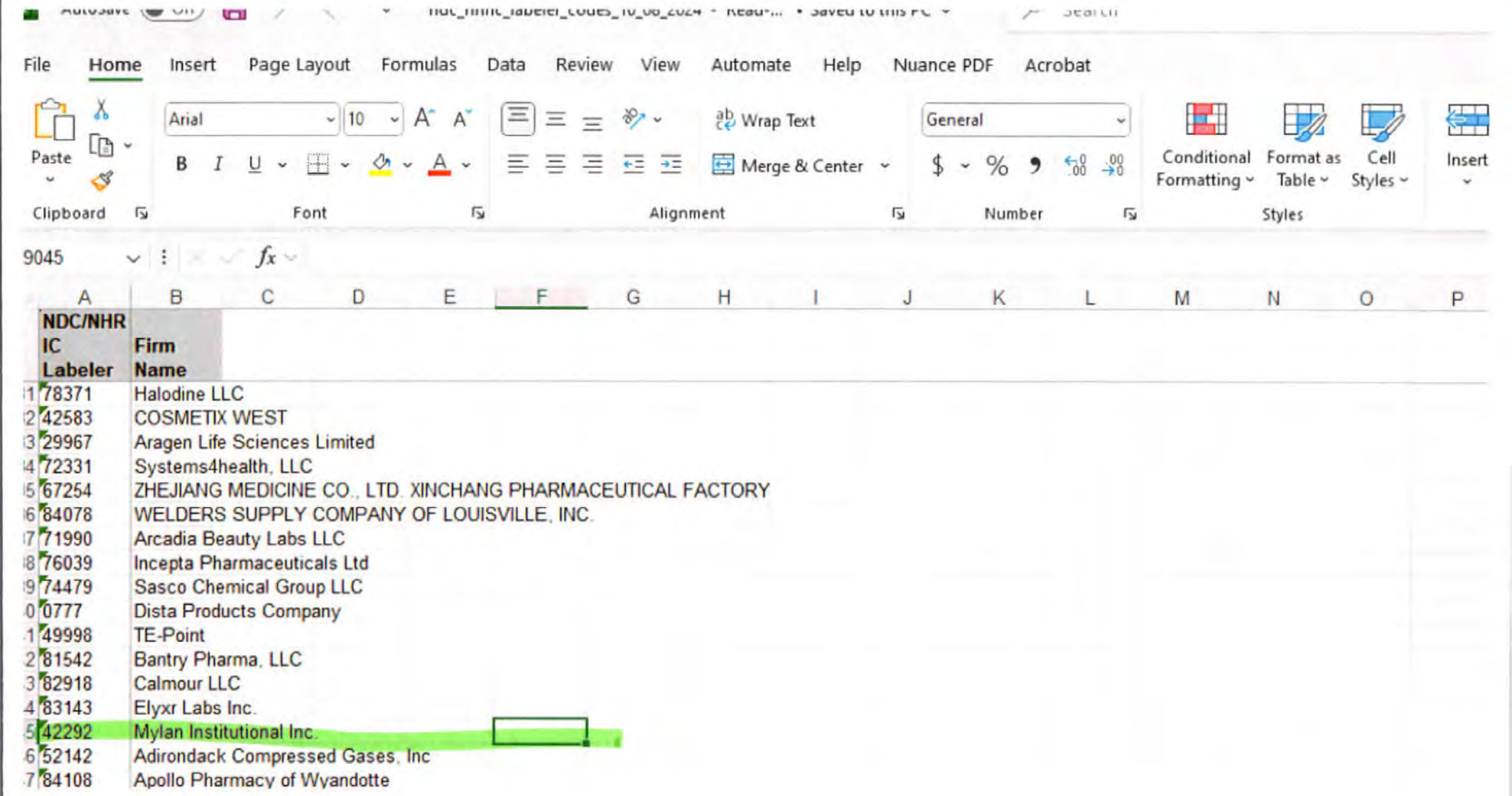
Mylan Institutional Inc.
Facility Name

Bradly M. Zambito
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

08/13/24
Date

Board Use Only	Date Received: 9/18/24	Amount: $1000 ck 13037



File Home Insert Page Layout Formulas Data Review View Automate Help Nuance PDF Acrobat

Paste Clipboard Arial 10 Font Wrap Text Merge & Center Alignment General Number Conditional Formatting Format as Table Cell Styles Styles Insert

9045

	A	B
	NDC/NHRIC Labeler	**Firm Name**
1	78371	Halodine LLC
2	42583	COSMETIX WEST
3	29967	Aragen Life Sciences Limited
4	72331	Systems4health, LLC
5	67254	ZHEJIANG MEDICINE CO., LTD. XINCHANG PHARMACEUTICAL FACTORY
6	84078	WELDERS SUPPLY COMPANY OF LOUISVILLE, INC.
7	71990	Arcadia Beauty Labs LLC
8	76039	Incepta Pharmaceuticals Ltd
9	74479	Sasco Chemical Group LLC
0	0777	Dista Products Company
1	49998	TE-Point
2	81542	Bantry Pharma, LLC
3	82918	Calmour LLC
4	83143	Elyxr Labs Inc.
5	42292	Mylan Institutional Inc.
6	52142	Adirondack Compressed Gases, Inc
7	84108	Apollo Pharmacy of Wyandotte

Mylan Pharmaceuticals Inc.
3711 Collins Ferry Rd.
Morgantown WV 26505

NABP e-Profile ID (If applicable): 1631173

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

Drug Establishments Current Registration Site

New Search (default.cfm)

Search Results for **Mylan Institutional Inc**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Mylan Institutional Inc.	1419886	039615992	LABEL; PACK; RELABEL; REPACK;	1718 Northrock Court, Rockford, Illinois (IL) 61103, United States (USA)	12/31/2024

Showing 1 to 1 of 1 entries
Previous1Next
Data Current through: Wednesday, Nov 1, 2023

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Mylan Institutional Inc. - Contract Manufacturers

CMO Name	CMO Address	FEIN	Alabama	Arizona	Oklahoma
Alcami Corporation	4221 Faber Place Dr., North Charleston, SC 29405	1000110990	Withdrawn	M001578	88-M-6337
Aspen Notre Dame de Bondeville, S.A.S.	1 Rue de L'Abbaye 76960, Notre Dame de Bondeville, Seine Maritime, France	3002808079	N/A - Foreign	N/A - Foreign	
Chemi S.p.A.	Via del Lavoratori, 54 20092 Cinisello Balsamo (MI), Italy	3000326763	N/A - Foreign	N/A - Foreign	
Gland Pharma Limited	Survey No. 143-148, 150 & 151, Near Gandimaisamma Cross Roads, D.P. Pally, Dundigal Gandimaisamma Mandal, Medchal-malkajgiri District, Hyderabad-500043, Telegana India	3002647489	N/A - Foreign	N/A - Foreign	88-M-6477
Intas Pharmaceuticals Ltd.	Plot No 191, 218, 457, 458, Sarkhej Bavla Highway, Matoda Village, Sanand Taluka, Ahmedabad – 382210, Gujarat, India	3003157498	N/A - Foreign	N/A - Foreign	88-M-6202
NerPharMa S.r.L.,	Viale Pasteur 10, 20014 Nerviano (MI) Italy	3004762406	N/A - Foreign	N/A - Foreign	
Mylan Teoranta	Unit 6, Casla Industrial Estate, Co. Galway, Ireland	3002806521	N/A - Foreign	N/A - Foreign	88-M-7015
Mylan Laboratories Limited	No. 284-B/1, Bommasandra Jigani Link Road, Industrial Area, Jigani Hobli, Anekal Taluk, Bengaluru – 560105, India	3007512701	N/A - Foreign	N/A - Foreign	88-M-6998
Mylan Laboratories Limited	Specialty Formulation Facility, No. 284-B/1, Bommasandra Jigani Link Road, Industrial Area, Jigani Hobli, Anekal Taluk, Bengaluru – 560105, India	3007648351	N/A - Foreign	N/A - Foreign	88-M-7021
Mylan Laboratories Limited	Plot No. 14, Sipcot Phase II, Krishnagiri Road, Hosur – 635 109, Tamil Nadu, India	3008255419	N/A - Foreign	N/A - Foreign	88-M-7002
Steriscience Specialties Private Limited	Opp IIM, 154/11 Bilekahalli. Bannergatta Road, Bengaluru, Karnataka – 560076, INDIA	3003813519	N/A - Foreign	N/A - Foreign	
Terumo BCT, Ltd.	Old Belfast Road, Millbrook, Larne, BT40 2SH, United Kingdom	3002545766	N/A - Foreign	N/A - Foreign	
InfoRLife SA	Casai 1, CH-7748 Campasicio, Switzerland	3004537783	N/A - Foreign	N/A - Foreign	88-M-6649
Aphena Pharma Solutions	1920 Fisk Road, Cookeville, Tennessee	3003849479	Pending	N/A - Foreign	
Kavis Pharma LLC	12720 Dairy Ashford,Sugar Land, TX, USA	1610608	196416	M002324	88-M-8318

Mylan Institutional Inc. is a corporation company organized under the laws of the State of Delaware.
Mylan Inc. owns 100% of Mylan Institutional Inc. 1000 Mylan Boulevard, Canonsburg, PA 15317

President **Katelyn Duchardt** 1000 Mylan Boulevard Canonsburg, PA 15317		**Secretary** **Thomas Salus** 1000 Mylan Boulevard Canonsburg, PA 15317
Assistant Secretary **Kevin Macikowski** 1000 Mylan Boulevard Canonsburg, PA 15317	**Vice President** **Michael Rainerman** 1000 Mylan Boulevard Canonsburg, PA 15317 724.514.1852	**Treasurer** **John Miraglia** 1000 Mylan Boulevard Canonsburg, PA 15317

File Number 5221-619-2

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

I, **Alexi Giannoulias,** *Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that*

MYLAN INSTITUTIONAL INC., A DOMESTIC CORPORATION, INCORPORATED UNDER THE LAWS OF THIS STATE ON NOVEMBER 13, 1980, APPEARS TO HAVE COMPLIED WITH ALL THE PROVISIONS OF THE BUSINESS CORPORATION ACT OF THIS STATE, AND AS OF THIS DATE, IS IN GOOD STANDING AS A DOMESTIC CORPORATION IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 31ST *day of* JANUARY *A.D.* 2024 .

Authentication #: 2403102986 verifiable until 01/31/2025
Authenticate at: https://www.ilsos.gov

SECRETARY OF STATE

2024

North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner
Food and Drug Protection Division

LICENSE/CERTIFICATE NO.
1890

NOT TRANSFERABLE
STATUTE GS 81.106.119

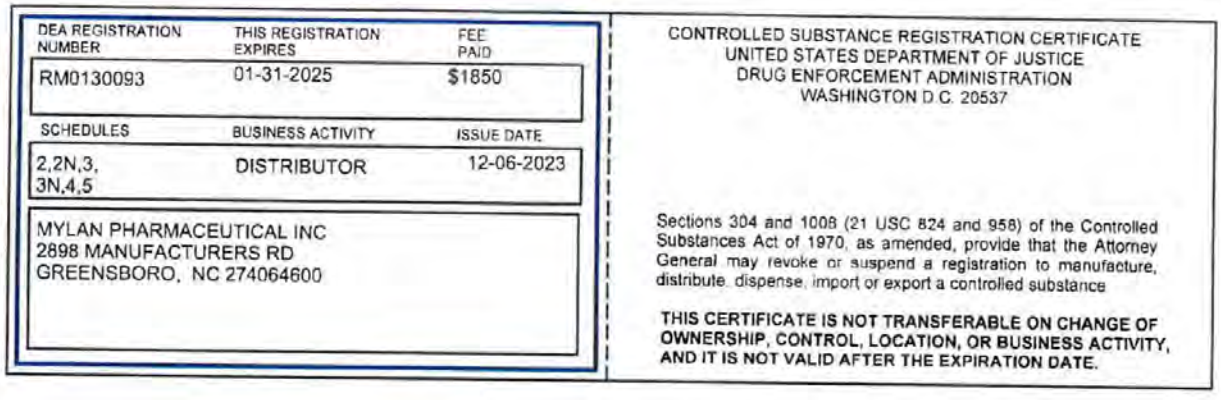
LICENSE/CERTIFICATE: **Virtual Manufacturer**
TYPE
Expiration Date **12/31/2024**

LICENSEE OR CERTIFICATOR
MYLAN INSTITUTIONAL INC.
2898 MANUFACTURERS ROAD OFFICE 116
GREENSBORO NC 27406

LICENSED 2024 NORTH CAROLINA

THIS LICENSE/CERTIFICATE MAY BE SUBJECT TO REVOCATION OR SUSPENSION AS PROVIDED BY LAW

STEVE TROXLER, COMMISSIONER



DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RM0130093	01-31-2025	$1850

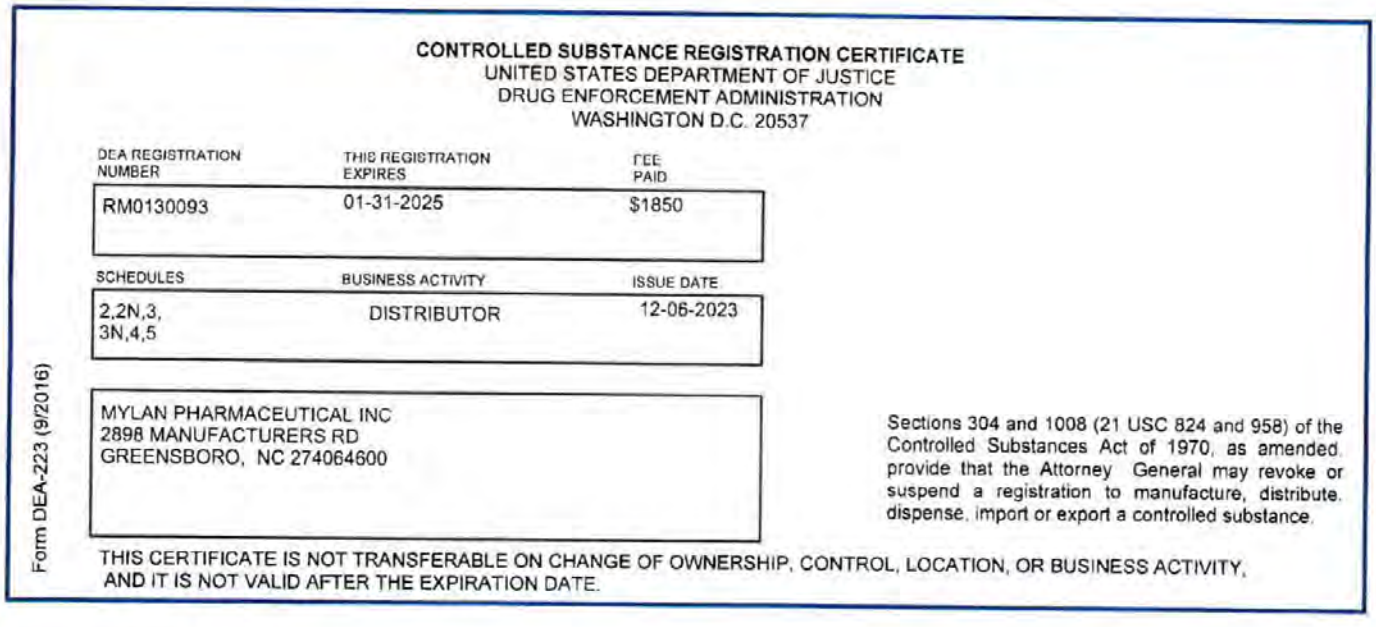
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	12-06-2023

MYLAN PHARMACEUTICAL INC
2898 MANUFACTURERS RD
GREENSBORO, NC 274064600

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.



CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RM0130093	01-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	12-06-2023

MYLAN PHARMACEUTICAL INC
2898 MANUFACTURERS RD
GREENSBORO, NC 274064600

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

ACORD

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
09/22/2022

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Marsh USA Inc.
Six PPG Place, Suite 400
Pittsburgh, PA 15222-5499
(412) 552-5249

CN131854506--GAWUP-22-23

CONTACT NAME: Leslie Kress
PHONE (A/C, No, Ext): 412-552-5249 **FAX (A/C, No):** 412-552-5999
E-MAIL ADDRESS: leslie.a.kress@marsh.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Zurich American Insurance Company	16535
INSURER B : N/A	N/A
INSURER C : N/A	N/A
INSURER D : N/A	N/A
INSURER E : (See Attached)	
INSURER F :	

INSURED
Viatris Inc.
1000 Mylan Boulevard
Canonsburg, PA 15317-8574

COVERAGES **CERTIFICATE NUMBER:** CLE-006596716-24 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			GLO 9300946 21	09/30/2022	09/30/2023	EACH OCCURRENCE	$	2,000,000
	CLAIMS-MADE [X] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	2,000,000
							MED EXP (Any one person)	$	10,000
							PERSONAL & ADV INJURY	$	2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	4,000,000
	POLICY [ ] PRO-JECT [X] LOC						PRODUCTS - COMP/OP AGG	$	N/A
	OTHER:							$	
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$	
	ANY AUTO						BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$	
	DED RETENTION $							$	
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						PER STATUTE / OTH-ER		
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) N / A						E.L. EACH ACCIDENT	$	
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$	
							E.L. DISEASE - POLICY LIMIT	$	
E	Products/Completed Operations			(See Attached)	09/30/2022	09/30/2023	Each Occurrence		See Attached
	Liability - Claims Made						Aggregate		See Attached

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
EVIDENCE OF INSURANCE FOR VAWD ACCREDITED FACILITY (MYLAN PHARMACEUTICALS INC, GREENSBORO, NC)

CERTIFICATE HOLDER

MYLAN INC. & SUBSIDIARIES
1000 MYLAN BOULEVARD
CANONSBURG, PA 15317

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
of Marsh USA Inc.

Marsh USA Inc.

© 1988-2016 ACORD CORPORATION. All rights reserved.

AGENCY CUSTOMER ID: CN131854506
LOC #: Pittsburgh

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Marsh USA Inc.	Viatris Inc. 1000 Mylan Boulevard Canonsburg, PA 15317-8574
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

PRODUCTS/COMPLETED OPERATIONS POLICY COVERAGE - CLAIMS MADE

Mylan Inc. has product liability coverage limits of $50,000,000 each occurrence / $50,000,000 aggregate underlying of the insurance carrier below through its insurance captive, American Triumvirate Insurance Company (ATIC).

ATIC provides primary and non-contributory product liability insurance coverage to its certificate holders.
The products/completed operations liability policy coverage form provides additional insured status for vendors, subject to the terms and conditions outlined therein.
Certificate holder is included as an additional insured with respect to the above captioned product liability policy where required by written contract, subject to the terms and conditions of the policy.

PRODUCTS/COMPLETED OPERATIONS
Insurer Affording Coverage: American Triumvirate Insurance Company*
Policy Number: 2023-007-PROD
Effective Date: 9/30/2022
Expiration Date: 9/30/2023
Limits: $50,000,000 SIR each occurrence / $50,000,000 SIR aggregate

Insurer Affording Coverage: RSG Underwriting Managers, LLC on behalf of Underwriters at Lloyds, London
Policy Number: LSR-PCO-00456-22
Effective Date:9/30/2022
Expiration Date: 9/30/2023
Limits: $10,000,000 xs $50,000,000 SIR

*The American Triumvirate Insurance Company (ATIC) policy is a direct placement. Willis Management (Vermont) Ltd. manages the captive insurer indicated here.

© 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

VERIFICATION CERTIFICATE FOR INDEFINITE TERM SURETY BOND

THIS IS TO CERTIFY that Bond Number 019039472 issued by Liberty Mutual Insurance Company, as Surety, dated the 2nd day of February, 2012, in the amount of One Hundred Thousand & 00/100 ($ 100,000.00), on behalf of Mylan Institutional Inc., as Principal, and in favor of Maryland Board of Pharmacy, as Obligee, covers a term which began on the 2nd day of February, 2012, and ends only with the cancellation of said bond or other legal termination thereof; and that the said bond remains in effect, subject to all its agreements, conditions and limitations.

Signed, sealed and dated this 21st day of December, 2021.

Liberty Mutual Insurance Company
Surety

By: Karen L Roider
Karen L. Roider Attorney-in-Fact



Liberty Mutual. SURETY

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8204866

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint,

Karen L. Roider

all of the city of St. Louis, state of Missouri each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 15th day of February, 2021.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 15th day of February, 2021, before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 21st day of December, 2021

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Liberty Mutual.
SURETY

As part of its business continuity efforts during the pendency of the COVID-19 pandemic, Liberty Mutual Insurance Company ("LMIC") on behalf of itself and the companies listed below has authorized its Attorneys-in-Fact to affix its corporate seal for surety obligations in a digital format in lieu of its traditional raised seal to any bond issued on its behalf by any such Attorney-in-Fact:

Liberty Mutual Insurance Company
Liberty Mutual Fire Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company
Safeco Insurance Company of America
American States Insurance Company

LMIC agrees and affirms on behalf of itself and the other companies listed herein, that the digital corporate seal referenced above has the same binding effect when affixed to a bond or a Power of Attorney document as if it were a raised corporate seal.

Effective this 23rd day of March, 2020.

By: _____
Renee C. Llewellyn, Assistant Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Mylan Institutional Inc

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 2898 Manufacturers Rd, Office 116

City Greensboro State NC Zip 27406

Mailing Address (if different from physical address) 3711 Collins Ferry Rd, Attn: Marie Kidder

City Morgantown State WV Zip 26505

Telephone 336-291-1400 Website www.viatris.com

Licensing Company Email compliance.mylan@gmail.com

Section 2: Personal Information

First Matthew Middle Lee Last Dildy

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Morgantown State WV Zip 26505

Telephone [redacted] Email marie.kidder@viatris.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of North Carolina at Greensboro		08/13 - 08/15	
Address	**City**	**State**	**Zip**
1400 Spring Garden St.	Greensboro	NC	27412
Diploma/Degree obtained, if any			
Graduate Certificate - Supply Chain, Logistics and Transportation Management			

School Name		From - To (MM/YY – MM/YY)	
University of North Carolina at Wilmington		08/04 - 08/10	
Address	**City**	**State**	**Zip**
601 College Rd	Wilmington	NC	28403
Diploma/Degree obtained, if any			
Business Administration / Operations Management			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/13 - Present	[redacted]	Greensboro	NC	27410
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Mylan Institutional, Inc.			10/2021 - Present	
Business Address		**City**	**State**	**Zip**
2898 Manufacturers Rd		Greensboro	NC	27406
Phone	**Title**		**Number of Employed Hours**	
815-282-1201	Senior Manager, Distribution		40 KT	

Description of Duties
Support the NA Commercial Supply Chain Organization. Oversee and support monthly financial reporting and yearly budgeting processes related to NA Logistics OPEX ($41.8M). Oversee NA transportation provider selection. Facilitate vendor agreements. Manage compliance as it relates to Logistics performance levels. Plan, manage and direct the daily operations as it relates to Transportation management and logistics execution. Oversee our site PTP processes. Develop and manage KPIs and supporting analytical capabilities. Drive business intelligence from facts and trends presented.

Business Name			From - To (MM/YY – MM/YY)	
Mylan Institutional, Inc.			10/2018 - 03/2021	
Business Address		**City**	**State**	**Zip**
2898 Manufacturers Rd		Greensboro	NC	27406
Phone	**Title**		**Number of Employed Hours**	
815-282-1201	Manager, Distribution Analytics and Project Management		40 KT	

Description of Duties
Serve as project manager for key strategic business initiatives including regulatory, technology and product acquisition activities, manage all projects associated with new business integrations and represent. Logistics within broader Mylan Revenue Cycle functions. Project responsibilities include monitoring, analyzing, and reporting on program tasks and milestones as they are related to North America Logistics. Play a key role in the planning and preparation of the site capital budget and $19M operational budget.

Business Name			From - To (MM/YY – MM/YY)	
Mylan Institutional, Inc.			07/2017 - 10/2018	
Business Address		**City**	**State**	**Zip**
2898 Manufacturers Rd		Greensboro	NC	27406
Phone	**Title**		**Number of Employed Hours**	
815-282-1201	Regulatory, Compliance and Inventory Lead Specialist		40 KT	

Description of Duties
Serve as the Foreign Trade Zone (FTZ) site administrator. Create and assist with the submission of government reporting. Create and assist with the submission of DEA Import/Export applications and permits as well as monthly state reporting. Maintain inventory records for all Class II controlled substances. Directly support all inventory control functions and programs including cycle counting, investigations, discrepancies, continuous improvement deployment and supply chain planning and execution.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Matthew Gilly
Original Signature (electronic, copies or stamps not accepted)

08-15-2024
Date

I, Matthew Dildy, **certify that as the designated representative for**

Mylan Institutional Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MD I am at least 21 years of age;
3. MD I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MD I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MD I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MD I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MD I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Matthew Dildy

Print Name (First, Last)

Matthew Dildy

Original Signature (electronic, copies or stamps not accepted)

04-15-2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Matthew Dildy

Print Name (First, Last)

Matthew Dildy

Original Signature (electronic, copies or stamps not accepted)

08-15-2024

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Guilford

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Matthew Dildy

Original Signature

08-15-2024

Date

Subscribed and Sworn to before me this 15 day of August 2024

Julie O. Morgan

Notary Public Signature

My commission expires 04-04-2028

JULIE O MORGAN Notary Public Guilford County, NC (Seal)

Maria Herrera

From: compliance.mylan@gmail.com
Sent: Thursday, October 3, 2024 12:02 PM
To: Maria Herrera
Subject: RE: Nevada Out-of-State Wholesaler Application-Mylan Institutional, Inc.
Attachments: 2024 DEA Distributor Reg RM0130093.pdf; MYL-MII-COGS.pdf

Categories: Already printed

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Hello Maria,

Please attached for the requested information and responses below in blue.

Kind Regards,

Mylan Compliance Team

From: Maria Herrera <m.herrera@pharmacy.nv.gov>
Sent: Wednesday, October 2, 2024 7:19 PM
To: Compliance at Mylan <compliance.mylan@gmail.com>
Subject: Nevada Out-of-State Wholesaler Application-Mylan Institutional, Inc.

The Nevada State Board of Pharmacy received an Out-of-State Wholesaler application from Mylan Institutional, Inc. The application is incomplete due to the following missing item(s).

- Certificate of Corporate Status or Certificate of Good Standing obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the **last 12 months**.
- Copy of the current DEA -3PL DEA License attached
- The full list of employees in the facility is required Pursuant to **NRS 639.500 (2)** – This is a Virtual Manufacturer, the only employee is Matthew Lee Dildy (Designated Representative)

North Carolina Department of Agriculture
and Consumer Services
Food and Drug Protection Division

Inspection Report

Mylan Institutional, Inc.(Virt)
2898 Manufacturers Road
Greensboro, NC 27406
(336) 291-1400

Inspected 06/20/2024
By: Ed Lukeman, Drug Regulatory Specialist

Steven W. Troxler
Commissioner

North Carolina Department of Agriculture and Consumer Services
Food and Drug Protection Division

Christina L. Waggett
Assistant Commissioner
for Consumer Protection

Anita MacMullan
Director

Inspection Report

Mylan Institutional, Inc. (Virt)
2898 Manufacturers Road
Greensboro, NC 27406
(336) 291-1400

Inspected 06/20/2024
By: Ed Lukeman

History of Business

Mylan Pharmaceuticals, a subsidiary of Mylan Inc., was incorporated in West Virginia in 1961 and began as a private label manufacturer. In 1965, Mylan began manufacturing generic drug products under its own label. The Greensboro location, the only national distribution center for Mylan, began operations in June 1988. Operations were moved to the current facility in 1998, which was expanded in 2006 and again in 2012. In 2020, Mylan merged with Upjohn to form a new company, Viatris; at the time of this inspection, transition into the new corporate entity was almost complete.

Corporate Address

Mylan Institutional, NC.
1718 Northrock Court
Rockford, IL 61103
(724) 514-1852

Corporate Officers

Katelyn Duchardt	President
Michael Rainerman	Vice-President
John Miraglia	Treasurer
Thomas Salus	Secretary
Kevin Macikowski	Assistant Secretary

Person(s) Interviewed and Individual Responsibilities

Credentials were presented to, and Notice of Inspection issued to Mr. Matthew Dildy, Senior Manager, Distribution Services. He and Mr. Bob Teper, Director of Distribution Operations, Ms. Janet Kinsley, Director of Quality, Compliance, Ms. Elizabeth Joyce, Manager of Regulatory Compliance/Inventory Control, accompanied me throughout the visual inspection of the facility, and arranged for collection of written procedures and all answered questions and provided information regarding operations.

Background

This visit was an initial inspection of this virtual manufacturer. The purpose of this inspection was to verify compliance relative to NCGS §106 Article 12A (Wholesale Prescription Drug Distributors). Mylan maintains an active Third-party Logistics Provider license #094-372 in good standing with NCDA&CS at this facility. And was issued the Virtual Manufacturer license number 092-1890.

There were no objectionable conditions noted during the previous inspection conducted by NCDA&CS on 10/17/2023, and an observation sheet was not issued.

Operations

This facility distributes generic prescription drug products and biosimilars manufactured by Mylan Pharmaceuticals and affiliated manufacturers: Mylan Institutional, Mylan Specialty, Mylan Respiratory, Viatris Specialty, and Greenstone; Viatris Specialty and Greenstone are virtual manufacturers with corporate offices located at this facility. Manufacturing firm(s) not associated with Mylan are contracted for some product(s). Currently, the majority of products are oral solid dose (OSD).

The warehouse currently consists of approximately 485,000 square feet of storage space. It was expanded in 2006 by the addition of 156,177 square feet of space, including 31,168 square feet of mezzanine area, and again in 2012 by the addition of 162,000 square feet of space. As a result of the expansion, the warehouse is physically separated into three sections by firewalls. In 2023, the security cage previously used for storage of schedule III – V controlled substances was decommissioned to allow for storage of non-controlled drug products. All schedule III – V controlled substances are being stored in the vault, along with schedule II controlled substances.

The original warehouse area, known as Phase I, contains two walk-in refrigerated storage areas of approximately 15,000 square feet each. This section of the facility contains the shipping and receiving area for all controlled substances, a vault for the storage of schedule II - V controlled substances, and a Free Trade Zone for export products; a segregated and secured area for returned products awaiting disposition and damaged or outdated products awaiting destruction by a contract service provider is also located in Phase I. The second warehouse expansion, known as Phase II, is primarily used for the storage of products supplied by Mylan divisions, order fulfillment, and a shipping area and for outbound shipments. The last expansion, known as Phase III, is used for receiving inbound deliveries, and for bulk storage of products and some order fulfillment.

The entire warehouse is environmentally controlled, with temperature and relative humidity probes placed at strategic locations; data is downloaded and electronically stored at routine intervals. Personnel are notified of any temperature or humidity excursions outside established parameters.

The virtual manufacturer storage and quarantine area will be housed inside of office #116. A datalogger will be maintained to monitor/record storage conditions. This was necessary for regulatory reasons and probably will never be utilized. It shares the same security measures as the rest of the facility. Mylan Institutional, Inc. will be contractions third party manufacturers which have the required equipment necessary to comply with good manufacturing practices to produce its products. Accordingly, Mylan will never actually physically manufacture or distribute any legend or controlled substance product. Also, all distribution of its products to wholesalers, hospitals, pharmacies, and community pharmacies will be conducted by a third party logistic provider.

The facility is surrounded by chain-link fencing and access to the property is controlled by security personnel on-site 24/7. Access to all areas of the warehouse is limited by card-swipe entry. Security cameras are used throughout the facility. Generators are available for use during a loss of power, and two compressors, used in an alternating method, are used for maintaining temperature in the refrigerated storage areas.

Products are inspected upon receipt, and bar-code scanned for entry into the ERP computer inventory system. Products are scanned again when pulled to fill orders, providing verification of correct item, quantity, location, and a "real-time" inventory count. Cycle counts of non-controlled substances are performed daily, the drug vault and cage are inventoried daily, and full physical inventories of controlled substances are performed quarterly with the DEA-required biennial inventory every year. All products are cycle counted four times per year regardless of volume and value. Quality Control is responsible for product status in the inventory system (Hold, Unrestricted, etc.), and Inventory Control can adjust product counts. Product rotation is at the discretion of the client, but is typically FEFO (first expired, first out); item selection for order fulfillment is controlled by the ERP system, which automatically blocks inventory items with less than six months of shelf life.

Observations

There were no significant objectionable conditions noted during this inspection, and an observation sheet was not issued

Compliance

This facility will be re-inspected on a routine annual or as-needed basis.

Attachments

Notice of Inspection

4Z

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Sintetica US LLC

Physical Address: 301 Carnegie Center, Suite 304

City: Princeton State: NJ Zip: 08540

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 484-354-5700 Website: www.sintetica.com

Name of Designated Representative (DR): Zeel Shah

Licensing Company Email: compliance.sintetica@gmail.com DR Email: compliance.sintetica@gmail.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Injectables, Hospital and Clinic products	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Sintetica SA
Address: Via Penate 5 6850 Mendrisio Switzerland City: _____ State: _____ Zip: _____

Name: Eversana Life Science Services
Address: 4580 Mendenhall Road City: Memphis State: TN Zip: 38141

Name: MSN Laboratories Private Limited.
Address: Formulation Division, Unit - II, City: Ranga Reddy Dist State: India Zip: N/A

Name: Hainan Poly Pharm. Co., Ltd. Guilinyang Economic
Address: Development Area Meilan District, City: Haikou Hainan State: China Zip: N/A

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any): _____
Corporation Name: _____
Mailing Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____
Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): Sintetica Holdings US Inc.
Corporation/Organization Name: Sintetica US LLC
Mailing Address: 301 Carnegie Center
City: Princeton State: NJ Zip: 08540
Telephone: 484-354-5700 Email: compliance.sintetica@gmail.com
Contact Person Name: Francis William Mullery

Section 6: Partnership

Partnership Name: N/A
Mailing Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____
Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: N/A
Business Name: _____
Business Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner **owning more than 10% of the business stocks/shares**. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Sintetica US LLC

Facility Name

Zeel Shah

Print Name of Authorized Person Submitting Application

ZShah

Original signature of Authorized Person (copies or stamps not accepted)

08/05/2024

Date

Board Use Only	Date Received: 8/9/24	Amount: $1000 ck 12967 ✓

National Drug Code Directory

Current through February 20, 2024

You have searched Finished drug products

Search Results: *'sintetica'*

Back to Search Page () | Search Again ()

CSV Excel

Display 50 records per page

Search for text in the table:

Labeler Code:83090

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class
ARSENIC TRIOXIDE	83090-009-01	1 mg/mL	INJECTION, SOLUTION	INTRAVENOUS	ANDA217413	Sintetica US LLC	83090-009	arsenic trioxide	ARSENIC TRIOXIDE	HUMAN PRESCRIPTION DRUG	11/09/2023	N/A	ANDA	1 VIAL, SINGLE-DOSE in 1 CARTON (83090-009-01) / 10 mL in 1 VIAL, SINGLE-DOSE (83090-009-05)	N/A
ARSENIC TRIOXIDE	83090-009-10	1 mg/mL	INJECTION, SOLUTION	INTRAVENOUS	ANDA217413	Sintetica US LLC	83090-009	arsenic trioxide	ARSENIC TRIOXIDE	HUMAN PRESCRIPTION DRUG	11/09/2023	N/A	ANDA	10 VIAL, SINGLE-DOSE in 1 CARTON (83090-009-10) / 10 mL in 1 VIAL, SINGLE-DOSE (83090-009-05)	N/A
ARSENIC TRIOXIDE	83090-010-01	2 mg/mL	INJECTION, SOLUTION	INTRAVENOUS	ANDA217413	Sintetica US LLC	83090-010	arsenic trioxide	ARSENIC TRIOXIDE	HUMAN PRESCRIPTION DRUG	11/09/2023	N/A	ANDA	1 VIAL, SINGLE-DOSE in 1 CARTON (83090-010-01) / 6 mL in 1 VIAL, SINGLE-DOSE (83090-010-05)	N/A
ARSENIC TRIOXIDE	83090-010-10	2 mg/mL	INJECTION, SOLUTION	INTRAVENOUS	ANDA217413	Sintetica US LLC	83090-010	arsenic trioxide	ARSENIC TRIOXIDE	HUMAN PRESCRIPTION DRUG	11/09/2023	N/A	ANDA	10 VIAL, SINGLE-DOSE in 1 CARTON (83090-010-10) / 6 mL in 1 VIAL, SINGLE-DOSE (83090-010-05)	N/A
Bortezomib	83090-008-01	3.5 mg/3.5mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS; SUBCUTANEOUS	ANDA209622	Sintetica US LLC	83090-008	Bortezomib	BORTEZOMIB	HUMAN PRESCRIPTION DRUG	07/15/2023	N/A	ANDA	1 VIAL, SINGLE-DOSE in 1 CARTON (83090-008-01) / 3.5 mL in 1 VIAL, SINGLE-DOSE	Proteasome Inhibitor [EPC], Proteasome Inhibitors [MoA]
daptomycin	83090-011-01	500 mg/20mL	INJECTION, POWDER, LYOPHILIZED, FOR SUSPENSION	INTRAVENOUS	ANDA215890	Sintetica US LLC	83090-011	daptomycin	DAPTOMYCIN	HUMAN PRESCRIPTION DRUG	11/05/2023	N/A	ANDA	1 VIAL, SINGLE-DOSE in 1 CARTON (83090-011-01) / 10 mL in 1 VIAL, SINGLE-DOSE	Lipopeptide Antibacterial [EPC], Lipopeptides [CS]
NA	68055-641-10	10 mg/mL	INJECTION, SOLUTION	INFILTRATION	ANDA214267	SINTETICA SA	68055-641	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE ANHYDROUS	HUMAN PRESCRIPTION DRUG	09/19/2022	N/A	ANDA	10 AMPULE in 1 CARTON (68055-641-10) / 2 mL in 1 AMPULE (68055-641-01)	Amide Local Anesthetic [EPC], Amides [CS], Antiarrhythmic [EPC], Local Anesthesia [PE]
NA	68055-642-10	10 mg/mL	INJECTION, SOLUTION	INFILTRATION	ANDA214267	SINTETICA SA	68055-642	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE ANHYDROUS	HUMAN PRESCRIPTION DRUG	09/19/2022	N/A	ANDA	10 AMPULE in 1 CARTON (68055-642-10) / 5 mL in 1 AMPULE (68055-642-01)	Amide Local Anesthetic [EPC], Amides [CS], Antiarrhythmic [EPC], Local Anesthesia [PE]
NA	68055-643-10	10 mg/mL	INJECTION, SOLUTION	INFILTRATION	ANDA214267	SINTETICA SA	68055-643	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE ANHYDROUS	HUMAN PRESCRIPTION DRUG	09/19/2022	N/A	ANDA	10 AMPULE in 1 CARTON (68055-643-10) / 10 mL in 1 AMPULE (68055-643-01)	Amide Local Anesthetic [EPC], Amides [CS], Antiarrhythmic [EPC], Local Anesthesia [PE]

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class
NA	68055-645-10	20 mg/mL	INJECTION, SOLUTION	INFILTRATION	ANDA214267	SINTETICA SA	68055-645	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE ANHYDROUS	HUMAN PRESCRIPTION DRUG	09/19/2022	N/A	ANDA	10 AMPULE in 1 CARTON (68055-645-10) / 2 mL in 1 AMPULE (68055-645-01)	Amide Local Anesthetic [EPC], Amides [CS], Antiarrhythmic [EPC], Local Anesthesia [PE]
NA	68055-646-10	20 mg/mL	INJECTION, SOLUTION	INFILTRATION	ANDA214267	SINTETICA SA	68055-646	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE ANHYDROUS	HUMAN PRESCRIPTION DRUG	09/19/2022	N/A	ANDA	10 AMPULE in 1 CARTON (68055-646-10) / 5 mL in 1 AMPULE (68055-646-01)	Amide Local Anesthetic [EPC], Amides [CS], Antiarrhythmic [EPC], Local Anesthesia [PE]
NA	68055-647-10	20 mg/mL	INJECTION, SOLUTION	INFILTRATION	ANDA214267	SINTETICA SA	68055-647	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE ANHYDROUS	HUMAN PRESCRIPTION DRUG	09/19/2022	N/A	ANDA	10 AMPULE in 1 CARTON (68055-647-10) / 10 mL in 1 AMPULE (68055-647-01)	Amide Local Anesthetic [EPC], Amides [CS], Antiarrhythmic [EPC], Local Anesthesia [PE]
NA	68055-649-10	40 mg/mL	INJECTION, SOLUTION	RETROBULBAR	ANDA214269	SINTETICA SA	68055-649	Lidocaine Hydrochloride	LIDOCAINE HYDROCHLORIDE ANHYDROUS	HUMAN PRESCRIPTION DRUG	05/05/2022	N/A	ANDA	10 AMPULE in 1 CARTON (68055-649-10) / 5 mL in 1 AMPULE (68055-649-01)	Amide Local Anesthetic [EPC], Amides [CS], Antiarrhythmic [EPC], Local Anesthesia [PE]
NA	83090-007-10	40 mg/mL	INJECTION, SOLUTION	RETROBULBAR	ANDA214269	Sintetica US LLC	83090-007	Lidocaine Hydrochloride	LIDOCAINE HYDROCHLORIDE ANHYDROUS	HUMAN PRESCRIPTION DRUG	11/15/2022	N/A	ANDA	10 AMPULE in 1 CARTON (83090-007-10) / 5 mL in 1 AMPULE (83090-007-01)	Amide Local Anesthetic [EPC], Amides [CS], Antiarrhythmic [EPC], Local Anesthesia [PE]
NA	83090-001-10	10 mg/mL	INJECTION, SOLUTION	INFILTRATION	ANDA214267	Sintetica US LLC	83090-001	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE ANHYDROUS	HUMAN PRESCRIPTION DRUG	11/15/2022	N/A	ANDA	10 AMPULE in 1 CARTON (83090-001-10) / 2 mL in 1 AMPULE (83090-001-01)	Amide Local Anesthetic [EPC], Amides [CS], Antiarrhythmic [EPC], Local Anesthesia [PE]
NA	83090-002-10	10 mg/mL	INJECTION, SOLUTION	INFILTRATION	ANDA214267	Sintetica US LLC	83090-002	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE ANHYDROUS	HUMAN PRESCRIPTION DRUG	11/15/2022	N/A	ANDA	10 AMPULE in 1 CARTON (83090-002-10) / 5 mL in 1 AMPULE (83090-002-01)	Amide Local Anesthetic [EPC], Amides [CS], Antiarrhythmic [EPC], Local Anesthesia [PE]
NA	83090-003-10	10 mg/mL	INJECTION, SOLUTION	INFILTRATION	ANDA214267	Sintetica US LLC	83090-003	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE ANHYDROUS	HUMAN PRESCRIPTION DRUG	11/15/2022	N/A	ANDA	10 AMPULE in 1 CARTON (83090-003-10) / 10 mL in 1 AMPULE (83090-003-01)	Amide Local Anesthetic [EPC], Amides [CS], Antiarrhythmic [EPC], Local Anesthesia [PE]
NA	83090-004-10	20 mg/mL	INJECTION, SOLUTION	INFILTRATION	ANDA214267	Sintetica US LLC	83090-004	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE ANHYDROUS	HUMAN PRESCRIPTION DRUG	11/15/2022	N/A	ANDA	10 AMPULE in 1 CARTON (83090-004-10) / 2 mL in 1 AMPULE (83090-004-01)	Amide Local Anesthetic [EPC], Amides [CS], Antiarrhythmic [EPC], Local Anesthesia [PE]
NA	83090-005-10	20 mg/mL	INJECTION, SOLUTION	INFILTRATION	ANDA214267	Sintetica US LLC	83090-005	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE ANHYDROUS	HUMAN PRESCRIPTION DRUG	11/15/2022	N/A	ANDA	10 AMPULE in 1 CARTON (83090-005-10) / 5 mL in 1 AMPULE (83090-005-01)	Amide Local Anesthetic [EPC], Amides [CS], Antiarrhythmic [EPC], Local Anesthesia [PE]
NA	83090-006-10	20 mg/mL	INJECTION, SOLUTION	INFILTRATION	ANDA214267	Sintetica US LLC	83090-006	LIDOCAINE HYDROCHLORIDE	LIDOCAINE HYDROCHLORIDE ANHYDROUS	HUMAN PRESCRIPTION DRUG	11/15/2022	N/A	ANDA	10 AMPULE in 1 CARTON (83090-006-10) / 10 mL in 1 AMPULE (83090-006-01)	Amide Local Anesthetic [EPC], Amides [CS], Antiarrhythmic [EPC], Local Anesthesia [PE]

Showing 1 to 20 of 20 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Sintetica®
Improving therapies

Sintetica US LLC Owner and Officer List

List of Current Officer:

- Full Name: Francis William Mullery
- Title/Position: President, Sintetica US
- [redacted]

Sintetica Corporate Structure

Sintetica US LLC is owned by Sintetica Holdings US Inc (100%).

Sintetica SA owns Sintetica Holdings US Inc and is Sintetica US Grandparent Company

Sintetica Holdings US Inc. Address: 301 Carnegie Center Princeton, NJ 08540

Sintetica Holdings Officers and Board Members:

- Board Members
  - Hubert Puech d'Alissac - CEO
  - Luca Casella - CFO
  - Sameer Agarwal - CCO
  - Mirco Montella - Deputy Commercial Officer and Chief Innovation Officer
- Officer
  - Frank Mullery - President

Formation of US Subsidiaries

- Form US holding company as a Delaware corporation and form US operational company as a Delaware limited liability company.
- Sintetica Holdings US Inc. will file a US C corporation tax return and act as a "blocker" so that Sintetica S.A. is not required to file a US tax return and pay US tax.
- Dividend distributions from Sintetica Holdings US Inc. will be subject to US tax at a reduced withholding rate of 5% (as compared to the default 30% rate) under the US-Switzerland Tax Treaty.
- Sintetica US LLC will be disregarded for US tax purposes. Its operations will be reported on Sintetica Holdings US Inc.'s tax return.
- Operational licenses will be obtained for Sintetica US LLC rather than Sintetica Holdings US Inc.



Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SINTETICA US LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINETEENTH DAY OF APRIL, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "SINTETICA US LLC" WAS FORMED ON THE FOURTEENTH DAY OF JULY, A.D. 2022.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.





6913503 8300

SR# 20241527034

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203289486

Date: 04-19-24

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0751227

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 – "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: [X] manufacturer [X] wholesaler which conducts business at the following locations in this State:

301 CARNEGIE CTR, STE 304 PRINCETON, NJ 08540-

Reg. No.
5006257

SINTETICA US, LLC
301 CARNEGIE CTR, STE 304
PRINCETON, NJ 08540-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2025

Establishment Copy

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 8/6/2024

Registration Number: 5006257 **Registered as:** Manufacturer and Wholesale
Name: SINTETICA US, LLC
DBA:
Address: 301 CARNEGIE CTR, STE 304, PRINCETON, NJ 08540
Original Issue Date: 02/01/2023 **Expiration Date:** 01/31/2025
Current Issue Date: 01/24/2024
Disciplines: No

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0205333	08-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	08-09-2024

EVERSANA LIFE SCIENCE SERVICES, LLC
4580 S MENDENHALL RD
MEMPHIS, TN 381416700

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0205333	08-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	08-09-2024

EVERSANA LIFE SCIENCE SERVICES, LLC
4580 S MENDENHALL RD
MEMPHIS, TN 381416700

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0205333	08-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	08-09-2024

EVERSANA LIFE SCIENCE SERVICES, LLC
4580 S MENDENHALL RD
MEMPHIS, TN 381416700

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 810018499

Application/License No. _____

SINTETICA US LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 301 CARNEGIE CENTER, Princeton, NJ, 08540 (Address of Applicant/Principal), as PRINCIPAL, and Atlantic Specialty Insurance Company (Surety Company), a corporation organized under the laws of the state of New York (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One State Street Plaza, Floor 31 NEW YORK NY 10004 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on Jun 13, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 18th day of June, 20 24.

APPLICANT/PRINCIPAL

SINTETICA US LLC

Authorized Representative

SURETY COMPANY

Atlantic Specialty Insurance Company

Surety Company's Representative

John D. Weisbrot, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

AMY MOSHO
Notary Public, State of New Jersey
My Commission Expires Feb 7, 2027

Countersigned by:

Nevada Resident Agent

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

Posted February 20, 2020

intact INSURANCE

Power of Attorney

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **John D. Weisbrot, Steven M. Varga, Melissa L. McDade**, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this twenty-seventh day of April, 2020.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Paul J. Brehm, Senior Vice President

STATE OF MINNESOTA
HENNEPIN COUNTY

On this twenty-seventh day of April, 2020, before me personally came Paul J. Brehm, Senior Vice President of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and he acknowledged the execution of the same, and being by me duly sworn, that he is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON DWAN NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2025

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 18th day of June, 2024.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

This Power of Attorney expires
January 31, 2025

_____
Kara Barrow, Secretary

Please direct bond verifications to surety@intactinsurance.com

intact specialty solutions

Atlantic Specialty Insurance Company

Period Ended 12/31/2022

Dollars displayed in thousands

Admitted Assets	
Investments:	
Bonds	$ 2,216,201
Preferred Stocks	-
Common Stocks	752,567
Mortgage Loans	-
Real Estate	-
Contract Loans	-
Derivatives	-
Cash, Cash Equivalents & Short Term Investments	306,498
Other Investments	20,805
Total Cash & Investments	3,296,071
Premiums and Considerations Due	332,718
Reinsurance Recoverable	39,231
Receivable from Parent, Subsidiary or Affiliates	2,250
All Other Admitted Assets	79,777
Total Admitted Assets	3,750,047

Liabilities and Surplus	
Liabilities	
Loss Reserves	$ 1,093,968
Loss Adjustment Expense Reserves	347,884
Total Loss & LAE Reserves	1,441,852
Unearned Premium Reserve	735,813
Total Reinsurance Liabilities	42,785
Commissions, Other Expenses, and Taxes due	68,767
Derivatives	-
Payable to Parent, Subs or Affiliates	-
All Other Liabilities	632,508
Total Liabilities	2,921,725
Capital and Surplus	
Common Capital Stock	9,001
Preferred Capital Stock	-
Surplus Notes	-
Unassigned Surplus	174,556
Other Including Gross Contributed	644,763
Capital & Surplus	828,322
Total Liabilities and C&S	3,750,047

State of Minnesota
County of Hennepin

I, Kara L.B. Barrow, Secretary of Atlantic Specialty Insurance Company do hereby certify that the foregoing statement is a correct exhibit of the assets and liabilities of the said Company, on the 31st day of December, 2022, according to the best of my information, knowledge and belief.

Secretary

Subscribed and sworn to, before me, a Notary Public of the State of Minnesota on this 16th day of March, 2023.

Notary Public

KERRI RIECHERS
Notary Public
Minnesota
My Commission Expires January 31, 2025

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Sintetica US LLC

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 301 Carnegie Center, Suite 304

City: Princeton State: NJ Zip: 08540

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 484-354-5700 Website: www.sintetica.com

Licensing Company Email: compliance.sintetica@gmail.com

Section 2: Personal Information

First: Zeel Middle: Last: Shah

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Avenel State: NJ Zip: 07001

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Rutgers University		06/20 - 12/22	
Address	**City**	**State**	**Zip**
57 US Highway 1.	New Brunswick	NJ	08901
Diploma/Degree obtained, if any			
MBS			

School Name		From - To (MM/YY – MM/YY)	
Rutgers University		06/15 - 12/17	
Address	**City**	**State**	**Zip**
57 US Highway 1.	New Brunswick	NJ	08901
Diploma/Degree obtained, if any			
BS (Bachelors of science)			

School Name		From - To (MM/YY – MM/YY)	
Sharda Mandir Vinay Mandir		07/07 - 05/11	
Address	**City**	**State**	**Zip**
8 New sharda Mandir Rd, near Shreyas Flyover (INDIA)	Ahmedabad	GJ	380015
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/17 - Current	[redacted]	Avenel	NJ	07001
11/14-10/17		Fords	NJ	08863
11/13 - 10/14		Fords	NJ	08863
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Sintetica US LLC			07/23 - current	
Business Address		**City**	**State**	**Zip**
301 Carnegie Center Ste 304		Princeton	NJ	08540484
Phone	**Title**		**Number of Employed Hours**	
484-354-5700	Commercial Project Manager			
Description of Duties				
See attached				

Business Name			From - To (MM/YY – MM/YY)	
Otsuka Pharmaceuticals			09/20 - 07/23	
Business Address		**City**	**State**	**Zip**
508 Carnegie Center Dr		Princeton	NJ	08540
Phone	**Title**		**Number of Employed Hours**	
(609) 524-6788	Project Manager, Global Quality Operations			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

ZEEL SHAH
[redacted]

EDUCATION

Master of Business and Science – Analytics with Business Intelligence and Analytics concentration Jan 2023
Rutgers University, New Brunswick, NJ

Bachelor of Science - Biotechnology with Bioinformatics concentration Jan 2018
Rutgers University, New Brunswick, NJ

WORK EXPERIENCE

Commercial Project Manager Jun 2023 – Current
Sintetica, Princeton, NJ

- Driving successful conduct and completion of assigned portfolio of projects, including selected departmental initiatives, by ensuring clarity on objectives, deliverables and timelines to support the project's goals.
- Managing day to day activities for exciting customer / vendor / partner projects, serves as a point of contact for 3PL, Pharmacovigilance and other key partners focused on new product launches and oversight of existing products and services.
- Working with the President of Sintetica US as a business partner focused on a wide range of commercial and operational items.
- Collaborates with the Sintetica Global team aligning on key initiatives across Commercial /Marketing, Supply Chain, R&D, Regulatory, Operations and other teams.
- Driving preparation of project updates and summaries to allow for awareness and decision-making (inclusive of timelines, milestones, interdependencies, issues, risks and actions). Serving as a central connector for cross-functional teams.
- Managing key commercial items, sales reporting, customer onboarding, maintain pricing and new customer setup.
- Responsible for making sure timelines are met, project scope is defined, and key action items are completed for all key projects.
- Preparing Customer and key partner presentations as wells as business unit updates.
- Attending key meetings, defines action items, assigns or performs the actions and drives business performance.
- Collaborating across the business ranging from development, commercial, operations, and business development.

Project Manager – GxP Systems and Solutions, Global Quality Operations Sep 2020 – Jun 2023
Otsuka, Princeton, NJ

- Performed successful conduct and completion of assigned portfolio of projects, including selected departmental initiatives, by ensuring clarity on objectives, deliverables and timelines to support the project's goals.
- Implemented project management and change management practices to assigned projects.
- Provided insights on the progress of the projects to leadership and other key stakeholders/sponsors and identifying areas that require intervention or are potential risks (e.g., KPIs for tracking of progress against roadmaps).
- Provided day-to-day oversight of assigned portfolio inclusive of communication and governance. Coordinating and driving performance of cross-functional project teams.
- Contributed to department-level portfolio review, forecasting and budget tracking regarding assigned portfolio.
- Participated in the development and enhancement of computerized systems related to Quality Assurance and Quality Control (e.g. Global Audits and Findings, Deviation and CAPA, Inspections, and Learning Management, Document Portals) to ensure its quality and compliance.
- Functioned as a knowledge base and resource to project teams for GxP systems (e.g. TrackWise & TrackWise Digital – Quality, Compliance Wire – learning management , ALVIS – Quality Documentation Review, ACE – Inspection and Audit tool etc.). Serving as a point of escalation and resolution for the Global Quality Operations – Solutions initiatives.
- Collaborated with IT to understand the necessary infrastructure components of the business needs and working closely with various vendors to fulfill business requirements for GxP systems.
- Developed and maintained strong relationships with other functions and external stakeholders, fostering positive interactions and ultimately support achieving desired project outcomes.
- Communicated effectively in a remote/virtual environment and in an open, balanced and objective manner.
- Worked creatively within predefined standard and balancing a focus on both, execution methods as well as outcomes.

Data Analyst Extern - Budget and Finance (Rutgers Externship Program) May 2022 – Sep 2022
Rutgers Institutional Planning and Operations, New Brunswick, NJ

- Conducted research on collected extensive vendor data on each commodity usage and cost for all Rutgers campus buildings
- Derived clean data utilizing Python programming in order to utilize for data exploration
- Conceptualized and produced Tableau dashboard to present insights on trends and correlation to drive strategic decision making

Project Manager, Strategy and Operations - Center for Observational and Real-World Evidence (CORE) Sep 2019 - Sep 2020
Merck, Rahway, NJ

- Assessed all documents submitted to the CORE DRC (Document Review Committee) for readiness of review, facilitating the review process and documenting the outcome of the review process. Provided global support to Merck (Merck Inc and MSD).
- Coordinated all aspects of planning and implementing observational or non-interventional research studies and activities such as primary data collection studies, chart review studies, database studies and molecular epidemiology studies under general supervision of director.
- Assisted the research manager with study design (including protocol preparation, study questionnaires, and data analysis plan) and providing operational support for study conduct. Providing all required guidance and making sure that documents are adhered to the CORE SOPs.
- Performed Quality Check for DRC submission of various types of studies (CORE study, LDG - Local data generation study and PASS - Post Approval Safety Study), assessing and assigning to reviewers, providing up to date and accurate communications on study status and study-related issues to internal and external stakeholders.
- Provided accurate DRC recommendations to scientists and performing validation check prior to the final approvals.

- Provided project management support such as authoring statements of work for outsourced projects, leading review committee activities through execution, internal/external meeting management, liaising with cross functional teams to communicate status or needs, preparing agenda, tracking timelines/deliverables, following up on action items.

Associate Research Coordinator – Data Management, Oncology Jul 2018 – Sep 2019
Perlmutter Cancer Center, NYU Langone Health, New York, NY

- Responded to clinical calls related to protocol questions, study eligibility, follow-up methods for missed visits, lost patients, handling SAEs with the scientific writing, etc.
- Responded to IRB queries from enrolling center after consultation with CRA and/or PM. Reviewed yearly IRB approval and any modifications in consent for each enrolling center.
- Assisted QA team for the internal audits, sponsors audits and FDA audits. Filled out CAPA forms and provided corrective action plan to internal stakeholders for the specific findings in Phase 1 clinical research studies.
- Worked closely with business unit regarding the budget management for phase 1 studies. Handled various projects regarding the billing grids for studies & NCI submissions and meet the timelines.
- Led Phase 1 clinical trial studies and special project teams as necessary. Trained Research Data Associates for addressing queries and data entry in EDC for clinical trial studies. Reached out to related vendors prior to the study initiation and work with them on everyday basis.
- Participated in weekly safety meetings regarding medical affairs held by CRO along with medical monitors, treating physicians and principal investigators. Prepared reports, meeting minutes, presentations, abstracts and manuscripts for internal and external audiences under the direction of the program manager.

Quality Control Documentation Specialist Jan 2018 - Jun 2018
LANXESS Corp., Fords, NJ

- Quality system: Managed reviewing workflow for ISO documents, maintained document control system including periodic review of the documents, maintained quality alert system, maintained relevant product and instrumentation SPC data, and managed SQC data collection.
- Materials release: Reviewed and entered analytical data into SAP, created CoA, reviewed Bill of Lading, released shipments, kept track of updated batch identification information, managed production samples coming to QC (request samples, update status, etc).
- Inventory Management: QC inventory management, created purchase requisitions and goods receipts in SAP.

Product Development and Analytical R&D Intern & Co-Op Jun 2017 - Dec 2017
Tris Pharma Inc., South Brunswick, NJ

- Participated in equipment set-up, weighing of materials and manufacturing of experimental batches of various drug products (solutions, suspensions, tablets etc.).
- Effectively compiled data from experiments conducted in tabulation and graphical form.
- Performed different experiments to evaluate various characteristics of drug products.
- Participated in product testing using analytical instruments such as HPLC, UPLC, dissolution apparatus, pH meter, etc. in cGMP environment. Performed calculations associated with analyses along with preparation of the report.

SKILLS

- Computer Applications: Excel, Word, PowerPoint, Microsoft Teams, SharePoint, Power BI, Adobe, SAP, iMedidata, EDC, Veeva Vault
- Inter-personal Skills: Scientific Writing, Project management, Leadership, Effective Communication
- Programming Languages: Java, C, R Studio, Python (Sci-Kit, Numpy, Pandas), Tableau, SQL
- Operating Systems: Mac OSX, Windows 10/XP/Vista/7
- Instrumentation & Techniques: PCR, Gel Electrophoresis, Spectrophotometry, HPLC, ICP, Fluid Bed Dryer
- Languages: English, Hindi, Gujarati

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

ZShah

Original Signature (electronic, copies or stamps not accepted)

09/12/2024

Date

I, Zeel Shah, certify that as the designated representative for

Sintetica US LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ZS I am at least 21 years of age;
3. ZS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ZS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ZS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ZS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ZS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Zeel Shah

Print Name (First, Last)

ZShah

Original Signature (electronic, copies or stamps not accepted)

09/12/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Zeel Shah

Print Name (First, Last)

ZShah

Original Signature (electronic, copies or stamps not accepted)

09/12/2024

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Hudson

I, Zeel Shah, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

ZShah

Original Signature

09/12/2024

Date

Subscribed and Sworn to before me this 12th day of September.

Erica Sanders

Notary Public Signature

ERICA SANDERS
NOTARY PUBLIC, STATE OF NEW JERSEY
COMMISSION # 50207494
MY COMMISSION EXPIRES 3/1/2028

(Seal)

Sintetica US – Princeton Office Employees (On site and/or Hybrid Employee list) :

Name	Role
Frank Mullery	President
Christine Pepitone	Finance Director
Zeel Shah	Sr. Commercial Project Manager
Veronica Della Franco	Office Manager & Executive Admin
Rachel Papaycik	Sr. Commercial Project Manager

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Sintetica US LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 301 Carnegie Center, Suite 304

City: Princeton State: NJ Zip: 08540

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 484-354-5700 Website: www.sintetica.com

Licensing Company Email: compliance.sintetica@gmail.com

Section 2: Personal Information

First: Francis Middle: William Last: Mullery

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Newtown Square State: PA Zip: 19073

Telephone: 484-354-5700 Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Villanova University		2008- 2010	
Address	**City**	**State**	**Zip**
800 Lancaster Ave	Villanova	PA	19085
Diploma/Degree obtained, if any			
Executive Master of Business Administration (EMBA)			

School Name		From - To (MM/YY – MM/YY)	
Kings College		1994-1998	
Address	**City**	**State**	**Zip**
133 N River St		PA	18705
Diploma/Degree obtained, if any			
Bachelor of Science - Accounting			

School Name		From - To (MM/YY – MM/YY)	
Coughlin High School		1991-1994	
Address	**City**	**State**	**Zip**
Main Street	Wilkes-Barre	PA	18705
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2018 - Current	[redacted]	Newtown Square	PA	19073
04/2023 - 06/2018		McMurray	PA	15367

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Sintetica US			02/2022 - current	
Business Address		**City**	**State**	**Zip**
301 Carnegie Center Ste 304		Princeton	NJ	08540
Phone	**Title**			
484-354-5700	President			
Description of Duties				
Please see attached.				

Business Name			From - To (MM/YY – MM/YY)	
STI Pharma, LLC			09/2019 - 11/2021	
Business Address		**City**	**State**	**Zip**
32 Blacksmith Rd		Newtown	PA	18940
Phone	**Title**			
215 710 3270	President and Chief Commercial Officer			
Description of Duties				
Please see attached.				

Business Name			From - To (MM/YY – MM/YY)	
Mylan, Inc.			2012 - 2019	
Business Address		**City**	**State**	**Zip**
1000 Mylan Blvd		Canonsburg	PA	
Phone	**Title**			
(724) 514-1800	President, Mylan Institutional Business			
Description of Duties				
Please see attached.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Francis Mullery

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) Date 8/5/24

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Mercer

I, Francis Mullery, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature **Date** 8/5/24

Subscribed and Sworn to before me this 5th day of August 2024.

Notary Public Signature

AMY MOSHO
Notary Public, State of New Jersey
My Commission Expires Feb 7, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Sintetica US LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 301 Carnegie Center, Suite 304

City: Princeton State: NJ Zip: 08540

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 484-354-5700 Website: www.sintetica.com

Licensing Company Email: compliance.sintetica@gmail.com

Section 2: Personal Information

First: Zeel Middle: Last: Shah

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Avenel State: NJ Zip: 07001

Telephon: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Rutgers University		06/20 - 12/22	
Address	City	State	Zip
57 US Highway 1.	New Brunswick	NJ	08901
Diploma/Degree obtained, if any			
MBS (Master of Business and Science)			

School Name		From - To (MM/YY – MM/YY)	
Ruthets		06/15 - 12/17	
Address	City	State	Zip
57 US Highway 1.	New Brunswick	NJ	08901
Diploma/Degree obtained, if any			
BS (Bachelors of science)			

School Name		From - To (MM/YY – MM/YY)	
Sharda Mandir Vinay Mandir		07/07 - 05/11	
Address	City	State	Zip
8 New sharda Mandir Rd, near Shreyas Flyover (INDIA)	Ahmedabad	GJ	380015
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/17 - Current	[redacted]	Avenel	NJ	07001
11/14-10/17		Fords	NJ	08863
11/13 - 10/14		Fords	Nj	08863
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Sintetica US LLC			07/23 - current
Business Address	**City**	**State**	**Zip**
301 Carnegie Center, Suite 304	Princeton	NJ	08540
Phone	**Title**		
484-354-5700	Commerical Project Manager		
Description of Duties			
See attached			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Zeel Shah

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/05/2024

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Mercer

I, Zeel Shah, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

08/05/2024

Date

Subscribed and Sworn to before me this 5th day of August 2024.

Notary Public Signature

AMY MOSHO
Notary Public, State of New Jersey
My Commission Expires Feb 7, 2027

(Seal)

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER, ENVIRONMENTAL AND OCCUPATIONAL HEALTH SERVICE
PUBLIC HEALTH AND FOOD PROTECTION PROGRAM
P.O. BOX 369, TRENTON, NJ 08625-0369
609-826-4935

REPORT OF INSPECTION

Assignment No **17879**
Inspection End Date **06/11/2024**

Registration #	Category	Inspection Type	Evaluation
5006257	**Wholesale Drug/Medical Device**	**Initial**	**Satisfactory**

Name of Owner or Corporation	Trade Name	Activity
Sintetica US LLC	**Sintetica US LLC**	**Office Only**

Establishment Street Address	City	ZIP	County
301 Carnegie Center, Suite 304	**Princeton**	**08540**	**Mercer**

Establishment Mailing Address (if different)	Phone Number	Fax Number
	609-212-2176	

Name and Title of Inspecting Official	REHS Lic. #	Operational Status	Embargo	Reinspect on or After
Annie Pullockaran, REHI 2	**B-150656**	**Operational**	**No**	

Name and Title of Designated Representative	Email
Frank Mullery, President	**fmullery@sintetica.com**

Products
☒ Prescription Drugs ☐ OTC Drugs ☐ Class I Medical Devices ☐ Class II Medical Devices ☐ Class III Medical Devices
☐ Drug-Device ☐ API ☐ Veterinary Drugs ☒ No Products Stored/Handled Onsite

TIME/ACTIVITY REPORT (1-TRAVEL, 2-INSPECTION, 3-ADMINISTRATION, 4-PERSONAL) TOTAL HOURS: 02.50

DATE	CODE	BEGIN	END	CODE	BEGIN	END	CODE	BEGIN	END
06/11/2024	1	08:30	09:00	2	09:00	10:00	1	10:00	10:30
06/11/2024	3	15:15	15:45						

		YES	NO	N/A
	N.J.A.C. 8:21-3A.7 Personnel Requirements			
	Personnel employed by a wholesale distributor have appropriate education and/or experience to assume responsibility for positions related to compliance with State registration requirements	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.8 Facility *Facilities at which drugs are stored, warehoused, handled, held, offered, marketed or displayed:*			
(a) 1	Of suitable size and construction to facilitate cleaning, maintenance, and proper operations	☒	☐	☐
(a) 2	Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions	☐	☐	☒
(a) 3	Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened	☐	☐	☒
(a) 4	Maintained in a clean and orderly condition	☒	☐	☐
(a) 5	Free from infestation by insects, rodents, birds, or vermin of any kind	☒	☐	☐
Note				

		YES	NO	N/A
	N.J.A.C. 8:21-3A.9 Security			
(a)	Facility is secured from unauthorized entry	☒	☐	☐
(a) 1	Access from outside premises is kept to a minimum and is well controlled	☒	☐	☐
(a) 2	The outside perimeter of the premises is well-lighted	☒	☐	☐
(a) 3	Entry into areas where drugs are held shall be limited to authorized personnel	☐	☐	☒
(b)	All facilities are equipped with an alarm system to detect entry after hours	☒	☐	☐
(c)	Facilities are equipped with a security system that provides suitable protection against theft and diversion. When applicable, the security system provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.10 Storage			
(a)	All drugs are stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, of the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).	☐	☐	☒
(b)	If no storage requirements are established for a drug, the drug is held at controlled room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected	☐	☐	☒
(c)	Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs are utilized to document proper storage of drugs	☐	☐	☒
(d)	For prescription drugs a record is maintained that includes the date, time, thermometer temperature, and the initials of the person recording the data	☐	☐	☒
Note				
	N.J.A.C. 8:21-3A.11 Examination of Materials			
(a)	Upon receipt, each outside shipping container is visually examined for identity and to prevent the acceptance of contaminated drugs or drugs that are otherwise unfit for distribution. This examination is adequate to reveal container damage that would suggest possible contamination or other damage to the contents.	☐	☐	☒

		YES	NO	N/A
(b)	Each outgoing shipment is carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.	☐	☐	☒
Note				
	N.J.A.C. 8:21-3A.12 Returned, Damaged and Outdated Drugs			
(a)	Outdated, damaged, deteriorated, misbranded, or adulterated drugs are quarantined and physically separated from other drugs until they are destroyed or returned to their supplier	☒	☐	☐
(b)	Drugs whose immediate or sealed outer or sealed secondary containers have been opened or used are identified as such, quarantined and physically separated from other drugs until they are either destroyed or returned to the supplier	☒	☐	☐
(c)	If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug is destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.13 Recordkeeping			
(a)	Inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs are maintained	☒	☐	☐
(a) 1	Source of drugs, name and principal address of the seller or transferor, and address from which drugs were shipped are maintained	☒	☐	☐
(a) 2-3	Identity and quantity of drugs received and distributed/disposed, date of receipt and distribution, disposal.	☒	☐	☐
(a) 5	A complete and accurate annual record of all stock of drugs on hand.	☒	☐	☐
(d)	An ongoing listing of all retail and wholesale establishments with whom they do business.	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.14 Due Diligence *Firm is performing due diligence of other wholesale establishments with whom they do business, which requires that prior to the initial purchase or acquisition of drugs from another wholesale distributor, a wholesale distributor shall obtain the following information from the selling wholesale distributor:*			
(a) 1	Copies of all state and Federal regulatory licenses and registrations	☒	☐	☐
(a) 2	The wholesale distributor's most recent facility inspection reports	☒	☐	☐
(a) 3	A list of other names under which the wholesale distributor is doing business or by which the wholesale distributor was formerly known	☒	☐	☐

		YES	NO	N/A
(a) 4	A list of corporate officers and managerial employees and designated representatives	☒	☐	☐
(a) 5	A verification of the selling wholesale distributor's status as an authorized distributor of record, if applicable.	☒	☐	☐
(b)	At least annually, a wholesale distributor that purchases drugs from another wholesale distributor updates the information set forth in (a) 1-5 above.	☒	☐	☐
(c)	No purchases were placed from any storage facility, manufacturer or wholesale distributor not having a current license or registration within the jurisdiction of the establishment location from where product is purchased.	☒	☐	☐
(d)	No purchase or acquisition has been made from a firm that has not provided complete information as set forth in (a) 1-5 above.	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.15 Availability of Records and Inventories			
(a)	Records and inventories, including those related to salvage and reprocessing, are made available for inspection and photocopying by authorized Federal, State, or local law enforcement agency officials for a period of 3 years after the date of their creation	☒	☐	☐
(b)	Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means are readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable are made available for inspection within 2 working days of a request by an authorized official of a Federal, State, or local law enforcement agency	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.16 Policies and Procedures			
(a)	Firm established and follows written policies and procedures for the receipt, security, storage, inventory, and distribution of drugs	☒	☐	☐
(a)	Firm has policies for identifying, recording and reporting losses or thefts and correcting errors in inventories	☒	☐	☐
(a) 1	Firm has a procedure where oldest stock is distributed first.	☒	☐	☐
(a) 2	Firm has a procedure for handling recalls/withdrawals of drugs.	☒	☐	☐
(a) 3	Firm has a procedure for preparation, protection and proper handling of any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster	☒	☐	☐
(a) 4	Firm has a procedure for handling return of outdated drugs; segregation and written documentation of disposal, by either returning the drug to the manufacturer or destruction of the drug. This documentation shall be maintained for 2 years after disposition of the outdated drugs.	☒	☐	☐

		YES	NO	N/A
Note				
	N.J.A.C. 8:21-3A.17 List of Responsible Persons			
	A current list of officers, directors, managers, and other personnel in charge of wholesale distribution, storage, and handling of drugs is maintained at the firm	☒	☐	☐
	Description of duties and qualifications of personnel is maintained at the firm	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.19 Salvage; Reprocessing			
	Salvaging and reprocessing operation is in compliance with 21 CFR 207, 210, 211	☐	☐	☒
Note				

Note: Products were launched for distribution as of April, 2023. In addition, this firm anticipates launching more products this year.

Jamie Pulbekaran

Inspecting Official

NABP ACCREDITED
DRUG DISTRIBUTOR

Eversana Life Science Services, LLC

located at
4580 Mendenhall Rd, Memphis, TN 38141

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

10/17/2021 - 10/16/2024
Period of Accreditation

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF FORMATION OF "SINTETICA US LLC", FILED IN THIS OFFICE ON THE FOURTEENTH DAY OF JULY, A.D. 2022, AT 2:53 O`CLOCK P.M.

Jeffrey W. Bullock, Secretary of State

6913503 8100
SR# 20222991656

Authentication: 203924216
Date: 07-15-22

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Delaware
Secretary of State
Division of Corporations
Delivered 02:53 PM 07/14/2022
FILED 02:53 PM 07/14/2022
SR 20222991656 - File Number 6913503

STATE OF DELAWARE
CERTIFICATE OF FORMATION
OF LIMITED LIABILITY COMPANY

The undersigned authorized person, desiring to form a limited liability company pursuant to the Limited Liability Company Act of the State of Delaware, hereby certifies as follows:

1. The name of the limited liability company is Sintetica US LLC.

2. The Registered Office of the limited liability company in the State of Delaware is located at 850 New Burton Road, Suite 201 (street), in the City of Dover, Zip Code 19904. The name of the Registered Agent at such address upon whom process against this limited liability company may be served is COGENCY GLOBAL INC.

By: /s/ Rebecca Lewis
Authorized Person

Name: Rebecca Lewis
Print or Type

List of Contract Manufacturers and 3PL

All Sintetica US CMOs are located out of the country.

Company	Address and Contact Information	Product
MSN Laboratories	MSN Laboratories Private Limited. Formulation Division, Unit - II, Sy No 1277 & 1319 to 1324 Nandigama Village & Mandal Ranga Reddy Dist Telangana State, India. PIN 509228 **Contact :** +91 84553 05600 (POC: Sameera Mandadi sameera.mandadi@msnlabs.com **DUNS:** 3011033544	Bortezomib, Arsenic Trioxide
Hainan Poly Pharma	Hainan Poly Pharm. Co., Ltd. Guilinyang Economic Development Area Meilan District, Haikou, Hainan 571127, China (CHN) **Contact:** +86-571-89385086 polysrv-us@hnpoly.com **DUNS:** 654561638	Daptomycin, Lacosamide (launching soon)
Sintetica SA	Via Penate 5 6850 Mendrisio Switzerland T. +41 91 640 42 50 info@sintetica.com **DUNS:** 480895478	Lidocaine

3PL Information

- **Name of 3PL** : EVERSANA Life Science Services
- **Address of 3PL**: 4580 S. Mendenhall Road, Memphis, TN 38141
- **3PL DEA Number**: RD0205333
- **Name of 3PL Responsible Person**: Duane Allison
- **3PL phone number**: 901-797-8885

4AA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Teleflex LLC

Physical Address: 16 Elizabeth Drive

City: Chelmsford State: MA Zip: 01824

Mailing Address (if different from physical address): Teleflex LLC attention Bettina Knight 3015 Carrington Mill Blvd

City: Morrisville State: NC Zip: 27560

Telephone: _____ Website: https://teleflex.com

Name of Designated Representative (DR): Bernarda Cedeno Morel

Licensing Company Email: statelicensing@teleflex.com DR Email: bernarda.morel@teleflex.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: wholesaler, distributor

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Arrow International LLC

Address: 16 Elizabeth Drive City: Chelmsford State: MA Zip: 01824

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Teleflex Life Sciences II LLC

Corporation/Organization Name: Teleflex LLC

Mailing Address: Teleflex LLC attention Bettina Knight 3015 Carrington Mill Blvd

City: Morrisville State: NC Zip: 27560

Telephone: 919-544-8000 Email: statelicensing@teleflex.com

Contact Person Name: Matthew Howald

Section 6: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Teleflex LLC

Facility Name

Matthew Howald

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

JUNE 4, 2024

Date

Board Use Only	Date Received: 6/10/24	Amount: $1000-cc

Please note: Teleflex LLC is the distribution entity in the United States. Arrow is an affiliate of Teleflex LLC, sharing common ownership. Arrow holds the FDA registration because of other manufacturing activities it conducts at the facility.

FDA

FDA Home[1] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
Arrow International, LLC (Subsidiary Of Teleflex, Incorporated)
Business Trade Name:
Arrow International LLC

16 Elizabeth Dr
Chelmsford, MA 01824
Registration Number: 3010532612
FEI Number*: 3010532612
Status: Active
Date Of Registration Status: 2024

Owner/Operator:
Arrow International LLC (Subsidiary Of Teleflex Incorporated)[6]
3015 Carrington Mill Blvd
Morrisville, NC US 27560
Owner/Operator Number: 2518433[7]

Official Correspondent:
Trey Smith
Teleflex, Inc.
3015 Carrington Mill Blvd
Morrisville, NC 27560
Phone: 1-336-8288038

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Links on this page:
1. http://www.addthis.com/bookmark.php?v508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=@Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2518433&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishmentType=&PAGENUM=10&SortColumn=
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=@Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2518433&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishmentType=&PAGENUM=10&SortColumn=

Page Last Updated: 04/15/2024

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of Health & Human Services

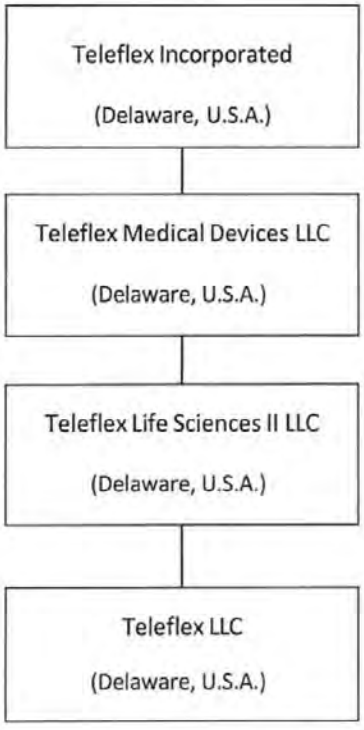
Links on this page:
1. http://www.addthis.com/bookmark.php?v508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=@Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2518433&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishmentType=&PAGENUM=10&SortColumn=
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=@Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2518433&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishmentType=&PAGENUM=10&SortColumn=

verified M.H 7/26/24 exempt.

OFFICERS OF TELEFLEX LLC

OFFICERS	*TITLE*
Jay White jay.white@teleflex.com ***Director*	*President*
John Robert Deren john.deren@teleflex.com ***Director*	*Vice President*
Mikhail Kryukov michael .kryukov@teleflex.com	*Vice President & Secretary*
Matthew Howald matt.howald@teleflex.com ***Director*	*Vice President & Treasurer*

Teleflex LLC
2024



Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "TELEFLEX LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FOURTH DAY OF APRIL, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "TELEFLEX LLC" WAS FORMED ON THE TWENTIETH DAY OF AUGUST, A.D. 2018.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

7023120 8300

SR# 20241306195

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203182259

Date: 04-04-24

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **TELEFLEX LLC**, as a FOREIGN LIMITED-LIABILITY COMPANY duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 02/05/2019, and is in good standing in this state.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 02/05/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202402054327382
You may verify this certificate online at http://www.nvsos.gov

From: Admin, Pharmacy (DPH)
To: Knight, Bettina
Subject: Re: IABP Pumps - license
Date: Monday, April 8, 2024 10:03:14 AM
Attachments: Outlook-rnrz34mo.png

Hello-
The Board does not license these facilities.

Please review the Drug Control Program's website to determine if a registration is required by that agency:
https://www.mass.gov/orgs/massachusetts-controlled-substances-registration

Thank you.

Massachusetts Board of Registration in Pharmacy
250 Washington Street
Boston, MA 02108
pharmacy.admin@mass.gov
(617) 973-0960

Renewal reminders are now only sent by email.
Please keep your **email address and other contact information updated** using this link:
https://healthprofessionlicensing.mass.gov/login-register

Consider being added to the Board's email distribution list so you are notified of changes to MA regulations and other updates by emailing us at pharmacy.admin@mass.gov

150 YEARS
OF ADVANCING
PUBLIC
HEALTH

When writing or responding, please remember that the Secretary of State's Office has determined that e-mail is a public record.

From: Knight, Bettina <Bettina.Knight@teleflex.com>
Sent: Monday, April 8, 2024 10:00 AM
To: Admin, Pharmacy (DPH) <Pharmacy.Admin@MassMail.State.MA.US>
Subject: IABP Pumps - license

CAUTION: This email originated from a sender outside of the Commonwealth of Massachusetts mail system. Do not click on links or open attachments unless you recognize the sender and know the content is safe.

Home state - Massachusetts

Massachusetts only licenses facilities distributing controlled substances.

The facility does not handle prescription drugs recognized as controlled substances in Massachusetts, therefore no home license is needed.

Attached is an email from the MA Board of Pharmacy that confirms the facility located in Chelmsford, MA does not need a home state license.

For more information, see Massachusetts Controlled Substance Registration:

https://www.mass.gov/orgs/massachusetts-controlled-substances-registration.

Good morning,

I am responsible for maintaining state licenses for all the Teleflex facilities.

Our facility in Massachusetts manufactures Intra-Aortic Balloon (IAB) Pumps which are designed to assist patients who need mechanical circulatory support during cardiac events. The IAB Pump uses Helium to inflate and deflate the balloon. In connection with the distribution of the IAB Pumps, the facility will distribute Helium tanks, which are labeled as "Rx-Only".

Bases upon our reading of the Pharmacy law, the facility is not required to be licenses in MA.
In connection with sales/shipments of the products into the other states, we need to obtain wholesaler/manufacturer licenses. Most applications require a copy of the home state license.
Would it be possible to get a letter from the MA Board of Pharmacy to confirm that the facility does not need a home license?

Let me know if you need more information.

Kind regards

Bettina

Bettina Knight (she/her)
State Licensing Lead

M: 1 (919) 397-4470

Teleflex

This e-mail message, including any attachment(s), is for the sole use of the intended recipient(s) and may contain confidential, proprietary and/or privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please notify the sender by reply e-mail and delete, and/or otherwise destroy, all copies of the original message, including any attachment(s).

Please consider the environment before printing this email

NEVADA STATE BOARD OF PHARMACY
431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 800142112

Application/License No. _____

Teleflex LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 16 Elizabeth Drive, Chelmsford, MA 01824 (Address of Applicant/Principal), as PRINCIPAL, and Atlantic Specialty Insurance Company (Surety Company), a corporation organized under the laws of the state of New York (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 605 Highway 169 North, Suite 800, Plymouth, MN 55441 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on July 17, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 17 day of July, 2024.

APPLICANT/PRINCIPAL

Teleflex LLC

Authorized Representative

SURETY COMPANY

Atlantic Specialty Insurance Company

Surety Company's Representative

Bianca M. Phillips, Attorney-in-fact

print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

NA

intact INSURANCE

Power of Attorney

Surety Bond No: 800142112

Principal: Teleflex LLC

Obligee: Nevada State Board of Pharmacy

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: Bianca M. Phillips, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this twenty-seventh day of April, 2020.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Sarah A. Kolar, General Counsel

STATE OF MINNESOTA
HENNEPIN COUNTY

On this twenty-seventh day of April, 2020, before me personally came Paul J. Brehm, Senior Vice President of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and he acknowledged the execution of the same, and being by me duly sworn, that he is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON DWAN NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2025

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 17th day of July, 2024

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

_____
Kara Barrow, Secretary

Please direct bond verifications to surety@intactinsurance.com

MEMORANDUM OF INSURANCE	DATE 28-Aug-2024

This Memorandum is issued as a matter of information only to authorized viewers for their internal use only and confers no rights upon any viewer of this Memorandum. This Memorandum does not amend, extend or alter the coverage described below. This Memorandum may only be copied, printed and distributed within an authorized viewer and may only be used and viewed by an authorized viewer for its internal use. Any other use, duplication or distribution of this Memorandum without the consent of Marsh is prohibited. "Authorized viewer" shall mean an entity or person which is authorized by the insured named herein to access this Memorandum via https://marshdigital.marsh.com/marshconnect/viewMOI.action?clientId=582422257. The information contained herein is as of the date referred to above. Marsh shall be under no obligation to update such information.

PRODUCER	COMPANIES AFFORDING COVERAGE
Marsh USA LLC ("Marsh")	Co. A Travelers Property Casualty Company of America
INSURED Teleflex Incorporated and Subsidiaries 550 E. Swedesford Road Suite 400, Wayne Pennsylvania 19087 United States	Co. B Travelers Casualty & Surety Company
	Co. C Columbia Casualty Company
	Co. D
	Co. E
	Co. F

COVERAGES

THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS MEMORANDUM MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS

CO LTR	TYPE OF INSURANCE	POLICY NUMBER	POLICY EFFECTIVE DATE	POLICY EXPIRATION DATE	LIMITS (LIMITS IN USD UNLESS OTHERWISE INDICATED)	
A	GENERAL LIABILITY Commercial General Liability Occurrence	TJGLSA2J706154TIL24	01-Sep-2024	01-Sep-2025	GENERAL AGGREGATE	2,000,000
					PRODUCTS - COMP/OP AGG	Excluded
					PERSONAL AND ADV INJURY	1,000,000
					EACH OCCURRENCE	1,000,000
					FIRE DAMAGE (ANY ONE FIRE)	1,000,000
					MED EXP (ANY ONE PERSON)	5,000
A	AUTOMOBILE LIABILITY Any Auto Hired Autos Non-Owned Autos	TJCAP2J706166TIL24	01-Sep-2024	01-Sep-2025	COMBINED SINGLE LIMIT	2,000,000
					BODILY INJURY (PER PERSON)	
					BODILY INJURY (PER ACCIDENT)	
					PROPERTY DAMAGE	
A	EXCESS LIABILITY Other than Umbrella Form	EX6S79096124NF	01-Sep-2024	01-Sep-2025	EACH OCCURENCE	10,000,000
					AGGREGATE	10,000,000
A	WORKERS COMPENSATION / EMPLOYERS LIABILITY THE PROPRIETOR / PARTNERS / EXECUTIVE OFFICERS ARE Included	UB8N3139892451K (AOS)	01-Sep-2024	01-Sep-2025	WORKERS COMP LIMITS	Statutory
B		UB8N3113332451R (Retro)	01-Sep-2024	01-Sep-2025	EL EACH ACCIDENT	1,000,000
					EL DISEASE - POLICY LIMIT	1,000,000
					EL DISEASE - EACH EMPLOYEE	1,000,000

C	Primary Products Liability - Clinical Trials	ADT2091141649	01-Sep-2024	01-Sep-2025	Each Claim / Aggregate: 15,000,000 / 15,000,000

The Memorandum of Insurance serves solely to list insurance policies, limits and dates of coverage. Any modifications here to are not authorized.

MEMORANDUM OF INSURANCE | **DATE** 28-Aug-2024

This Memorandum is issued as a matter of information only to authorized viewers for their internal use only and confers no rights upon any viewer of this Memorandum. This Memorandum does not amend, extend or alter the coverage described below. This Memorandum may only be copied, printed and distributed within an authorized viewer and may only be used and viewed by an authorized viewer for its internal use. Any other use, duplication or distribution of this Memorandum without the consent of Marsh is prohibited. "Authorized viewer" shall mean an entity or person which is authorized by the insured named herein to access this Memorandum via https://marshdigital.marsh.com/marshconnect/viewMOI.action?clientId=582422257. The information contained herein is as of the date referred to above. Marsh shall be under no obligation to update such information.

PRODUCER
Marsh USA LLC
("Marsh")

INSURED
Teleflex Incorporated and Subsidiaries
550 E. Swedesford Road
Suite 400, Wayne
Pennsylvania 19087
United States

ADDITIONAL INFORMATION
ADDITIONAL INFORMATION
Provisions that we can include upon request:
Automobile
1. Broad Named Insured
2. Employees as Insureds
3. Additional Insured Lessor and Loss Payee as Required by Written Contract.

Workers Compensation:
1. Waiver of Subrogation as Required by Written Contract

General Liability and Premises Operations:
1. Broad Named Insured
2. Blanket Additional Insured as Required by Written Contract
3. Waiver of Subrogation as Required by Written Contract

Products Liability:
1. Worldwide Coverage Territory
2. Vendors are included as insureds as required by written contract
3. See key policy definition of Insured Product below
Note:
Excess Liability applies over General Liability, Automobile Liability and Employers Liability.

CNA policy definition of Insured Product
INSURED PRODUCT
Insured product means any goods or products:
A. manufactured, developed, designed, created, or tested;
B. sold, leased, licensed, rented, handled, marketed, distributed to others; or
C. disposed of;
by the Insured Entity or others on the Insured Entitys behalf, including but not limited to:
1. biological products, pharmaceutical drugs, medical devices, nutraceuticals; or
2. products that are used, or are intended for use in clinical trials, health care or the providing of

professional services; or
3. containers (other than vehicles), materials, parts or equipment furnished in connection with such goods or products.
Insured product includes:
a. warranties or representations made at any time with respect to the fitness, quality, durability, performance, use, handling, operation or safety of insured product; and
b. the providing of or failure to provide warnings or instructions.

The Memorandum of Insurance serves solely to list insurance policies, limits and dates of coverage. Any modifications hereto are not authorized.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Teleflex LLC MDEG License # (if applicable) _____

Physical Address 16 Elizabeth Drive

City Chelmsford State MA Zip 01824

Mailing Address (if different from physical address) Teleflex LLC attention Bettina Knight 3015 Carrington Mill Blvd

City Morriville State NC Zip 27560

Telephone 919-397-4470 Website https://teleflex.com

Licensing Company Email statelicensing@teleflex.com

Section 2: Personal Information

First Bernarda Middle _____ Last Cedeno Morel

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN _____ Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City Chelmsford State MA Zip 01824

Telephone [redacted] Email bernarda.morel@teleflex.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: Aristides Garcias Mella		From - To (MM/YY – MM/YY)	
Address: Laromana Dominican Republic	City: Laromana	State	Zip
Diploma/Degree obtained, if any: Highschool			
School Name: Academia de Belleza Nacidit		From - To (MM/YY – MM/YY): 1980-1984	
Address: Ensanche Ozama	City: Santo Domingo	State	Zip
Diploma/Degree obtained, if any: YES			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2014 - present	[redacted]	Tyngsboro	MA	01879 ~~08179~~
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

cbm 29 Jul 2024

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
Teleflex LLC		11/14/2000 - present	
Business Address	City	State	Zip
16 Elizabeth Drive	Chelmsford	MA	01824
Phone	Title	Number of Employed Hours	
978-250-5100	Quality Control Manager	46,000.00	
Description of Duties			
Manage the Quality Control department on both shifts, Incoming, inprocess and Final release teams, Coordinate the shipping of Sterile Product to the Distribution Center.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

O Bernard
Original Signature (electronic, copies or stamps not accepted)

29 Jul 2024
Date

I, Bernarda Cedeno Morel, **certify that as the MDEG Administrator for**

Teleflex LLC,

that I (initial that you have read and meet the following requirements):

1. BCM Have a high school diploma or its equivalent;
2. BCM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. BCM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. BCM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bernarda Morel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

29 Jul 2024

Date

Board Use Only	Date Received: 8/5/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Teleflex LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 16 Elizabeth Drive

City Chelmsford State MA Zip 01824

Mailing Address (if different from physical address) Teleflex LLC attention Bettina Knight 3015 Carrington Mill Blvd

City Morrisville State NC Zip 26560

Telephone 919-397-4470 Website https://teleflex.com

Licensing Company Email statelicensing@teleflex.com

Section 2: Personal Information

First Bernarda Middle _____ Last Cedeno Morel

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN _____ Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City Chelmsford State MA Zip 01824

Telephone 978-250-5100 Email bernarda.morel@teleflex.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name ~~ARISTIDES~~ ARISTIDES GARCIAS MELLA		From - To (MM/YY – MM/YY)	
Address LAROMANA DOMINICAN REP.	City LAROMANA	State	Zip
Diploma/Degree obtained, if any HIGH SCHOOL			
School Name ACADEMIA DE BELLEZA NACIDIT		From - To (MM/YY – MM/YY) 1980 - 1984	
Address ENSANCHE OZAMA	City SANTO DOMINGO	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
AUG 2014	[redacted]	TYNGSBORO	MA	01879
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Teleflex LLC			From - To (MM/YY – MM/YY): 14 NOV 2000
Business Address: 16 Elizabeth Drive	City: Chelmsford	State: MA	Zip: 01824
Phone: 978-250-5100	Title: Qualiy Control Manager		Number of Employed Hours: 46,000.00
Description of Duties: MANAGE THE INCOMING; INPROCESS AND FINAL RELEASED TEAM. COORDINATE THE SHIPPING OF STERILE PRODUCT TO THE NADC			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title: N/A		Number of Employed Hours
Description of Duties: BCM 09 May 2024			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

N/A

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

BCM 09 May 2024

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	N/A	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

N/A BM
09/11/May 2024

Provide explanation below:

BMorel
Original Signature (electronic, copies or stamps not accepted)

09 May 2024
Date

I, Bernarda Cedeno Morel, **certify that as the designated representative for**

Teleflex LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. BCM I am at least 21 years of age;
3. BCM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. BCM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. BCM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. BCM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. BCM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Bernarda Cedeno Morel

Print Name (First, Last)

BCMorel

Original Signature (electronic, copies or stamps not accepted)

09 May 2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bernarda Cedeno Morel

Print Name (First, Last)

BCMorel — 09 May 2024

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Massachusetts, ss. County of Middlesex

I, BERNARDA CEDENO MOREL, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

BCMorel — 09 May 2024

Original Signature — **Date**

Subscribed and Sworn to before me this 9 day of May.

RICHARD A MARQUIS
NOTARY PUBLIC
COMMONWEALTH OF MASSACHUSETTS
My Comm. Expires August 12, 2027

Notary Public Signature

(Seal)

List of employees

First Name	Last Name	Position Title
Abdul	Mayambala	Medical Device Assembler
Abrahan	Rijo	Lead Mechanical Assembler
Adam	Osborne	Production Supervisor
Adol	Mashut	Medical Device Assembler
Adrian	Ortiz	Medical Device Assembler
Alenida	onsalve Zapata Urizar	Medical Assembler 1
Alexia	Casey	Temp-Administrative Assistant
Alexis	Matos Falcon	Facilities Maintenance Technician
Allan	Maina	Test Technician
Amanda	Loch	Line Lead
Amara	Chhaya	Medical Device Assembler
Amelia	Mom	Dip Room Operator
Amine	Zerouali	Maintenance & Facilities Manager
Ana	Moundele	Quality Control Inspector
Ana	Iribe Aviles	Manufacturing Engineer IV
Analiza	Pista	Documentation Specialist
Andrew	Raneri	Medical Assembler 1
Anisha	Khalifa	Medical Device Assembler Operator
Anmol	Nagre	Senior Design Development Manager
Ann Marie	Lamontagne	Medical Assembler 1
Asia	Yang	Medical Device Assembler
Bai	Bangura	Dip Room Operator
Benito	Vazquez	Line Lead
Berkis	Polanco	Medical Device Manufacturing Operator
Bernarda	Cedeno-Morel	Quality Control Manager
Bhavesh	Jani	Medical Device Assembler
Bidur	Badal	Manufacturing Engineer III
Bijalbahen	Patel	Medical Device Assembler
Brailin	Valdez	Medical Assembler 1
Brandon	Lieu	Temp-Tipping Operator
Brenda	Kluck	Test Technician
Bret	Viray	Enterprise Excellence Engineer
Brian	Cannon	Project/Program (Design) Mgmt 5
Bryan	Christie	Temp-Medical Device Assembler
Bunnarin	Bo	Line Lead
Bunthan	Chan	Temp-Test Technician
Carolina	Solano	Medical Assembler 1
Catalina	Jaramillo	QC Inspector
Channary	Moun	Value Stream Supervisor
Channy	Tep	Medical Assembler 1
Chantana	Sok	Medical Assembler 1
Chek	Kong	Temp-Medical Device Assembler
Chhoeu	Nha	Medical Assembler 2

First Name	Last Name	Position Title
Christen	Agnew	Temp-Tipping Operator
Christian	Ortega	Test Technician
Christian	Kabuye	Medical Device Assembler
Christopher	Bell	Mechanical Assembler
Christy	Samba	Medical Device Assembler
Constance	Cross	IABP Assembly Operator
Cristian	Varona Nuñez	Medical Assembler 1
Cristina	Mejia	QC Inspector
Cristina	Liu	Team Lead- Purchasing
Crystal	Som	Medical Device Assembler
Dahiana	Trocoso	Temp-IAB Assembly Operator
David	Morales Rascon	Manufacturing (Industrial) Engineer, IV
David	Boketshu	Value Stream Supervisor
Davide	Tassi	Line Lead
Debra	Vance	Sr. Production Control Coordinator
Delmy	Morales	Medical Device Assembler
Deven	Rashid	Material Handler
Dina	In	line lead
Donald	Dacosta	Line Lead
Donald	Fortin	Medical Device Assembler
Douglas	Bridell	Value Stream Manager
Edwin	Montalvo	Line Lead
Ehku	Hser	Medical Device Assembler
Eileen	Izaguirre	Senior Material Handler
Elizah	Yost	IABP Assembly Operator
Emely	Genao Ramos	Medical Device Assembler
Emily	Brown	Operations Training Leader
Erika	Vaquerano	Group Lead
Eunice	Gomez	Mechanical Assembler
Fabiola	Pacheco	Medical Device Assembler
Fernando	Batista	Tooling Technician
Frank	Kalume	Medical Assembler 1
Frantz	Alexandre	Medical Assembler 1
Gary	Swaim	Documentation Specialist 3
Gemma	Ouellette	QC Inspector
Gennaro	Mom	Manufacturing Technician
George	Cruz	Temp-IAB Assembly Operator
Gloria	Zapata	Medical Assembler 1
Glorisela	Jimenez	Medical Device Assembler
Guadalupe	Pina	Medical Device Assembler
Guang Xing	Huang	Manufacturing Engineering Technician
Hannah	Dobrovolskiy	Human Resources Manager
Ho	Duong	Medical Assembler 1
Holly	Trinh	QC Inspector
Hong	An	Medical Assembler 2
Ismariel	Garcia	Medical Assembler 1

First Name	Last Name	Position Title
Jack	Black	IABP Assembly Operator
Jacob	King	Temp- Medical Device Assembler
James	Cam	Temp-Medical Device Assembler
James	Luraghi	Sr. Manufacturing Engineering Manager
Jamie	Buchannan	Warehouse Manager
Janice	Dill	Medical Device Assembly Operator
Jasmine	Martinez Rodriguez	Medical Device Assembler
Jefna	Dadaille	Medical Device Assembler
Jeniffer	Lugo	Medical Device Assembler
Jennifer	Resto	Medical Device Assembler
Jessika	Jeamaux	Medical Device Assembler
Joanna	Fajardo	Temp-Medical Device Assembler
Jocelyn	Martinez Vega	QC INSPECTOR 2
Jodi	Schrader	Enterprise Excellence Manager
Joelky	Reynoso	Material Handler
Joey	Ouk	Medical Assembler 1
Johanis	Garcia	Temp-Medical Device Assembler
Johnsel	Garcia	Temp-Medical Device Assembler
Jonathan	Maza	Material Handler
Jorge	Martinez-Fernandez	Medical Assembler 1
Jose	Rivera	Medical Device Assembler
Jose	Rivera Roig	Medical Assembler 1
Jose	Araujo Ozuna	Medical Device Assembler
Joseph	Karuri	Temp- Medical Device Assembler
Joshua	Mukandila	Dip Room Operator
Joshua	Nutter	Medical Device Assembler
Jovannie	Ferrer	Material Handler
Juan	Martinez	Test Technician
Juan Isidro	Serrano	Material Handler
Juana	Sanchez	Medical Device Assembler
Julian	Phachansiri	Medical Device Assembler
Julie	Mannorind	Medical Assembler 2
Julie	Rodriguez	Medical Assembler 1
Junyu	Huang	Medical Device Assembler
Justin	Sar	Temp- Medical Device Assembler
Kalvein	Oum	Temp-Medical Device Assembler
Kanchan	Lumb	Line Lead
Katelyn	Matias	Temp-Medical Device Assembler
Kathryn	Licata	Sr. Quality Engineer
Katrina	Nguyen	Temp-Medical Device Assembler
Keaton	Thoeuk	Medical Device Assembler
Kelvin	Martinez	Medical Device Assembler
Kenneth	Twining	EHS Engineer
Kennry	Khiev	QC Inspector
Kenny	Chea	IABP Assembly Operator
Keo	Sokuntheary	Medical Device Manufacturing Operator

First Name	Last Name	Position Title
Kevin	Kong	QC Inspector
Khim	Lim	Value Stream Supervisor
Kimleang	Thon	Medical Assembler 1
Kimunn	Oeung	Line Lead
Korinna	Gouveia	Temp-Medical Device Assembler
Kruti	Vora	Process Development Engineer II
Kupesa	Williams	Temp-Material Handler
Laban	Wanjiku	Medical Device Assembler
Laihieng	Phoeuk	Medical Assembler 2
Lakhena	Lor	Medical Assembler 2
Laura	Vivas Rojas	Line Lead
Leidy	Zapata	Line Lead
Leidy	Lozano	Medical Device Assembler
Leila	Rodriguez	Medical Device Assembler
Liliana	Gonzalez	Temp-Tipping Operator
Lina	Kuch	Medical Assembler 1
Lorena	Marinez	Production Manager
Lourdes	Vincent	Medical Assembler 1
Luis	Ortiz	Medical Assembler 3
Luis	Santana	Medical Device Manufacturing Operator
Lynn	Lain	Medical Device Assembler
Madhuri	Balineni	QC Inspector 1
Maleneth	Leng	QC Inspector
Manuel	Santiago	Medical Device Assembler
manuth	pen	Medical Device Assembler
Marady	Meas	Medical Assembler 1
Maria	Izaguirre	Value Stream Supervisor
Mark	Castiglione	Sr. Site Buyer
Mary	Stone	Medical Device Assembler
Mary Ellen	Mastacouris	Sr Documentation Specialist
Mashal	Noori	Medical Device Assembler
Matilde	Soliman	Medical Assembler 2
Mavrick	Mejia	Manufacturing Maintenance Repair Technician
Melinda	Neang	Medical Assembler 1
Michael	Simard	Mechanical Assembler
Michael	Bahou Jr	Medical Device Assembler
Michael	Morrison	Sr. Materials Manager
Michelle	Douston	Medical Assembler 1
Minaben	Patel	Medical Assembler 1
Minh	Koeun	Medical Device Assembler
Miriam	Gonzalez	Medical Assembler 2
Mom	Try	Medical Device Assembler
Monica	Bou	Temp-Medical Device Assembler
Nancy	Pou	Medical Device Assembler
Natalie	Beng	Medical Assembler 2
Nathanael	Zegarski	Quality Engineer II, Product Quality Assurance

First Name	Last Name	Position Title
Neha	Muttal	Sr. Quality Assurance Engineer
Ngan	Trinh	Medical Device Manufacturing Operator
Nilofar	Salejwala	Medical Device Assembler
Oscar	Jimenez	IABP Assembly Operator
Patrick	Lay	Test Technician
Patrick	Calascibetta	Temp-Dip Room Operator
Paul	Em	Temp-Medical Device Assembler
Paula	Meas	Medical Assembler 2
Pedro	De Aza	Medical Device Assembler
Peter	Cintron	Medical Device Assembler
Peter	Brown	Manufacturing Engineer, III
Phalla	Nou	Temp-Packaging Operator
Phoeurn	Hin	Medical Assembler 1
Phouvieng	Mannorind	Medical Assembler 1
Pichsonita	Tat	Line Lead QC Inspector
Prince	Ntalagana	Medical Device Assembler
Priya	Sampath	Sr. Quality Assurance Manager
Puthavy	Aong	Medical Assembler 2
Raascye	Keo	Temp-Medical Device Assembler
Rachel	Higgins	Quality Engineer, II
Rady	Bou	Medical Assembler 1
Rafael	Rivera	Medical Assembler 2
Rahul Reddy	Sangabathula	Manufacturing Engineer II
Ramiz	Khalifa	Medical Device Assembler
Raquel	Veras	Line Lead
Ratana	Thon	Medical Assembler 1
Recarlo	Blackman	Manufacturing Support Specialist
Ricky	Khampannha	Test Technician
Ritha	Sam	Test Technician
Robin	McClarney	Quality Systems Manager
Ronald	Kiggundu	Mechanical Assembler
Ronaldo	Ribeiro Rua	Medical Device Assembler
Rosemary	Mukai	Medical Device Assembler
Rotha	Hay	Manufacturing Technician
Rotha	Meas	Quality Inspector
Rushikesh	Bhagat	Line Lead
Sabera	Gafur	Medical Assembler 1
Salimbhai	Khalifa	Medical Assembler 1
Samira	Pocha	Medical Device Assembler
Sandra	Leonardo-Marin	Medical Assembler 1
Santos	Gutarra Morales	Medical Assembler 1
Saqib	Jalees	Sr. Process Development Engineer
Saram	Chum	Medical Device Assembler
Sareth	Chann	Medical Assembler 2
Savady	Vann	Medical Device Assembler
Savanna	Mckay	Temp- Medical Device Assembler

First Name	Last Name	Position Title
Scott	Moschella	Manager, IABP Operations Everett
Seang	Khan	Medical Assembler 2
Sereimongkol	Sy	Test Technician
Setha	Keo	Test Technician
Seyha	Oeng	Medical Device Assembler
Shakayla	Wright	Temp-Dip Room Operator
Shanawaz Pasha	Mohammed	Manufacturing Engineer II
Sherri	DiGiovanni	QC Inspector
Shilpi	Verma	Dip Room Operator
Shivani	Patel	Temp-Medical Device Assembler
Shobhana	Patel	Calibration Technician
Simon	Dolera	IABP Mechanical Assembly Operator
Sineth	Deth	Lead Test Technician
Sinthy	Nou	Medical Assembler 2
Sitha	Nhim	Medical Assembler 2
Sivchou	Chhiv	Medical Assembler 2
Smita	Patel	Medical Assembler 1
Soan	Leng	Medical Assembler 1
Socheata	Uong	Medical Assembler 1
Socheath	Heyl	Medical Assembler 1
Sodavin	Phat	Medical Device Assembler
Sodie	San	Manufacturing Technician
Sofia	Rodriguez	Medical Assembler 1
Sol	Pen	IABP Assembly Operator
Sombo	Sorng	Medical Device Assembler
Sopheany	Thon	Line Lead
Sophoas	In	Medical Assembler 1
Sophorn	Van	Material Handler
Sorithyvong	Mey	Medical Device Assembler
Sotheany	Ven	Medical Assembler 1
Sovan	Chhoy	Medical Device Assembler
Sovanndara	Neang	Medical Assembler 1
Sovichea	Kheang	Medical Assembler 2
Spesioza	Moriasi	Temp-Medical Device Assembler
Srey Pech	Phat	Medical Device Assembler
Sreyleak	Song	QC Inspector
Sreypao	Suy	Medical Device Assembler
Stephen	Jansen	Mechanical Assembler
Steven	Helser	Plant Manager
Susan	Sum	Medical Assembler 1
Ta	Ry	Medical Device Assembler
Tamara	Salazar	Line Lead
Tea	Sinkler	Temp-Molding Operator
Thanareth	Sarith	Material Handler
Thanh	Doan	Medical Assembler 2
Theard	Jourdan	Stockroom Lead

First Name	Last Name	Position Title
Theary	Lim	Medical Assembler 1
Theng Hong	Lay	IABP Assembly Operator
Thida	Pheng	Line Lead
Thoeun	Nhet	Temp-IAB Assembly Operator
Timothy	Seng	Medical Device Assembler
Tina	Kuy	Medical Device Assembler II
Tony	Dinh	QC Inspector
Tony	Chan	Senior Manufacturing Planner
Vanny	Hang	Medical Device Assembler
vanthon	huy	Medical Device Assembler
Varshaben	Patel	Medical Assembler 1
Vasant	Patel	Medical Assembler 1
Vathana	Sap	Line Lead QC Inspector
Visith	Dou	Test Technician
Vuon	Lieu	Inside Technical Service Supervisor
Wilfrido	Ortiz	Material Handler
William	Singleton	Electrical Engineer
William	Burns	Manufacturing Engineering, III
Yansel	Garcia	Temp-Medical Device Assembler
Yenifer	Paulino	Medical Device Assembler
Yong	Chan	Medical Assembler 1
Yonsaktyna	Keo	Medical Device Assembler
Yosary	Joga Nunez	Medical Assembler 1
Zawadi	Atanga	Medical Assembler 1

4BB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: UTOPIC PHARMACEUTICALS INC.

Physical Address: 5850 CORAL RIDGE DR STE 309

City: CORAL SPRINGS State: FL Zip: 33076

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 9545924118 Website: WWW.UTOPICPHARMA.COM

Name of Designated Representative (DR): ALLEN YANG

Licensing Company Email: N/A DR Email: ALLEN.YANG@UTOPICPHARMA.COM

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	■ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

4/3/24
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: YICHANG HUMANWELL PHARMACEUTICALS CO.

Address: NO.19 DALIAN ROAD City: YICHANG,HUBEI,CHINA State: N/A Zip: 443005

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DELAWARE

Parent Company (if any): DYNAMIC SKY LIMITED

Corporation/Organization Name: UTOPIC PHARMACEUTICALS INC.

Mailing Address: 5850 CORAL RIDGE DR STE 309

City: CORAL SPRINGS State: FL Zip: 33076

Telephone: 9545924118 Email: GENERAL@UTOPICPHARMA.COM

Contact Person Name: ALLEN YANG

Section 6: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

UTOPIC PHARMACEUTICALS INC.

Facility Name

ALLEN YANG

Print Name of Authorized Person Submitting Application



Original signature of Authorized Person (copies or stamps not accepted)

4/3/24

Date

Board Use Only	Date Received: 7/8/24	Amount: $1000-ck 1911

UTOPIC PHARMACEUTICALS

State Licensing Application

Utopic Pharmaceuticals FDA Information

Firm Name	FDA Establishment Identifier	Duns	Business Operations	Address	Registration Expiration Date	Contact Person
Utopic Pharmaceuticals Inc.	3030319262	119189453	LABEL	5850 Coral Ridge Dr Ste 309, Coral Springs, Florida (FL) 33076, United States (USA)	12/31/2024	Name: Allen Yang Email: allen.yang@utopicpharma.com

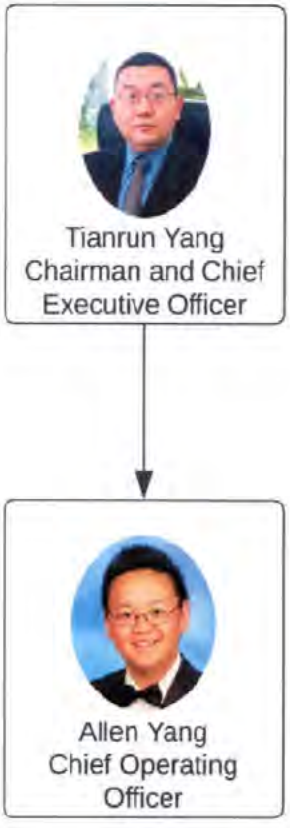
ALL INFORMATION ABOVE IS OBTAINED DIRECTLY FROM THE FDA DATABASE.

Verified 7/3/24 11:11

UTOPIC PHARMACEUTICALS

State Licensing Application

Utopic Pharmaceuticals Organizational Chart



Officer Information

Name: Tianrun Yang
Title: Chief Executive Officer
[redacted]
Percent Ownership: 0%

Name: Allen Yang
Title: Chief Operating Officer
Percent Ownership: 0%

State of Florida

Department of State

I certify the attached is a true and correct copy of the application by UTOPIC PHARAMACEUTICALS INC., a Delaware corporation, authorized to transact business within the State of Florida on January 25, 2024 as shown by the records of this office.

The document number of this corporation is F24000000388.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-fifth day of January, 2024

Cord Byrd
Secretary of State

CR2E022 (01-11)

State of Florida

Department of State

I certify from the records of this office that UTOPIC PHARAMACEUTICALS INC., is a corporation organized under the laws of Delaware, authorized to transact business in the State of Florida, qualified on January 25, 2024.

The document number of this corporation is F24000000388.

I further certify that said corporation has paid all fees due this office through December 31, 2024, and its status is active.

I further certify that said corporation has not filed a Certificate of Withdrawal.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-fifth day of January, 2024

Cord Byrd
Secretary of State

CR2E022 (01-11)

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "UTOPIC PHARMACEUTICALS INC" IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SECOND DAY OF JANUARY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "UTOPIC PHARMACEUTICALS INC" WAS INCORPORATED ON THE FIFTH DAY OF JANUARY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL FRANCHISE TAXES HAVE BEEN ASSESSED TO DATE.

Jeffrey W. Bullock, Secretary of State

2890890 8300

SR# 20240193372

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202635680

Date: 01-22-24

UTOPIC PHARMACEUTICALS

State Licensing Application
Utopic Pharmaceuticals Related Entities

1. **AMTA LABS LIMITED:** Co-Licensed Partner and ANDA Holder
2. **YICHANG HUMANWELL CHINA**: Contract Manufacturer
3. **RXCROSSROADS 3PL LLC**: 3PL Provider
4. **KTK SOLUTIONS**: Industry Consultant

Ron DeSantis, Governor

Melanie S. Griffin, Secretary

Florida dbpr

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

FLORIDA DRUGS, DEVICES AND COSMETICS

THE Prescription Drug Manufacturer - Virtual HEREIN HAS REGISTERED UNDER THE PROVISIONS OF CHAPTER 499, FLORIDA STATUTES

UTOPIC PHARMACEUTICALS INC

5850 CORAL RIDGE DR
STE 309
CORAL SPRINGS FL 33076

LICENSE NUMBER: 4537

EXPIRATION DATE: MAY 31, 2026

Always verify licenses online at MyFloridaLicense.com

ISSUED: 06/17/2024

Do not alter this document in any form.

This is your license. It is unlawful for anyone other than the licensee to use this document.

THE OFFICIAL SITE OF THE FLORIDA DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

Florida dbpr Department of Business & Professional Regulation

ONLINE SERVICES

Apply for a License
Verify a Licensee
View Food & Lodging Inspections
File a Complaint
Continuing Education Course Search
View Application Status
Find Exam Information
Unlicensed Activity Search
AB&T Delinquent Invoice & Activity List Search

LICENSEE DETAILS

6:18:39 AM 6/20/2024

Licensee Information

Name:	**UTOPIC PHARMACEUTICALS INC** (Primary Name)
Main Address:	**5850 CORAL RIDGE DR STE 309 CORAL SPRINGS Florida 33076**
County:	**BROWARD**
License Location:	**5850 CORAL RIDGE DR STE 309 CORAL SPRINGS FL 33076**
County:	**BROWARD**

License Information

License Type:	**Prescription Drug Manufacturer - Virtual**
Rank:	**Rx Drug Manu V**
License Number:	**4537**
Status:	**Current**
Licensure Date:	**05/24/2024**
Expires:	**05/31/2026**

Alternate Names

View Related License Information
View License Complaint

2601 Blair Stone Road, Tallahassee FL 32399 :: Email: Customer Contact Center :: Customer Contact Center: 850.487.1395

The State of Florida is an AA/EEO employer. Copyright ©2023 Department of Business and Professional Regulation - State of Florida. Privacy Statement

Under Florida law, email addresses are public records. If you do not want your email address released in response to a public-records request, do not send electronic mail to this entity. Instead, contact the office by phone or by traditional mail. If you have any questions, please contact 850.487.1395. *Pursuant to Section 455.275(1), Florida Statutes, effective October 1, 2012, licensees licensed under Chapter 455, F.S. must provide the Department with an email address if they have one. The emails provided may be used for official communication with the licensee. However email addresses are public record. If you do not wish to supply a personal address, please provide the Department with an email address which can be made available to the public. Please see our Chapter 455 page to determine if you are affected by this change.

UTOPIC PHARMACEUTICALS

Pertinent Company Information

Federal Regulatory Identification Numbers

ESTABLISHMENT DUNS NUMBER	119189453
FDA ESTABLIMSHMENT NUMBER	3030319262
LABELER CODE	84063
NABP E-PROFILE ID	1799544

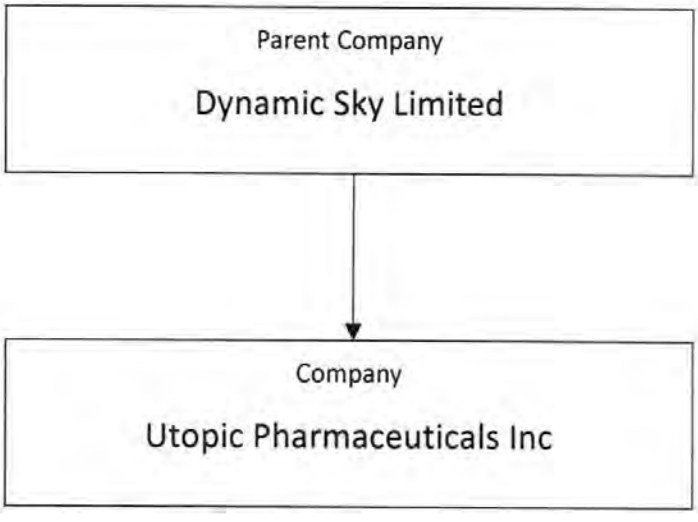
Business Regulatory Identification Numbers

DELAWARE CORPORATION NUMBER	2890890
FLORIDA FOREIGN REGISTRATION NUMBER	F24000000388
EIN	99-0673229

UTOPIC PHARMACEUTICALS

State Licensing Application

Utopic Pharmaceuticals Corporate Organizational Chart



Parent Company Information:

Name: Dynamic Sky Limited
Address: Room 801-2, 8/F., Easey Commercial Building, 253-261 Hennessy Road, Wanchai, Hong Kong
Phone Number: (852)28249890
Email Address: adminas02@biznetvigator.com

Company Information:

Name: Utopic Pharmaceuticals Inc.
Address: 5850 Coral Ridge Dr STE 309, Coral Springs, FL, 33076
Phone Number: +1(954)592-4118
Email Address: general@utopicpharma.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. SU 7111389-0000

Application/License No. _____

Utopic Pharmaceuticals Inc (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5850 Coral Ridge Dr, STE 309 Coral Springs FL 33076 (Address of Applicant/Principal), as PRINCIPAL, and Arch Insurance Company (Surety Company), a corporation organized under the laws of the state of Missouri (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is Harborside 3, 210 Hudson Street, Suite 300, Jersey City NJ 07311 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 06/22/2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 24th day of June, 2024.

APPLICANT/PRINCIPAL
Utopic Pharmaceuticals Inc

Authorized Representative

SURETY COMPANY
Arch Insurance Company

Surety Company's Representative

Christopher Kolger, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Aaron Steffey

Witness Konae Mignott

Countersigned by:

Nevada Resident Agent

AIC 0000348983

Bond SU 7111389-0000

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated. Not valid for Note, Loan, Letter of Credit, Currency Rate, Interest Rate or Residential Value Guarantees.

POWER OF ATTORNEY

Know All Persons By These Presents:
That the Arch Insurance Company, a corporation organized and existing under the laws of the State of Missouri, having its principal administrative office in Jersey City, New Jersey (hereinafter referred to as the "Company") does hereby appoint:

Aaron Steffey and Chris Kolger of Houston, TX (EACH)

its true and lawful Attorney(s)in-Fact, to make, execute, seal, and deliver from the date of issuance of this power for and on its behalf as surety, and as its act and deed: Any and all bonds, undertakings, recognizances and other surety obligations, in the penal sum not exceeding One Million Five Hundred Thousand Dollars (1,500,000.00). This authority does not permit the same obligation to be split into two or more bonds In order to bring each such bond within the dollar limit of authority as set forth herein.

The execution of such bonds, undertakings, recognizances and other surety obligations in pursuance of these presents shall be as binding upon the said Company as fully and amply to all intents and purposes, as if the same had been duly executed and acknowledged by its regularly elected officers at its principal administrative office in Jersey City, New Jersey.

This Power of Attorney is executed by authority of resolutions adopted by unanimous consent of the Board of Directors of the Company on December 11, 2020, true and accurate copies of which are hereinafter set forth and are hereby certified to by the undersigned Secretary as being in full force and effect:

"VOTED, That the Chairman of the Board, the President, or the Executive Vice President, or any Senior Vice President, of the Surety Business Division, or their appointees designated in writing and filed with the Secretary, or the Secretary shall have the power and authority to appoint agents and attorneys-in-fact, and to authorize them subject to the limitations set forth in their respective powers of attorney, to execute on behalf of the Company, and attach the seal of the Company thereto, bonds, undertakings, recognizances and other surety obligations obligatory in the nature thereof, and any such officers of the Company may appoint agents for acceptance of process."

This Power of Attorney is signed, sealed and certified by facsimile under and by authority of the following resolution adopted by the unanimous consent of the Board of Directors of the Company on December 11, 2020:

VOTED, That the signature of the Chairman of the Board, the President, or the Executive Vice President, or any Senior Vice President, of the Surety Business Division, or their appointees designated in writing and filed with the Secretary, and the signature of the Secretary, the seal of the Company, and certifications by the Secretary, may be affixed by facsimile on any power of attorney or bond executed pursuant to the resolution adopted by the Board of Directors on December 11, 2020, and any such power so executed, sealed and certified with respect to any bond or undertaking to which it is attached, shall continue to be valid and binding upon the Company. **In Testimony Whereof**, the Company has caused this instrument to be signed and its corporate seal to be affixed by their authorized officers, this **6th day of August, 2021**

Attested and Certified

Regan A. Shulman, Secretary

Arch Insurance Company
CORPORATE SEAL 1971
Missouri

Arch Insurance Company

Stephen C. Ruschak, Executive Vice President

STATE OF PENNSYLVANIA SS
COUNTY OF PHILADELPHIA SS

I, **Michele Tripodi**, a Notary Public, do hereby certify that Regan A. Shulman and Stephen C. Ruschak personally known to me to be the same persons whose names are respectively as Secretary and Executive Vice President of the Arch Insurance Company, a Corporation organized and existing under the laws of the State of Missouri, subscribed to the foregoing instrument, appeared before me this day in person and severally acknowledged that they being thereunto duly authorized signed, sealed with the corporate seal and delivered the said instrument as the free and voluntary act of said corporation and as their own free and voluntary acts for the uses and purposes therein set forth.

Commonwealth of Pennsylvania - Notary Seal
MICHELE TRIPODI, Notary Public
Philadelphia County
My Commission Expires July 31, 2025
Commission Number 1168822

Michele Tripodi, Notary Public
My commission expires 07/31/2025

CERTIFICATION 7

I, **Regan A. Shulman** , Secretary of the Arch Insurance Company, do hereby certify that the attached **Power of Attorney dated August 6, 2021** on behalf of the person(s) as listed above is a true and correct copy and that the same has been in full force and effect since the date thereof and is in full force and effect on the date of this certificate; and I do further certify that the said Stephen C. Ruschak, who executed the Power of Attorney as Executive Vice President, was on the date of execution of the attached Power of Attorney the duly elected Executive Vice President of the Arch Insurance Company.

IN TESTIMONY WHEREOF, I have hereunto subscribed my name and affixed the corporate seal of the Arch Insurance Company on this **24th day of June, 2024.**

Regan A. Shulman, Secretary

This Power of Attorney limits the acts of those named therein to the bonds and undertakings specifically named therein and they have no authority to bind the Company except in the manner and to the extent herein stated.

PLEASE SEND ALL CLAIM INQUIRIES RELATING TO THIS BOND TO THE FOLLOWING ADDRESS:
Arch Insurance – Surety Division
3 Parkway, Suite 1500
Philadelphia, PA 19102

To verify the authenticity of this Power of Attorney, please contact Arch Insurance Company at SuretyAuthentic@archinsurance.com Please refer to the above named Attorney-in-Fact and the details of the bond to which the power is attached.

Arch Insurance Company
CORPORATE SEAL 1971
Missouri

Printed in U.S.A.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler UTOPIC PHARMACEUTICALS INC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 5850 CORAL RIDGE DR STE 309

City CORAL SPRINGS State FL Zip 33076

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 9545924118 Website WWW.UTOPICPHARMA.COM

Licensing Company Email N/A

Section 2: Personal Information

First TIANRUN Middle _____ Last YANG

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Addres[redacted]

City PARKLAND State FL Zip 33076

Telephone 9545924118 Email ALLEN.YANG@UTOPICPHARMA.COM

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF IOWA		8/92-8/01	
Address	**City**	**State**	**Zip**
2900 UNIVERSITY CAPITOL CENTRE	IOWA CITY	IA	52242
Diploma/Degree obtained, if any			
BACHELORS OF SCIENCE IN CHEMISTRY, PHD IN PHARMACEUTICS			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/18-03/23	[redacted]	PARKLAND	FL	33076
01/01-08/18		CORAL SPRINGS	FL	33076
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
ANDOR PHARMCEUTICALS			06/15-12/23
Business Address	**City**	**State**	**Zip**
8250 SW 27TH AVE	OCALA	FL	34476
Phone	**Title**		**Number of Employed Hours**
9547557229	CO-FOUNDER, PRESIDENT		16000
Description of Duties			
Formulated, researched and commercialized generic version of concerta. Collaborated with Lannett to coordinate wholesale distribution and sales. Oversaw all recordkeeping in regards to sale and distribution of physical product.			

Business Name			From - To (MM/YY – MM/YY)
UTOPIC PHARMACEUTICALS INC			01/24-CURRENT
Business Address	**City**	**State**	**Zip**
5850 CORAL RIDGE DR STE 309	CORAL SPRINGS	FL	33076
Phone	**Title**		**Number of Employed Hours**
9545924118	CHIEF EXECUTIVE OFFICER		1800
Description of Duties			
Oversaw creation of all SOP's regarding recall, product management, security, temperature monitoring, etc. Ensured UTOPIC followed state, federal, and FDA regulations. 3PL implementation. Implement commercialization operations.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
1/17/2024	4/29/24	DE	WILMINGTON	NEW CASTLE COUNTY

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
N22C-06-078-EMD CCLD	SUPERIOR COURT OF THE STATE OF DELAWARE

Reason/Charge
BREACH OF CONTRACT INDEMNIFICATION CLAIM

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
PLAINTIFF/COUNTERCLAIM DEFENDANT	LAWSUIT

Name of Business/Industry/Entity
ANDOR PHARMACEUTICALS LLC

Provide explanation below:

Andor Pharmaceuticals entered into a joint licensing agreement with Lannett Company Inc to manufacture and sell generic drug forms of concerta. The lawsuit is a civil suit brought against Lannett Company by Andor Pharmaceuticals for a breach of contract in regards to unpaid royalty payments and damages.



Original Signature (electronic, copies or stamps not accepted)

11/08/2024

Date

I, TIANRUN YANG , **certify that as the designated representative for**

UTOPIC PHARMACEUTICALS INC ,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. TY I am at least 21 years of age;
3. TY I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. TY I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. TY I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. TY I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. TY I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

TIANRUN, YANG

Print Name (First, Last)



Original Signature (electronic, copies or stamps not accepted)

11/08/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

TIANRUN, YANG

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/08/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Broward

I, TIANRUN, YANG, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/08/2024

Date

Subscribed and Sworn to before me this 8th day of November 2024.

Notary Public Signature David Merkatz

David Merkatz
NOTARY PUBLIC
STATE OF FLORIDA
Appt. No. HH 367674
(Seal) Expires February 28, 2027
Online Notary Center

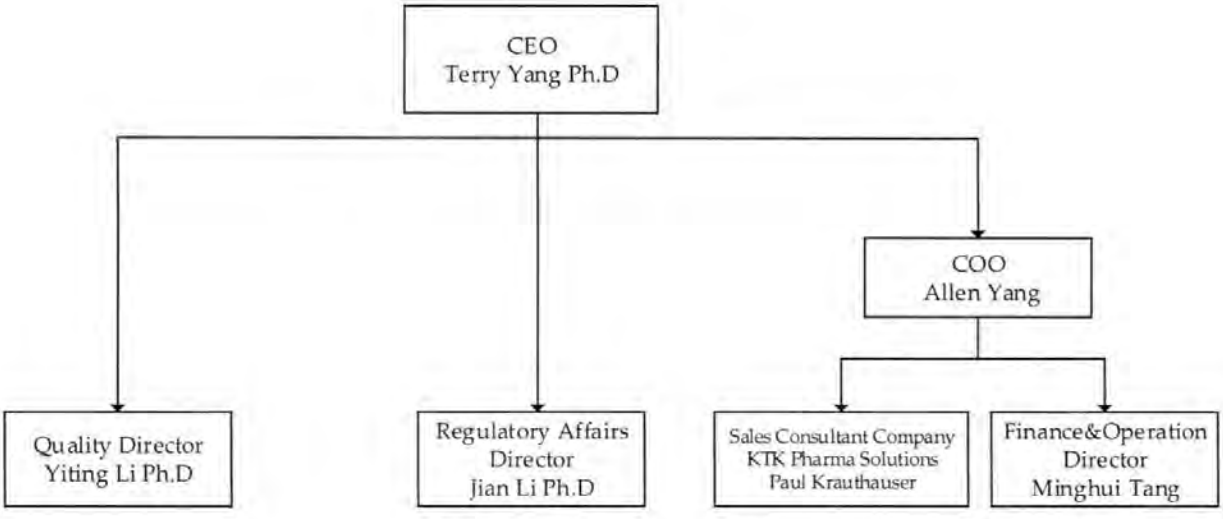
(X)produced Driver's License as ID

Notarial Act performed by Audio-Video Communication.

UTOPIC PHARMACEUTICALS

State Licensing Application

Utopic Pharmaceuticals Organizational Chart



Florida dbpr
Department of Business & Professional Regulation

2601 Blair Stone Road
Tallahassee, Florida 32399-1047
(850) 717-1800
www.myfloridalicense.com

ENTRY NOTICE AND ON-SITE INSPECTION REPORT

DBA Name:		Form Date:	May 22, 2024 10:04 - May 22, 2024 13:05
Full Legal Name:	UTOPIC PHARMACEUTICALS INC	Permit Number:	Rank:
Inspection Reason:	New Bus -X	Telephone Number:	9545924118
Address:	5850 CORAL RIDGE DR CORAL SPRINGS FL 33076	Inspection Visit ID:	8641416
		File Number:	60
		Permit Type:	3345

INSPECTION RESULT Completed

Inspection Authority 499.051 F.S., 61N-1.019, F.A.C. (03/10/2017)

Person Receiving Report/Title Allen Yang, Chief Operational Officer

Facility Hours 61N-1.015(2)(c), F.A.C.

Hours	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	9:00 am	9:00 am	9:00 am	9:00 am	9:00 am	Closed	Closed
Close	5:00 pm	5:00 pm	5:00 pm	5:00 pm	5:00 pm	Closed	Closed

FACILITY/STORAGE [(Rx drug establishments) FS 499.01(2) and 499.0121(1)(b),(d),(e)]

1. Is the establishment a residence? [F.S. 499.012(1)(b)]	No	
2. Lighting adequate? [(OTC drug manufacturers) FS 499.01(2)(n)3 and 21 CFR 211.44] [(Cosmetic manufacturers) 61N-1.010(2)(e), F.A.C.]	Yes	
3. Pest Free? [(OTC drug manufacturers) FS 499.01(2)(n)3 and 21 CFR 211.56] [(Cosmetic manufacturers) 61N-1.010(2)(b), F.A.C.]	Yes	Pest control to be provided from 3pl RxCrossroads
4. Clean and orderly? [(OTC drug manufacturers) 61N-1.014(4), F.A.C.] [(Cosmetic manufacturers) 61N-1.010(2)(a), F.A.C.]	Yes	

RECORD KEEPING [F.S. 499.0121(6)] [61N-1.012 F.A.C.]

5. All records computer based?	Yes	Hybrid (readily available for printing
6. Location of hard copy?		On-site
7. All records manual?	No	Hybrid
8. On-site storage?	No	Virtual manufacturer
9. Shares facility?	No	
10. If yes to #9, separate records?	No	

PRESCRIPTION DRUG ESTABLISHMENT

11. Is the name identical to another person authorized to purchase legend drugs? [F.S. 499.012(1)(c)] [61N-1.015(2)(b), F.A.C.]	No	Utopia
12. Is the person a broker only as defined under [61N-1.001(2)(d), F.A.C.]?	No	Virtual manufacturer

SECURITY [(Rx drug establishments) FS 499.0121(2)(a), (b) and 499.0121(10)(b) or 61N-1.013(1), F.A.C.]

13. Access restricted? [(OTC drug manufacturers) FS 499.01(2)(n)3 and 21 CFR 211.28(c)] [(Cosmetic manufacturers) 61N-1.010(4)(f), F.A.C.]	Yes	
14. Drug facility alarmed?	Yes	Yes

Florida dbpr Department of Business & Professional Regulation

2601 Blair Stone Road
Tallahassee, Florida 32399-1047
(850) 717-1800
www.myfloridalicense.com

15. Telephone monitoring?	Yes	
16. Controlled substance cage (CIII-CV)? [21 CFR 1301.72]	No	No control medication
17. Controlled Substance CII vault? [21 CFR 1301.72]	No	No control medication

STORAGE [(Rx drug establishments) FS 499.0121(3)(5) or 61N-1.013(3)(4), F.A.C.] [(OTC drug manufacturers) 61N-1.014, F.A.C., and/or FS 499.01(2)(n)3 and 21 CFR 211.46] [(Cosmetic manufacturers) 61N-1.010(2), F.A.C.]

18. Quarantine area?	Yes	Located at 3pl
19. Air conditioner?	Yes	
20. Method of monitoring?		Electronic 24 hr monitoring
21. Refrigeration present?	No	
22. Handles drugs or cosmetics requiring refrigeration?		No
23. Method of monitoring refrigeration?		N/a
24. Freezer present?	No	Virtual manufacturer
25. Handles drugs or cosmetics requiring freezing?	No	Virtual manufacturer
26. Method of monitoring freezing temperatures?		Virtual manufacturer

WRITTEN POLICIES AND PROCEDURES [(Rx drug establishments and OTC manufacturers) FS 499.0121(6)(8)(10), 499.01(2) and/or 21 CFR Part 211] [(Cosmetic manufactures) 61N-1.010, F.A.C.]

27. Exist?	Yes	
28. Rx drug annual examination? [F.S. 499.0121(5)(a)2]	Yes	
29. Drug FIFO inventory?	Yes	
30. Recalls/emergencies?	Yes	
31. Natural disasters for Rx drug establishments?	Yes	
32. Receipt and distribution business records?	Yes	
33. Transaction Information, History and Statement (T3) for Rx drug products?	No	Firm to send example of t3 from 3pl provider

INBOUND PRESCRIPTION DRUG BUSINESS RECORDS (Purchases and/or Receipts) [FS 499.0121(6)(b)] [61N-1.012(1)(a),(2)(a), F.A.C.]

34. What are firm's all-inclusive inbound business records that it receives from its Rx drug source(s) per firm for this establishment?	Invoice, packing list , and bill of lading , COA, COC

OUTBOUND PRESCRIPTION DRUG BUSINESS RECORDS (Sales or Otherwise) [FS 499.0121(6)(b)] [61N-1.012(1)(a),(2)(a), F.A.C.]

35. What are firm's all-inclusive typical outbound business records (e.g., sales invoice, packing list, etc.) that it provides to the purchaser and recipient for each Rx drug distribution from this establishment according to firm?		Invoice and packing list
36a. Did firm provide its all-inclusive outbound business records for one (1) of its typical Rx drug distribution?	Yes	Invoice was provided
36b. If yes to 36a, what is the tracking number (e.g., sales invoice or order number, etc.) and distribution date for this provided distribution document?		Invoice
37. Of the document(s) provided in 36a, which document contains the minimum required recordkeeping business elements according to firm?		Sample invoice

38. For the document type referenced in 37 regarding this establishment's outbound Rx drug distributions:

Florida dbpr
Department of Business & Professional Regulation

2601 Blair Stone Road
Tallahassee, Florida 32399-1047
(850) 717-1800
www.myfloridalicense.com

38a. Did firm mark "A" next to the field that lists the seller's name and address?	Yes	
38b. Did firm mark "B" next to the field that lists the seller's Florida permit number?	Yes	
38c. Did firm mark "C" next to the field that lists the shipper's name and address when different from the seller?	Yes	
38d. Did firm mark "D" next to the field that lists the distribution date?	Yes	Firm to update invoice
38e. Did firm mark "E" next to the field that lists the name, strength, dosage form, quantity, and (when assigned) the National Drug Code (NDC) of the Rx drug?	Yes	
38f. Did firm mark "F" next to the field that lists the financial data?	Yes	
38g. Did firm mark "G" next to the field that lists the purchaser's name, address, and Florida permit number?	Yes	
38h. Did firm mark "H" next to the field that lists the physical recipient's name, address and permit or license number, when the recipient is different from the purchaser?	Yes	

N/E = Not Evaluated

Inspection Notes

UTOPIC PHARMACEUTICALS INC
5850 Coral Ridge Drive STE 309,
Coral Springs, FL
Permit 3345

Entered facility at approximately 10:00 am and presented ID, credentials, and Bill of Rights to Allen Yang. This is an Inspection conducted by Drug Inspector Mickell Smith for a routine compliance inspection for a Virtual Prescription Drug Manufacturer Permit for UTOPIC PHARMACEUTICALS INC. Most of the inspection was conducted with Allen Yang Chief Operational Officer will also referred as (ALLEN)

For the purposes of this inspection report UTOPIC PHARMACEUTICALS INC
will be referred to by name or as UTO or firm. Unless specifically indicated by name provided information, answered questions, and provided documents during this inspection and will be referred to by name or collectively as firm. Other employee's inspector met with will be referred to by name.

The hours of operations are 9:00am to 5:00pm Monday to Friday o

Firm understands firm must be available for inspection during business hours. Firm to review 499.051 F.S., 61N-1.015(2)(c) F.A.C. and 61N-1.019 F.A.C

Firm does not share the physical location with any other business .

Firm is a Closely Held Corporation and is owned 100% by Dynamic Sky Limited.
Address: Room 801-2, 8/F., Easey Commercial Building, 253-261 Hennessy Road, Wanchai, Hong Kong
Phone Number: (852)28249890
Email Address: adminas02@biznetvigator.com

Discussed with Firm that a permit issued by DBPR/DDC is non-transferable and only valid for the entity to which it is issued per 499.012(6) F.S. A change in address, hours, ownership, or a closure of the permit, must be communicated to the department in writing before the date of the change.

Florida dbpr
Department of Business & Professional Regulation

2601 Blair Stone Road
Tallahassee, Florida 32399-1047
(850) 717-1800
www.myfloridalicense.com

Key employees/titles and description of job responsibilities are the following:

Terry Yang, Chief Executive Officer
Job description provided to inspector as word doc

Allen Yang, Chief Operating Officer.
Job description provided to inspector as word doc
Jian Li PH.D, Regulatory Affairs Director.
Job description provided to inspector as word doc
Yiting Li Ph.D, Quality Director
- Job description provided to inspector as word doc

Minghui Tang, Finance & Operation Director
Job description provided to inspector as word doc

Paul Krauthauser, Sales Consultant Company – KTK Pharma solution
- MJob description provided to inspector as word doc

Firm does not have any off-site space. All businesses are done from this facility.

Firm has 2 full time employees and other employees work on as needed basis.

ALLEN provided Firm's Organizational chart and ownership chart.

UTOPIC Pharmacueticals INC is a virtual manufacturer of Nisoldipine , an non FDA approved oral calcium channel blocker medication used for the treatment of high blood pressure.

Nisoldipine ER 8.5mg tablet NDC 8406300104 packaging
Labeler code 84063
ANDA holder : amta Labs (firm to provide validation to inspector
Provide information from FDA
None on file (cant find NDC on FDA site)

Firm provided documentation of approval from FDA and firm alerted inspector that firm company AMTA Labs will be ANDA holder . Firm was advised that any medication not approved by the FDA will be considered an adulterated drug.
Firm expressed no medication will be distributed or made until proper licensure.

Firm works with contract manufacturer (CMO) Yichang Humanwell Oral Solid dosage Plant to manufacture their products. Yichang is registered with the FDA, establishment number 3008984460. Note a search in www.myfloridalicense.com shows Yichang does not have an active Non-Resident Prescription Drug Manufacturer permit.

Yichang humanwell oral solid dosage plant currently in the application process (5/20/2024)

Firm's sources must be authorized sources properly permitted with the Department to sell and/or ship into or within Florida FS 499.005(14) and 499.01(2).

Firm is registered with the FDA and identifier is 3030319262.

Firm does not take physical possession of the RX drugs. Firms 3PL is RxCrossroad, located at 170 CLERMONT RD

Florida dbpr
Department of Business & Professional Regulation

2601 Blair Stone Road
Tallahassee, Florida 32399-1047
(850) 717-1800
www.myfloridalicense.com

SHEPHERDSVILLE, KY 40165
Permit# 02409 Exp 11/30/24

Labels were provided and state "Manufactured by Yichang Humanwell Oral solid dose plant .,), for Utopic Pharmaceuticals INC

Business Model

Who provides API/Raw materials for product, firm purchase final product from CMO
Yichang Humanwell Oral solid dose plant manufactures from API/raw materials to finished product and will ship the finished products to RxCrossroad third party logistic provider (3PL)(permit # 02409) located in Shepherdsville, Ky

RxCrossroads is firm's contracted 3PL for receiving, storage and distribution of firm's drug products to firm's customers.

all raw materials to include prescription drug API are purchased and paid for by the CMO. Firm pays the CMO for the finished Rx drug product.

Explain ordering process and shipping verification and temperature verification of product?

Firm clients will purchase prescription drug and Firm will then send order to CMO for manufacturing. Once manufactured firm will ship prescription drugs to the port of savannah (invoice and packing list will be included in shipping) . UTOPIC will receive notification of shipment prior to arrival of medication to the port of savannah through email(Mr. Allen Yang will be the one to notified). Once shipment arrives to Port of Savannah company CMO will hire the transportation to send to 3pl Rxcrossroads in Kentucky which will be CH Robinson a freight forwarder . Once arrival to Rx Crossroads, Utopic will be alerted via email. Firm will be able to access inventory of product via 3pl ERP system. Firm alerted to inspector that inventory will be done daily at 3PL location.
RxCrossroad (3PL) notifies UTOPIC that order was shipped and will send a copy of the packing slip with the shipment.
Firm stated the RxCrossroad(3pl) will handle the distribution and financial obligation to customers.
Firm notified and provided contract with 3PL provider (Rxcrossroads)

Firm aware that even though Rx Crossroad will be handling a portion of its day to day operation, ultimately Utopic will be held responsible its business handling.

Firm to provide inspector of sample t3 and detailed process

RxCrossroads provides packing slip to customer. UTOPIC provides invoice and T3 to customer after the product was shipped

When will payment
Payments are made directly to 3PL (Rx Crossroads) and then payment will be sent to UTOPIC .

Facility
Firm office facility is 1463 sq ft . and contains three offices and one conference room.

Security: Every entrance has maglock door technology that is always active during the after hours of operation and weekends. The maglock door will only open to 4 digit codes personalized to each suite owner. This system tracks all after hour entrances to the property. The building is also equipped with a full camera system that is active 24/7. The lights of the building are always active so that the cameras can capture clear surveillance. If a break in is attempted during after hours, the camera records each of the entrances and has a camera on the main and sole hallway on each of the three floors. The building will alert all suite owners and local police to the scene.

Pest control was provided by (ask for pest control from rx crossroads)
Firm to provide proof pest control at 3pl facility (prove pest free)

Florida dbpr Department of Business & Professional Regulation

2601 Blair Stone Road
Tallahassee, Florida 32399-1047
(850) 717-1800
www.myfloridalicense.com

Firm does not export drugs.

Policy and Procedures provided and reviewed. Firm also provided policy and procedures for 3PL.

Firm does not distribute controlled substances. Firm does not have a DEA registration.

RECORDS
Firm uses S3 amazon cloud computer system and NAS system
Per Firm, Firm receives all inbound shipping documents together prior to the time of shipment confirming the product is ready for pickup (inbound Invoice, inbound Packing Slip,). Bill of lading will be provided at arrival at port.

All records will be stored on a cloud based program (electronic format) and available as needed, or 6 years. Records received electronically such as emailed invoices and purchase orders.
Firm provided SOP for records

Firm advised that records/documents for RX drugs
Cannot be retroactively created and need to be static and can not be altered or defaced in any manner 61N-1.012(2)(d),(9)
Must be maintained by the person involved in the transaction 61N-1.012(8) F.S.
Readily available and retrievable 499.0121(6)(e)F.S. 61N-1.001(2)(s) F.A.C
Contain minimum key elements 499.0121(6)(b)F.S.
Maintained for not less than 6 years 499.0121(6)(f)F.S
Separate and distinct from other business 61N-1.012(12) F.A.C.
The name firm is doing business in should be the same as the permit name 61N-1.015(2)(a) F.A.C.

Outbound Records reviewed and included all key elements required such as: vendor name, address, permit number, date, drug name, strength, quantity, and NDC.

Firm to Update invoice to reflect changes and partnership with 3pl and send to inspector

UTOPIC plans to distributes to wholesalers and direct accounts through its 3PL

Firm to update SOP on transportation on what carrier 3pl will be used to ship

Inventory
Firm supplied SOP on Inventory
How will firm monitor inventory of product?
Firm will update SOP on Inventory to reflect procedure from 3PL.
Firm to provide SOP from 3pl to inspector at later date

Recalls and complaints
Firm to provide SOP on recalls and complaints

Destruction/ Reverse distribution:
Firm provided inspector with SOP on segregation and destruction but firm SOP vague on process that 3pl will do.
Firm to supply destruction SOP from 3pl to inspector at later date
RxCrossroads will takes care of the reverse distribution for Firm.

Firm had references for Chapter 499 and 61N but was advised bookmarked it to a web browser in order to stay up to date on changing rules and regulations.

Florida dbpr
Department of Business & Professional Regulation

2601 Blair Stone Road
Tallahassee, Florida 32399-1047
(850) 717-1800
www.myfloridalicense.com

A permit issued by DBPR/DDC is non-transferable and only valid for the entity to which it is issued per FS 499.012(6). A change in address or ownership, or a closure of the permit, must be communicated to the department in writing before the date of the change. A new application must be submitted and approved prior to the change as per 499.012 F.S. Any changes such as hours of operations or telephone must be reported to the department.

Firm must be available for inspection by the Department during business hours. Firm may not refuse inspection by the Department, including photographs and the review and copying of any record. Firm to review 499.051 F.S and 61N-1.015(2)(c) and 61N-1.019 F.A.C.

Must be compliant with federal, state and local laws as stated in 499.0121(10) F.S., including but not limited to 21-CFR Part 207.20.

Firm advised that the Department issue permitted must be posted in a conspicuous place as per 499.012(7) F.S

Business operations must be maintained separate and distinct from other business operations per 61N-1.012(12)F.A.C..

This report was reviewed and signed by Allen Yang Chief Operation Officer. A copy of the report was provided to by email to at Allen.yang@utopicpharma.com

Additional information related to this inspection may be requested from firm following the on-site inspection, if necessary.

Note that specific statues and rule citations have been included in this report for firms convenience and reference, but should not be considered as an all-inclusive representation of applicable regulations. Please refer to Chapter 499 Florida Statues and Rule 61N-1 Florida Administrative code. A link to the statues and rules can be found on the divisions' website www.myfloridalicense.com/dpbr/ddc.

Firm understands firm must be available for inspection during business hours. Firm to review 499.051 F.S., 61N-1.015(2)(c) F.A.C. and 61N-1.019 F.A.C

Firm understands they need to comply with Federal, State and local laws 499.0121(10) F.S. including reporting themselves annually to FDA.

Firm should establish, maintain and adhere to written policies & Procedures. F.S.499.01(2)(g), 499.0121(8).

Significant discrepancies must be investigated and handled in accordance to regulations. Rule 61N-1.013(6).

Items needed for clarification.
ANDA holder- clarify information
FDA approval of medication nisoldipine 8.5mg with NDC
Track and trace process and example
SOPs from 3pl concerning inventory, destruction/reverse distribution, temperature log monitor
Process for Recall and complaints and updated SOP
Pest control from 3pl
CMO status of permit prior to manufacturing
Updated Invoice (reflecting Florida requirements)

Florida dbpr
Department of Business & Professional Regulation

2601 Blair Stone Road
Tallahassee, Florida 32399-1047
(850) 717-1800
www.myfloridalicense.com

Licensee or Owner Signature

Allen Yang
Chief operation Officer
5850 Coral Ridge Drive Suite 309
Coral Springs, FL 33076
9545924118
May 22, 2024 13:04

Inspector Signature

Mickell Smith
Inspector
May 22, 2024 13:04

May 22, 2024 at 1:05:01 PM EDT
Location:
License #:
Inspector: Mickell Smith

Gmail

Allen Yang <allenkyang@gmail.com>

Re: UTOPIC Post Inspection Materials

Smith, Mickell <Mickell.Smith@myfloridalicense.com> Thu, Jun 13, 2024 at 8:49 PM
To: Allen <allen.yang@utopicpharma.com>
Cc: "allenkyang@gmail.com" <allenkyang@gmail.com>

Good Afternoon Mr. Allen Yang,

Thank you for sending all the post-inspection documents needed for your file to be up to date. I'm emailing you to confirm that all files have been added to our database.
As you know you been granted with a pass for your inspection and received your permit .

Licensee Information

Name:	UTOPIC PHARMACEUTICALS INC (Primary Name)
Main Address:	5850 CORAL RIDGE DR STE 309 CORAL SPRINGS Florida 33076
County:	BROWARD
License Location:	5850 CORAL RIDGE DR STE 309 CORAL SPRINGS FL 33076
County:	BROWARD

License Information

License Type:	Prescription Drug Manufacturer - Virtual
Rank:	Rx Drug Manu V
License Number:	4537
Status:	Current
Licensure Date:	05/24/2024

Best Regards,

Mickell Smith, PharmD

Drug Inspector

Florida Department of Business and Professional Regulation

Division of Drugs, Devices and Cosmetics

5080 Coconut Creek Pkwy. Ste. B

Margate, FL 33063-3942

Phone: 954-956-3681

Fax: 954-917-1343

Email: Mickell.Smith@myfloridalicense.com

NOTE: If you experience any difficulties in emailing large files to me, please use https://attach.dbpr.state.fl.us and select "Public Access" to provide the requested records. This secure portal should also provide you with transaction details listing the file's name and number of files sent at the time of upload for your records of submission. Thank you.

From: Allen <allen.yang@utopicpharma.com>
Sent: Friday, May 31, 2024 7:40 AM
To: Smith, Mickell <Mickell.Smith@myfloridalicense.com>
Subject: UTOPIC Post Inspection Materials

[NOTICE] This message comes from a system outside of DBPR. Please exercise caution when clicking on links and/or providing sensitive information. If you have concerns, please contact your Knowledge Champion or the DBPR Helpdesk.

Hi Mickell,

I have had my team revise and update all our SOP's and have included links for the 3PL SOP's which should allow you to view their materials.

Here is a synopsis of the changes in our SOP's:
1. Track and trace process (detailed DSCSA process): Refer to revision part of the SOP UT-009.
2. Update SOP on transportation on what carrier 3PL will be used to ship: Refer to 5.1.2 in the SOP UT-001.
3. Update SOP on Inventory to reflect procedure from 3PL: Refer to the "Inventory Check" part in 5.1 of the SOP UT-001.
4. Updated SOP for recalls: Refer to revision part of the SOP UT-003.
5. SOP for complaints: Refer to the newly prepared SOP UT-012 for complaint handling.
Remark: In this SOP, it is mentioned that the designated third-party vendor is responsible for receiving, recording, primary evaluation, communication and follow-up, responding for all the product complaints from US market.
6. Update SOP for destruction: Refer to the "Destruction of prescription drugs" part in 5.1 of the SOP UT-001; Refer to the revision part of the SOP UT-008.

Below is the relevant 3PL SOP's which will be viewable up till the end of next week (June 7th):

pdf icon DC001v2 Receiving Process SAP.pdf
pdf icon DC002v7 PPS.pdf
pdf icon EH-019v6 Security Policy.pdf
pdf icon HR001v16 Required Training.pdf
pdf icon IC001v2 Recalls Market Withdraw Notification.pdf
pdf icon IC006v3 Physical Inventory Scanning Process SAP.pdf
pdf icon IC009v4 Destruction Procedure.pdf
pdf icon MT001v4 Temp Deviation Management.pdf
pdf icon QA004v16 Nonconformances Corrective and Preventative Action.pdf
pdf icon QA021v13 Continuous Temperature Monitoring.pdf
pdf icon QM001v11 Quality Manual.pdf
pdf icon IC007v3 Returns Procedure SAP.pdf
pdf icon MT006v6 Pest Control.pdf

The unaltered SOP's are also included as well.

Under our SOP's, I have included the reference outbound business records, invoice and packing slip, for our customers which fulfills the listed requirements in the inspection items 38(a-h). We also would like to alter our response in question 37 to sample invoice and packing slip.

The invoice and packing slip attached is the reference one created by our 3PL which will utilize our information when we start conducting business. We are currently in the implementation stage within their system so an invoice tailored to our companies details has not been fully created yet.

The packing slip, according to my 3PL, would act as the T3 report as it would list on the bottom the transaction history of the product. (The empty table listed on the packing slip currently)

The customer can also access the T3 data online through electronic methods on the Mckesson platform.

Next, we would like to update the information regarding the financial services portion of our response within the inspection report.
Our 3PL will handle financial aspects of our operations such as calculating chargebacks and rebates, invoices, and generating financial reports. But during the transactions between customer and UTOPIC, customer will directly pay a UTOPIC receivables account.

Lastly, if all this information is sufficient, how can we obtain a copy of the final published inspection report?

If you believe there are still pieces of information our post inspection response lacks, please let me know!
Thanks,

Allen Yang
Chief Operating Officer
Cell: (954) 592 - 4118
Email: allen.yang@utopicpharma.com
www.utopicpharma.com

UTOPIC PHARMACEUTICALS

ENI for Utopic.pdf
167K

4CC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 3133	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Waylis Therapeutics LLC

Physical Address: 2131 Felver Court, Suite B

City: Rahway State: NJ Zip: 07065

Mailing Address (if different from physical address): Same as above.

City: _____ State: _____ Zip: _____

Telephone: 800-689-0255 Website: www.waylistherapeutics.com

Name of Designated Representative (DR): Himanshu Brahmbhatt

Licensing Company Email: Compliance.waylis@gmail.com DR Email: Compliance.waylis@gmail.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	■ Others: Over-the-counter drugs	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A				
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

1/30/2024

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Michigan

Parent Company (if any): WE2, LLC

Corporation/Organization Name: Waylis Therapeutics, LLC

Mailing Address: 2131 Felver Court, Suite B

City: Rahway State: NJ Zip: 07065

Telephone: 800-689-0255 Email: compliance.waylis@gmail.com

Contact Person Name: Ellen Gettenberg

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Waylis Therapeutics LLC

Facility Name

Himanshu Brahmbhatt

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

1/30/2024

Date

Board Use Only	Date Received: 8/20/24	Amount: $1000 - ck 12912

Licensing details

Applicant:

Waylis Therapeutics LLC
2131 Felver Court, Suite B
Rahway, NJ 07065
EIN: 85-2942824

Michigan Limited Liability Company incorporated on August 28, 2020

Parent Company:	WE2, LLC	100% Ownership
Method of Distribution:	Third Party Logistics Provider	
	RxCrossroads 3PL LLC 4200 Binion Way, Suite 200 Mason, OH 45036	DEA# RR0577241
Contracted CMO:	Avet Pharmaceuticals Inc. 21B Cotters Ln East Brunswick, NJ 08816, USA	FDA# 3005139373

Nature of Business:

Waylis Therapeutics LLC (Waylis) is a virtual manufacturer that intends to sell legend prescription drugs. Waylis will utilize contract manufacturers to produce its products and a licensed third-party logistics provider to warehouse and distribute. Waylis will never physically manufacture or distribute any products. Waylis is not required by the Drug Enforcement Administration to obtain registration, as there are no controlled substances on its premises. The state of Michigan does not inspect Virtual Manufacturers.

FDA Labeler Code:80725 ✓ Verified M.H 9/11/24

Waylis Therapeutics LLC
2131 Felver Ct., Suite B, Rahway, NJ 07065
Tel (800) 689-0255
www.waylistherapeutics.com

Waylis Therapeutics LLC Corporate Officers

Name: Himanshu Brahmbhatt

Title: CEO/President

Business Address: 2131 Felver Ct, Ste B, Rahway, NJ 07065

[redacted]

Name: David Risk

Title: Officer

Business Address: 2131 Felver Ct, Ste B, Rahway, NJ 07065

[redacted]

WE^2 – 100% ownership of Waylis Therapeutics LLC

47220 Cartier Dr, Ste. C

Wixom, MI 48393

47220 Cartier Drive, Suite B, Wixom, MI 48393 | P 248-313-9675 F 248-928-2046 | waylistherapeutics.com

Product List 2023

NDC	Product Name	Count	Reference Brand	Case Quantity	WAC Pricing
80725-250-01	Humatin® (Paromomycin Sulfate Capsules), 250mg	100	Humatin®	24	$10,312.20
80725-600-18	Eulexin® (Flutamide Capsules), 125mg	180	Eulexin®	24	$4,620.18
80725-004-01	Valium® (diazepam) Tablets, 2mg	100	Valium®	48	$488.00
80725-005-01	Valium® (diazepam) Tablets, 5mg	100	Valium®	48	$759.00
80725-006-01	Valium® (diazepam) Tablets, 10mg	100	Valium®	48	$1,277.00

© Waylis Therapeutics LLC

Waylis Therapeutics LLC



STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

WAYLIS THERAPEUTICS LLC
0450682910

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named Michigan Foreign Limited Liability Company was registered by this office on July 29, 2021.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

C T CORPORATION SYSTEM
820 BEAR TAVERN ROAD
WEST TRENTON, NJ 08628

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 5th day of February, 2024

Elizabeth Maher Muoio
State Treasurer

Certificate Number: 6150519444

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0749711

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 – "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

2131 FELVER CT, STE B RAHWAY, NJ 07065-

Reg. No.
5006358

WAYLIS THERAPEUTICS LLC
2131 FELVER CT, STE B
RAHWAY, NJ 07065-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2025

Establishment Copy

Ohio eLicense Ohio Professional Licensure

License Look Up

11/7/2023 9:52 AM

RxCrossroads 3PL LLC

License Number	0172000014
Status	Active
Sub-Status	
Board	Board of Pharmacy
License Type	Third-Party Logistics - Category 3
License Issue Date	01/09/2020
License Expiration Date	06/30/2025
License Effective Date	07/01/2023
Street Address	4200 Binion Way Ste 200
City	Mason
State	OH
Zipcode	45036-9469
Country	United States
Board Action	No

Supervised By:

Supervisor Name	Supervisor License	Status	Start Date	End Date
		Active		

Current date & time: **11/7/2023 9:52 AM**

Disclaimer: The Joint Commission and NCQA consider on-line status information as fulfilling the primary source verification requirement for verification of licensure in compliance with their respective credentialing standards.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RR0577241	04-30-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-08-2024

RXCROSSROADS 3PL LLC
4200 BINION WAY STE 200
MASON, OH 450369469

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RR0577241	04-30-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-08-2024

RXCROSSROADS 3PL LLC
4200 BINION WAY STE 200
MASON, OH 450369469

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RR0577241	04-30-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-08-2024

RXCROSSROADS 3PL LLC
4200 BINION WAY STE 200
MASON, OH 450369469

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

THE HARTFORD

Verification Certificate

This is to certify that Bond No. 45BSBIS0685 issued by the member company of The Hartford subscribing this certificate, dated July 14, 2021,

in the amount of One Hundred Thousand and 00/100 Dollars ($100,000.00)

on behalf of Waylis Therapeutics, LLC , as Principal,

and in favor of the State of Nevada and the Nevada State Board of Pharmacy , as Obligee,

covers an indefinite term which began on July 14, 2021 , and ends with the cancellation of said bond; that said bond is now in full force and effect and will continue in full force and effect until cancelled.

ANNIVERSARY PREMIUM PERIOD: July 14, 2022, to July 14, 2023.

Signed, Sealed, and Dated November 11, 2022.

Attest or Witness

Surety
Hartford Fire Insurance Company

By: Vicki S. Duncan (Seal)

Vicki S. Duncan , Attorney in fact

CC:

CC:

1030

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-12
One Hartford Plaza
Hartford, Connecticut 06155
Bond.claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: HYLANT GROUP INC
Agency Code(s): 35-351588, 35-350851, 81-151273

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [X] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [X] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast**, a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut, (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint, ***up to the amount of unlimited:***

Susan E. Hurd, Vicki S. Duncan, Michael M. Hylant, Jamie Laurencelle, Kristie A. Pudvan, Lisa M. Wilmot, Judy K. Wilson, Kathy S Zack, Terri Mahakian

their true and lawful Attorney(s)-in-Fact, each in their separate capacity if more than one is named above, to sign its name as surety(ies) only as delineated above by ☒, and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } **ss.** Lake Mary

On this 20th day of May, 2021, before me personally came Joelle L. LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone
My Commission HH 122280
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of **November 11, 2022.**

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Waylis Therapeutics LLC

Pharmacy/Wholesaler License # (if applicable): WH03133

Physical Address: 2131 Felver Court, Suite B

City: Rahway State: NJ Zip: 07065

Mailing Address (if different from physical address): Same as above.

City: State: Zip:

Telephone: 800-689-0255 Website: www.waylistherapeutics.com

Licensing Company Email: compliance.waylis@gmail.com

Section 2: Personal Information

First: Himanshu Middle: Last: Brambhatt

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Edison State: NJ Zip: 08817

Telephone: 800-689-0255 Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
North Bergen High School		09/91 - 05/95	
Address	**City**	**State**	**Zip**
7417 John F. Kennedy Blvd	North Bergen	NJ	07047
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Montclair State University		09/95 - 05/99	
Address	**City**	**State**	**Zip**
1 Normal Ave	Montclair	NJ	07043
Diploma/Degree obtained, if any			
Baccalaureate			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
Present	[redacted]	Edison	NJ	08817
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Waylis Therapeutics LLC			From - To (MM/YY – MM/YY)
Business Address: 2131 Felver Court, Suite B	City: Edison	State: NJ	Zip: 07065
Phone: 800-689-0255	Title: President & CEO		Number of Employed Hours
Description of Duties: Resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A				
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date 1/30/2024

I, Himanshu Brambhatt, **certify that as the designated representative for**

Waylis Therapeutics,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. HB I am at least 21 years of age;
3. HB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. HB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. HB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. HB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. HB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Himanshu Brambhatt

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/30/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Himanshu Brambhatt

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/30/24

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Union

I, HIMANSHU BRAHMBHATT, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/30/24

Date

Subscribed and Sworn to before me this 30th day of January

Notary Public Signature

CHRISTINA ABREU
NOTARY PUBLIC
STATE OF NEW JERSEY
ID # 2416998 (Seal)
MY COMMISSION EXPIRES FEB. 07, 2027

Himanshu Brahmbhatt

[redacted]

Practice Area:
Strategy and growth, operations, B2B Sales & marketing, corporate finance, Corporate social responsibility, sustainability, Organization performance (leadership, human capital management, Transformation and culture change), effective altruism (EA), Diversity, equity and inclusion (DE&I), public relations, social media, and public affairs.

Industry:
Pharmaceuticals & Life Sciences, Healthcare, Energy, Big tech, Telecom & Satellites, Global supply chain & Logistics, Media & Entertainment, Retail, Hospitality, Non-profit and government.

Summary:
Himanshu Brahmbhatt has over 20 years of experience as a business management executive and strategic advisor. His focus remains in business and growth strategy, sales and marketing, organization design, leadership, operations, corporate affairs and public affairs. He has held key executive positions within private sector and has served as an advisory in both public and private sector. Over the years he has worked with major organizations; including fortune 500 companies, private enterprises, and non-profits at local, national, and global platform.

History:

Jan 2005 – Present (CEO - Globe Communications)
Currently Himanshu is the Chief Executive at Globe Communications Inc; a business consultancy based in the US. Globe Comm is geared towards private enterprises, federal government, and Non-profits/NGO's. Its client base and operations are primarily in US, EU, UAE, and South East Asia. Globe undertakes wide range of projects for its portfolio of clients among various industries. Himanshu serves as a strategic advisor to clients providing key insights and decision making for given project while maximizing bottom line of the partner organization.

Jan 2006 – Present (VP, Sunrise Pharmaceutical, Inc – Generic Drug Manufacturer)
Himanshu is a partner and Vice president at Sunrise Pharmaceutical, Inc; a generic drug manufacturing organization based in the US. Sunrise manufactures and distributes generic drugs in both control substance (Class II, III, IV, V) and non-control drugs. At Sunrise Himanshu oversees Sales, Business Development, and corporate affairs. He is responsible for building and managing the entire client base, business development and operations for Sunrise Pharmaceutical. Himanshu oversees multiple business units while improving company's efficiency, productivity, and profitability.

Extracurricular:
In addition to his professional duties, he serves as Gov't relations and PR advisory for a UN affiliated NGO under United Nations Social and Economic Development (EcoSoc). Himanshu is a Six sigma black belt and holds a BS degree.

Waylis Therapeutics, LLC List of Employees

Himanshu Brahmbhatt, Designated Representative, Officer CEO/President

Jessica Reyes, Customer Service/Admin Assistant

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER, ENVIRONMENTAL AND OCCUPATIONAL HEALTH SERVICE
PUBLIC HEALTH AND FOOD PROTECTION PROGRAM
P.O. BOX 369, TRENTON, NJ 08625-0369
609-826-4935

REPORT OF INSPECTION

Assignment No **17736**
Inspection End Date **09/27/2023**

Registration #	Category	Inspection Type	Evaluation
5006358	**Wholesale Drug/Medical Device**	**Initial**	**Satisfactory**

Name of Owner or Corporation	Trade Name	Activity
Waylis Therapeutics LLC	**Waylis Therapeutics LLC**	**Office Only**

Establishment Street Address	City	ZIP	County
2131 Felver Court, Suite B	**Rahway**	**07065**	**Union**

Establishment Mailing Address (if different)	Phone Number	Fax Number
	(800) 689-0255	

Name and Title of Inspecting Official	REHS Lic. #	Operational Status	Embargo	Reinspect on or After
Katie Lasso, REHI	**B156230**	**Operational**	**No**	

Name and Title of Designated Representative	Email
Himanshu Brahmbhatt, President and CEO	**himanshu@waylistherapeutics.com**

Products
☐ Prescription Drugs ☐ OTC Drugs ☐ Class I Medical Devices ☐ Class II Medical Devices ☐ Class III Medical Devices
☐ Drug-Device ☐ API ☐ Veterinary Drugs ☒ No Products Stored/Handled Onsite

TIME/ACTIVITY REPORT (1-TRAVEL, 2-INSPECTION, 3-ADMINISTRATION, 4-PERSONAL) TOTAL HOURS: 00.00

DATE	CODE	BEGIN	END	CODE	BEGIN	END	CODE	BEGIN	END
09/27/2023	1	09:00	10:30	2	10:30	14:30	1	14:30	15:45
09/28/2023	3	13:45	14:15						

		YES	NO	N/A
	N.J.A.C. 8:21-3A.7 Personnel Requirements			
	Personnel employed by a wholesale distributor have appropriate education and/or experience to assume responsibility for positions related to compliance with State registration requirements	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.8 Facility *Facilities at which drugs are stored, warehoused, handled, held, offered, marketed or displayed:*			
(a) 1	Of suitable size and construction to facilitate cleaning, maintenance, and proper operations	☐	☐	☒
(a) 2	Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions	☐	☐	☒
(a) 3	Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened	☐	☐	☒
(a) 4	Maintained in a clean and orderly condition	☐	☐	☒
(a) 5	Free from infestation by insects, rodents, birds, or vermin of any kind	☐	☐	☒
Note				

		YES	NO	N/A
	N.J.A.C. 8:21-3A.9 Security			
(a)	Facility is secured from unauthorized entry	☒	☐	☐
(a) 1	Access from outside premises is kept to a minimum and is well controlled	☒	☐	☐
(a) 2	The outside perimeter of the premises is well-lighted	☐	☐	☒
(a) 3	Entry into areas where drugs are held shall be limited to authorized personnel	☐	☐	☒
(b)	All facilities are equipped with an alarm system to detect entry after hours	☒	☐	☐
(c)	Facilities are equipped with a security system that provides suitable protection against theft and diversion. When applicable, the security system provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.10 Storage			
(a)	All drugs are stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, of the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).	☐	☐	☒
(b)	If no storage requirements are established for a drug, the drug is held at controlled room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected	☐	☐	☒
(c)	Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs are utilized to document proper storage of drugs	☐	☐	☒
(d)	For prescription drugs a record is maintained that includes the date, time, thermometer temperature, and the initials of the person recording the data	☐	☐	☒
Note				
	N.J.A.C. 8:21-3A.11 Examination of Materials			
(a)	Upon receipt, each outside shipping container is visually examined for identity and to prevent the acceptance of contaminated drugs or drugs that are otherwise unfit for distribution. This examination is adequate to reveal container damage that would suggest possible contamination or other damage to the contents.	☐	☐	☒

		YES	NO	N/A
(b)	Each outgoing shipment is carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.	☐	☐	☒
Note				
	N.J.A.C. 8:21-3A.12 Returned, Damaged and Outdated Drugs			
(a)	Outdated, damaged, deteriorated, misbranded, or adulterated drugs are quarantined and physically separated from other drugs until they are destroyed or returned to their supplier	☐	☐	☒
(b)	Drugs whose immediate or sealed outer or sealed secondary containers have been opened or used are identified as such, quarantined and physically separated from other drugs until they are either destroyed or returned to the supplier	☐	☐	☒
(c)	If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug is destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity	☐	☐	☒
Note				
	N.J.A.C. 8:21-3A.13 Recordkeeping			
(a)	Inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs are maintained	☒	☐	☐
(a) 1	Source of drugs, name and principal address of the seller or transferor, and address from which drugs were shipped are maintained	☒	☐	☐
(a) 2-3	Identity and quantity of drugs received and distributed/disposed, date of receipt and distribution, disposal.	☒	☐	☐
(a) 5	A complete and accurate annual record of all stock of drugs on hand.	☒	☐	☐
(d)	An ongoing listing of all retail and wholesale establishments with whom they do business.	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.14 Due Diligence *Firm is performing due diligence of other wholesale establishments with whom they do business, which requires that prior to the initial purchase or acquisition of drugs from another wholesale distributor, a wholesale distributor shall obtain the following information from the selling wholesale distributor:*			
(a) 1	Copies of all state and Federal regulatory licenses and registrations	☐	☐	☒
(a) 2	The wholesale distributor's most recent facility inspection reports	☐	☐	☒
(a) 3	A list of other names under which the wholesale distributor is doing business or by which the wholesale distributor was formerly known	☐	☐	☒

		YES	NO	N/A
(a) 4	A list of corporate officers and managerial employees and designated representatives	☐	☐	☒
(a) 5	A verification of the selling wholesale distributor's status as an authorized distributor of record, if applicable.	☐	☐	☒
(b)	At least annually, a wholesale distributor that purchases drugs from another wholesale distributor updates the information set forth in (a) 1-5 above.	☐	☐	☒
(c)	No purchases were placed from any storage facility, manufacturer or wholesale distributor not having a current license or registration within the jurisdiction of the establishment location from where product is purchased.	☐	☐	☒
(d)	No purchase or acquisition has been made from a firm that has not provided complete information as set forth in (a) 1-5 above.	☐	☐	☒
Note				
	N.J.A.C. 8:21-3A.15 Availability of Records and Inventories			
(a)	Records and inventories, including those related to salvage and reprocessing, are made available for inspection and photocopying by authorized Federal, State, or local law enforcement agency officials for a period of 3 years after the date of their creation	☒	☐	☐
(b)	Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means are readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable are made available for inspection within 2 working days of a request by an authorized official of a Federal, State, or local law enforcement agency	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.16 Policies and Procedures			
(a)	Firm established and follows written policies and procedures for the receipt, security, storage, inventory, and distribution of drugs	☐	☒	☐
(a)	Firm has policies for identifying, recording and reporting losses or thefts and correcting errors in inventories	☐	☒	☐
(a) 1	Firm has a procedure where oldest stock is distributed first.	☒	☐	☐
(a) 2	Firm has a procedure for handling recalls/withdrawals of drugs.	☒	☐	☐
(a) 3	Firm has a procedure for preparation, protection and proper handling of any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster	☒	☐	☐
(a) 4	Firm has a procedure for handling return of outdated drugs; segregation and written documentation of disposal, by either returning the drug to the manufacturer or destruction of the drug. This documentation shall be maintained for 2 years after disposition of the outdated drugs.	☐	☒	☐

		YES	NO	N/A
Note	Product Disposition Procedure SOP 011 did not address cold chain product shipping from the manufacturing facility and third party logistics provider warehouse. There was no documented process to be followed for ensuring safety and quality of cold chain product while in transit. The firm did not have a written procedure for identifying, recording and reporting losses or thefts and correcting errors in inventory. The firm did not have a written procedure for handling return of outdated product including maintaining disposal records for 2 years after the disposition of the drug. The following documents were provided for review: Agreement between RxCrossroads 3PL LLC and Woodward Pharma Services LLC of September, 2021 Product Disposition Procedure SOP 011 Recall Procedure SOP 005 Business Continuity Disaster Recovery SOP 007 Compliant Handling Procedure SOP 010 Supplier Qualification Procedure SOP 013			
	N.J.A.C. 8:21-3A.17 List of Responsible Persons			
	A current list of officers, directors, managers, and other personnel in charge of wholesale distribution, storage, and handling of drugs is maintained at the firm	☒	☐	☐
	Description of duties and qualifications of personnel is maintained at the firm	☐	☒	☐
Note	**The firm did not maintain written descriptions of qualifications and job responsibilities.**			
	N.J.A.C. 8:21-3A.19 Salvage; Reprocessing			
	Salvaging and reprocessing operation is in compliance with 21 CFR 207, 210, 211	☐	☐	☒
Note				

K. Lasso

Inspecting Official

Waylis Therapeutics LLC
2131 Felver Court, Suite B, Rahway, NJ 07065
Tel (800) 689-0255
www.waylistherapeutics.com

Waylis THERAPEUTICS

Subject: Waylis Therapeutics, LLC –Change of Ownership Notice
Internal Company Restructure

This notarized document is to advise that the change in the ownership of the company, Waylis Therapeutics, LLC, has been transferred from Future Pak, LLC to WE2, LLC. The change is set to take effect on 11/15/23.

There will be no change in Waylis Therapeutics, LLC's policies.

Executed on this date 10/20/23

FUTURE PAK, LLC
Name: DAVID RISK
Title: Chairman
Dated: 10/20/23

WE2, LLC
Name: DAVID RISK
Title: Chairman
Dated: 10/20/23

State of Michigan
County of Oakland
This record was acknowledged before me on 10/20/2023 (date)
by David Risk (name(s) of individual(s)).
Notary Signature Jacey Schuetz
My commission expires 9/18/28

JACEY SCHUETZ
NOTARY PUBLIC - STATE OF MICHIGAN
COUNTY OF OAKLAND
My Commission Expires 9/18/2028
Acting in the County of Oakland

Oakland

Waylis Most-Recent Licenses as of 11/1/2023

State	Expiration Date	License Type	License/Registration Number
*DEA - RxC	Apr-24		
AL	Dec-23	Private Label Distributor (Virtual)	196163
AK			
AZ	Oct-24	Manufacturer - Virtual	M001836
AR	Dec-23	Wholesale Distributor	WD05570
CA			
CO			
CT	No expiration	Out of State Manufacturer of Drugs	CSM.0002039-OOS
DE			
DC	Nov-23	Non-Resident Manufacturer	DM2100222
FL	Jan-24	Non-Resident Rx Drug Manufacturer - Virtual	46308
GA	Jun-25	Wholesaler Pharmacy	PHWH005191
HI			
ID	Dec-23	Virtual Manufacturer Registration	M62800
IL			
IN			
IA	Dec-23	Wholesale Broker/Virtual Manufacturer	41471
IA CS	None required		
KS	Jun-24	Manufacturer	4-115930
KY	Sep-24	Wholesale Distributor	W04626
LA	Dec-23	Standard Distributor	10304
ME	None required		
MD	May-25	Distrubutor	DO6980
MA			
MI	Jan-25	Wholesale Distributor	5306006621
MI CS	Jan-25	Controlled Substance	5315221946
MN	May-24	Manufacturer	461974
MS	Dec-23	Virtual Manufacturer	18412/16.4AM
MS CS	Dec-23	Controlled Substance	CS-19158
MO	Oct-25	Drug Distributor	2021013874
MT	Nov-23	Wholesale Drug Distributor	PHA-WDD-LIC-79774
NE			
NV	Oct-24	Wholesaler	WH03133
NH	None required		
NJ	Jan-24	Manufacturer and Wholesaler	5005994
NM	Dec-23	Wholesaler Virtual Manufacturer	WD00012979
NM CS	May-25	Controlled Substance	CS00230996
NY	Sep-24	Wholesaler not NYS	039186
NC	Dec-23	Virtual Manufacturer Registration	1720
ND	Jun-24	Virtual Manufacturer	Whol2718
NV	Oct-24	Wholesale Distributor	WH03133
OH	Jun-25	Wholesale Distributor	132000088
OK	Jul-24	Manufacturer	88-M-7034
OK CS	Oct-24	Controlled Substance	10003266
OR	Sep-24	Manufacturer	M-0003612-CS
PA			
RI			
SC			
SD	Dec-23	Wholesale	600-3344
SD CS	Apr-24	Controlled Substance	RR0577241
TN	Jul-25	Manufacturer	00007010
TX	Jan-25	Wholesale Distributor	1003156
UT	Sep-25	Pharmacy - Class C, Manufacturer	12455929-1710
VT	Jul-25	Non-resident Manufacturer	163.0000534
VA	None required		
WA	Sep-24	Pharmaceutical Wholesaler	PHWH.FX.61200989
WV	Jun-24	Drug Manufacturer	MR0552237
WI			
WY			

Registration Number: 5005994 **Registered as:** Manufacturer and Wholesale Print Verification Certificate

Name: WAYLIS THERAPEUTICS LLC

DBA:

Address: 47220 CARTIER DR, STE B, WIXOM, MI 48393

Original Issue Date: 07/19/2021 **Expiration Date: 01/31/2024**

Current Issue Date: 01/20/2023

Disciplines: No

Registration Number: 5006358 **Registered as:** Wholesale Print Verification Certificate

Name: WAYLIS THERAPEUTICS LLC

DBA:

Address: 2131 FELVER CT, STE B, RAHWAY, NJ 07065

Original Issue Date: 10/20/2023 **Expiration Date: 01/31/2025**

Current Issue Date: 10/20/2023

Disciplines: No

4DD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: ZO Skin Health, Inc.

Physical Address: 9685 Research Drive

City: Irvine State: CA Zip: 92618

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: 949-988-7524 Website: http://www.zoskinhealth.com

Name of Designated Representative (DR): Hector Serna

Licensing Company Email: cngo@zoskinhealth.com DR Email: hserna@zoskinhealth.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☑ Pharmacies	☑ Dangerous Drugs	☐ Manufacturer
☑ Practitioners	☐ Controlled Substances	☐ Repacker
☑ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☑ Others: OTC, costmetics, topical	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☑ Others: Clinics		☑ Others: virtual manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

PAGE REVISED AFTER EXECUTION OF APPLICATION TO CORRECT DISCIPLINARY HISTORY QUESTION

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

See Attached Disciplinary Orders and Supporting Documents

Original Signature (electronic, copies or stamps not accepted)

8/22/2024
Date

ZO SKIN HEALTH, INC. SUMMARY OF DISCIPLINARY HISTORY

FDA WL 41-16

- Name: U.S. Food & Drug Administration
- Location of Facility: 5 Technology Drive, Irvine, CA 92618
- Date of Disciplinary Action: August 29, 2016
- Description of Action:
  - Warning Letter received regarding website claims that presented the cosmetic products being offered for sale by ZO Skin Health as being drug products under sections 201(g)(1)(B) and/or 201 (g)(1)(C) of the Federal Food, Drug and Cosmetic Act because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or articles intended to affect the structure or any function of the human body.
  - ZO Skin Health immediately corrected all product descriptions and claims on its website.
- Status of Case: Pending Closure

Alabama Case No. 19-L-0039

- Name: Alabama State Board of Pharmacy
- Location of Facility: 5 Technology, Irvine, CA 92618
- Date of Disciplinary Action: February 19, 2019
- Description of Action:
  - Violations of AL Board Rule 680-X-2.23 for the following previous issues:
    - FDA Warning Letter dated August 29, 2016 for website claims that presented the cosmetic products being offered for sale as being drug products under sections 201(g)(1)(B) and/or 201 (g)(1)(C) of the Federal Food, Drug and Cosmetic Act.
    - Consent Order by the OR State Board of Pharmacy on August 28, 2013 for engaging in the distribution of drugs into OR without first registering with the Board as a drug outlet.
    - Citation and Fine issued by the CA State Board of Pharmacy on February 22, 2018 for failure to timely notify the Board of the termination of employment of the designated representative-in-charge or responsible manager.
    - Citation and Fine issued by the CA State Board of Pharmacy on October 14, 2014 for shipping drug products to someone other than a licensed practitioner, shipping drug products to NY without proper licensure and/or improper recordkeeping.
- Status of Case: Resolved

Alabama Case No. 22-L-0311

- Name: Alabama State Board of Pharmacy
- Location of Facility: 57735 S. 134th Street, Suite 109
- Date of Disciplinary Action: October 5th, 2021
- Description of Action:
  - Violations of AL Board Rule 690-X–.23(10)(c) for the following previous issues:
    - Kansas Board of Pharmacy entered a Summary Order against applicant for a late notice regarding change in ownership at least 6 months of effective date. Applicant was fined $1,000 fine
- Status of Case: Resolved

Arkansas Case No. 2019-038

- Name: Arkansas State Board of Pharmacy
- Location of Facility: 7735 S 134th Street, Suite 109, Omaha, NE 68138
- Date of Disciplinary Action: March 31, 2021
- Description of Action:
  - AR Board Regulation 08-00-0003 requires that any change of ownership be reported to the Board within 14 days of the effective date of the change in ownership. ZO Skin Health did not notify the Board of Pharmacy of a change of ownership within the stated timeframe.

- Case was resolved via Consent Agreement and fine along with filing of the appropriate Change of Ownership form and applicable fee.
- Status of Case: Resolved

California CI 2012 55027

- Name: State of California Board of Pharmacy – Department of Consumer Affairs
- Location of Facility: 1 Technology Drive, Suite F201, Irvine, CA 92618

- Date of Disciplinary Action: October 14, 2014
- Description of Action:
    - ZO Skin Health distributed drug samples by mail or common carrier to sales representatives (unlicensed individuals) for use as car stock, instead of shipping it directly to a licensed practitioner.
    - ZO Skin Health did not have an appropriate sample request process where drug samples are sent in response to a written request made on an appropriate form and under a system which requires the recipient of the drug sample to execute a written receipt upon the sample's delivery and the return of the receipt to the manufacturer.
    - Citation was resolved through payment of applicable fine and corrective action.
- Status of Case: Resolved

California CI 2017 76997

- Name: State of California Board of Pharmacy – Department of Consumer Affairs
- Location of Facility: 5 Technology Drive, Irvine, CA 92618
- Date of Disciplinary Action: February 22, 2018
- Description of Action:
    - Failure by ZO Skin Health to timely notify the Board in writing within 30 days of the date when a designated representative-in-charge ceases to act as the designated representative-in-charge, and failure to propose another designated representative or pharmacist to take over as the designated representative-in-charge.
    - Citation was resolved through payment of applicable fine.
- Status of Case: Resolved

Illinois Case No. 2012-12691

- Name: State of Illinois Department of Financial and Professional Regulation – Division of Professional Regulation
- Location of Facility: 1 Technology Drive, Suite F201, Irvine, CA 92618
- Date of Disciplinary Action: 2012
- Description of Action:
    - This case was never noticed to ZO Skin Health, and ZO Skin Health was not aware of its existence until receiving a Notice of Intent to Deny Licensure from the Department upon submitting its wholesale drug distributor application.
    - Case was subsequently closed.
- Status of Case: Closed

Illinois Case No. 2013-02342

- Name: State of Illinois Department of Financial and Professional Regulation – Division of Professional Regulation
- Location of Facility: 1 Technology Drive, Suite F201, Irvine, CA 92618
- Date of Disciplinary Action: April 9, 2013
- Description of Action:
    - IL notified ZO Skin Health of its intent to deny licensure due to an existing case before the Department (Case No. 2012-12691), which was never brought to ZO Skin Health's attention.
    - ZO Skin Health explained to the Department that while it was awaiting its licensure application to be processed and approved, it had only distributed its products into the state of IL through a third-party logistics provider who was licensed to legally distribute into the state.
    - Department concluded that there had been no violations and closed out both cases, and

further approved ZO Skin Health's wholesale drug distributor license.
- Status of Case: Closed

Oregon Case 2013-0010
- Name: Oregon Board of Pharmacy
- Location of Facility: 1 Technology Drive, Suite F201, Irvine, CA 92618
- Date of Disciplinary Action: July 23, 2013
- Description of Action:
  - ZO Skin Health had recently begun distributing skin care products in the state of OR through a third-party logistics provider without previously registering as a Manufacturer with the OR Board of Pharmacy.
  - ZO Skin Health believed in good faith that it was complying with OR law by utilizing an OR-licensed third-party logistics provider to distribute its products.
  - OR Board of Pharmacy notified ZO Skin Health that it was required to register, and ZO Skin Health thereafter promptly registered as a Manufacturer with the OR Board of Pharmacy, which approved the registration.
- Status of Case: Resolved

Tennessee Case No. 201300037
- Name: State of Tennessee Department of Health – Bureau of Health Licensure and Regulation, Division of Health Related Boards
- Location of Facility: 1 Technology Drive, Suite F201, Irvine, CA 92618
- Date of Disciplinary Action: February 26, 2013
- Description of Action:
  - The Department received a complaint for an alleged unlicensed activity violation.
  - ZO Skin Health was an appropriately licensed Manufacturer/ Wholesaler/ Distributor with the state of TN, who utilized a third-party logistics provider who was also licensed in the state of TN to legally distribute drug products into TN.
  - The Department concluded that there had been no violations and closed the case.
- Status of Case: Closed

Virginia Case No. 148322
- Name: Commonwealth of Virginia Department of Health Professions
- Location of Facility: 1 Technology Drive, Suite F201, Irvine, CA 92618
- Date of Disciplinary Action: January 9, 2013
- Description of Action:
  - The Department received a complaint regarding drug products being shipped into the state of VA.
  - ZO Skin Health was an appropriately licensed Non-Resident Wholesale Distributor with the state of VA, who utilized a third-party logistics provider who was also licensed in the state of VA to legally distribute drug products into VA.
  - The Department concluded that there was no evidence of a violation of any VA statutes or regulations that governed the conduct of pharmacy and closed the case.
- Status of Case: Closed

STATE OF MAINE
DEPARTMENT OF PROFESSIONAL
AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION
MAINE BOARD OF PHARMACY
35 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0035

Janet T. Mills
Governor

Anne L. Head
Commissioner

October 13, 2022

Via email: ross.mansbach@ZO.com; CNgo@ZOSkinHealth.com

ZO Skin Health, Inc.
Attn: Mark Williams, President & CEO
35292 N 72nd Place
Scottsdale, AZ 85266-1120

Re: Complaint No. 2022-PHA-18300

Dear Mr. Williams:

Enclosed please find the fully executed consent agreement between you, the Maine Board of Pharmacy, and the Office of the Attorney General in the above referenced matter.

If the consent agreement requires you to pay a fine that you have not already paid in full please send payment as directed in the consent agreement. Please include the complaint number above.

If you have any questions, please feel free to contact our office at (207) 624-8651.

Sincerely,

Jessica Gowell

Jessica Gowell, Professional Licensing Supervisor

Enclosure

cc: Jennifer Willis, Esq., Assistant Attorney General
Geraldine Betts, Board Administrator
Thomas Avery, Board Investigator

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
ZO SKIN HEALTH, INC	)	CONSENT AGREEMENT
	)	
Case No. 2022-PHA-18300	)	

PARTIES

This document is a Consent Agreement regarding the pending application of ZO Skin Health, Inc., for the renewal of its prescription drug wholesaler license. The parties to this Consent Agreement are: ZO Skin Health, Inc. ("ZO"), the Maine Board of Pharmacy ("the Board"), and the Office of the Maine Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

STATEMENT OF FACTS

1. Since June 29, 2021, ZO has been licensed in Maine as a prescription drug wholesaler with a registered location of 7735 S 134th Street, Suite 109, Omaha, Nebraska (license number **WH70003237**).

2. On October 5, 2021, the Kansas Board of Pharmacy imposed discipline against ZO's Kansas registration as a non-resident wholesaler (Registration # 5-114611) in Case No. 21-184.

3. ZO then failed to report the Kansas disciplinary action to the Board within 10 days as required by 10 M.R.S. § 8003-G(2)(C).

4. On November 1, 2021, ZO applied for renewal of its license and reported to the Board for the first time that it had been disciplined by the Kansas Board of Pharmacy.

5. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C), the Board may deny, refuse to renew, suspend, or revoke a license and impose other discipline for failing to report a license disciplinary action to the Board within 10 days of that action.

6. At its meeting on September 1, 2022, the Board reviewed the above information and voted to preliminarily deny ZO's application for renewal of its license to be a prescription drug wholesaler. In lieu of the denial, the Board also voted to offer ZO this Consent Agreement. Unless ZO either requests, in writing, a hearing regarding the appeal of the preliminary denial within thirty (30) days of receipt of the Notice of Preliminary Denial, or accepts this Consent Agreement by signing and dating it and returning it to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333, by **October 6, 2022,** the preliminary denial of ZO's application for licensure as a prescription drug wholesaler will become final.

COVENANTS

7. ZO admits to the facts above and admits that such conduct constitutes grounds for denial of or refusal to renew its license and for the imposition of discipline pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C) for failing to report disciplinary action taken in another jurisdiction against a professional license no later than 10 days after the action was taken.

8. As discipline for the violation admitted to in paragraph 7 above, ZO agrees to accept the following DISCIPLINARY ACTION:

a) A REPRIMAND; and

b) A CIVIL PENALTY in the amount of five hundred dollars ($500.00) payment of which shall be made payable to the "Treasurer, State of Maine" and delivered to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333, and must be submitted with the signed Consent Agreement.

9. Upon receipt of the signed Consent Agreement with the enclosed payment of the civil penalty from ZO, the Board will renew ZO's license contingent upon it meeting all other eligibility criteria.

10. Violation of any of the terms or conditions of this Consent Agreement by ZO shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

11. The Board and ZO agree that no further agency action will be initiated against its license by the Board based upon the specific violations admitted to herein, except or unless ZO fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct if other allegations are brought against ZO, and this Consent Agreement will be admitted into evidence in any future adjudicatory hearing involving ZO. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining appropriate discipline in any further complaints against ZO.

12. This Consent Agreement is not appealable and is effective until modified or terminated by the parties hereto.

13. The Board and the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

14. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

15. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

16. This Consent Agreement may be signed in counterparts, with all counterparts together constituting one original instrument. Signatures below may be applied and/or saved electronically, and such electronic signatures will be given the same effect as a paper document signed in ink.

17. ZO acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

DATED: October 10, 2022

ZO SKIN HEALTH, INC.

By: _____

Print Name: Drew Bordages

Title: EVP, General Counsel

DATED: 10-11-22

EDWARD J. KANE, Esq., President
MAINE BOARD OF PHARMACY

DATED: 10-12-22

JENNIFER A. WILLIS
Assistant Attorney General

STATE OF MAINE
DEPARTMENT OF PROFESSIONAL
AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION
MAINE BOARD OF PHARMACY
35 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0035

Janet T. Mills
Governor

Anne L. Head
Commissioner

October 19, 2022

Sent via email: cngo@zoskinhealth.com

ZO Skin Health, Inc.
Attn: Mark Williams, President & CEO
35292 N 72nd Place
Scottsdale, AZ 85266-1120

Re: Complaint No. 2022-PHA-18300

Dear Mr. Williams:

This letter acknowledges receipt of your fine payment in the amount of $500.00. Your fine is paid in full.

As all conditions of the consent agreement have been fulfilled, this complaint file is now closed.

Please feel free to contact our office at (207) 624-8651 with any questions.

Sincerely,

Jessica Gowell

Jessica Gowell, Professional Licensing Supervisor

cc: Jennifer Willis Esq., Assistant Attorney General
Geraldine L. Betts, Board Administrator
Thomas Avery, Board Investigator

Arizona State Board of Pharmacy
P.O. Box 18520, Phoenix, AZ 85005
P) 602-771-2727 F) 602-771-2749
pharmacy.az.gov

November 8, 2022

ZO Skin Health, Inc. (W003534)
9685 RESEARCH DRIVE
IRVINE, CA 92618

Re: Case No. 22-0610

Dear Permit Holder

The Arizona State Board of Pharmacy is in receipt of your payment of the $250.00 civil penalty required by the Order for Non-Disciplinary Civil Penalty in Board Case No. 22-0610 executed on October 18, 2022.

Staff has determined that you have fulfilled the requirements of the Order.

If you have any questions regarding this notice, please contact the Board office.

Thank you,

Kam Gandhi

Kam Gandhi, PharmD
Executive Director

KG/jcm

Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Ste. 260, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
Phone: 602-771-2727 Fax: 602-771-2749 pharmacy.az.gov

Order for Non-Disciplinary Civil Penalty

In the Matter of:

Respondent Name	ZO Skin Health, Inc.
License/Permit No.	W003534
Board Case No.	22-0601

	Check all that apply:			Fine(s)
☐	Failing to submit a remodel application before remodeling a permitted facility.			$250
☐	Failing to provide notice before a business is relocated.			$500
☐	Failing to update contact information within 10 days.			$50
☐	Failing to update change of employment information within 10 days.			$50
☐	Failing to complete required continuing education for pharmacist. (First offense)	Deficient CEs:		$100/CE
☐	Failing to complete required continuing education for pharmacist. (Second offense)	Deficient CEs:		$150/CE
☐	Failing to complete required continuing education for technician. (First offense)	Deficient CEs:		$25/CE
☐	Failing to complete required continuing education for technician. (Second offense)	Deficient CEs:		$37.50/CE
☐	Failing to provide notice of a new pharmacist in charge within 14 days.			$100
☐	Failing to provide notice of a new designated representative within 10 days.			$100
☐	Failing to provide notice of a new criminal charge, arrest, or conviction in any jurisdiction.			$250
☐	Failing to provide notice of disciplinary action taken against the licensee or permittee in any jurisdiction.			$250
☐	Failing to renew a pharmacist license timely within 60 days and continuing to work with an expired license.*	Days worked:		$100/day
☐	Failing to renew a technician license timely within 60 days and continuing to work with an expired license. **	Days worked:		$50/day
☐	Failing to conduct a controlled substance inventory when there is a new pharmacist in charge within 10 days.			$250
☐	Failing to obtain a permit before shipping into Arizona anything for which a permit is required.			$100/Item
☐	Failing to respond timely to a subpoena.			$50
☒	Failing to provide notice before there is a change in ownership.			$250
☐	Failing to conduct required controlled substance inventories.			$250
☐	Failing to disclose disciplinary action on initial permit application.			$250
☐				
			TOTAL:	$250
*Max $1,000				
**Max $500				
For Office Use Only				
Comment:				

The non-disciplinary civil penalty shall be paid within 90 days from the date of issuance of this order. Failure to pay the non-disciplinary civil penalty within 90 days from date of issuance of this order shall result in this case being presented to the Board and may be subject to disciplinary action. If the licensee/permittee wishes to request a rehearing/review of the Order, the request shall be filed within 35 days of the issuance of the Order under the Board's Statutes and rule.

Payment can be made using check or money order to: Arizona State Board of Pharmacy
P.O. Box 18520
Phoenix, AZ 85005

Executive Director's Signature: Kam Gandhi **Issue Date:** October 18, 2022

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	**BOARD OF PHARMACY**
ZO SKIN HEALTH, INC.	)	
	)	**CASE NO.: 22-L-0311**
Private Label Distributor	)	
Permit No. 196194	)	

NOTICE OF HEARING

TO: **Zo Skin Health, Inc.**
7735 S. 134th Street, Suite 109
Omaha, Nebraska 68138

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34, § 34-23-52, § 34-23-92(12), § 34-23-132 and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on Oct 29, 2024 at 8:00 a.m., at the State Board of Pharmacy Hearing Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why your permit should not be revoked, suspended or otherwise disciplined in that it is alleged that you have failed to comply with all applicable state laws and regulations. Disciplinary action may include administrative fines not to exceed $1,000 per violation; and/or revocation, suspension, or denial of your license(s); and/or such other discipline as may be ordered by the Board. Code of Alabama (1975), § 34-23-33. You have the right to be represented by counsel at your own expense, to respond and present evidence and argument on all material issues, to cross-examine all witnesses who testify against you, and to request that witnesses and/or documents be subpoenaed on your behalf. Please refer to the enclosed Standard Scheduling Order for further information regarding responding to the charges, witnesses, exhibits, and prehearing matters.

STATEMENT OF CHARGES

COMES NOW Complainant Donna C. Yeatman, as Executive Secretary of the Alabama State Board of Pharmacy and, on behalf of the Alabama State Board of Pharmacy ("the Board"), charges Respondent **Zo Skin Health, Inc.** as follows:

On or around October 5, 2021, the Kansas Board of Pharmacy entered a Summary Order against you for late notice to the Kansas Board of Pharmacy regarding your change in ownership. Under Kansas law, you were to notify the Kansas Board of Pharmacy within 30 days, but you notified the Board approximately 6 months after the change in ownership. As such, you paid a $1000 fine.

On or October 12, 2022, you entered into a Consent Agreement with the Maine Board of Pharmacy and accepted a reprimand and paid a $500 civil penalty for failure to report the Kansas Summary Order on your renewal application.

VIOLATIONS

If proven true, you will be in violation of the following:

Code of Alabama (1975), §34-23-33(a)(12) and Ala. Admin. Code r. 680-X-2-.23(10)(c): by failing to comply with all applicable state laws and regulations.

PRAYER FOR RELIEF

WHEREFORE, Complainant, in her capacity as the Executive Secretary of the Alabama State Board of Pharmacy, requests that, upon hearing and proof, Respondent be found guilty of the aforementioned violation and that the Alabama State Board of Pharmacy take such disciplinary actions as it deems necessary.

Dated this the 25th day of July 2024.

ALABAMA STATE BOARD OF PHARMACY

Donna C. Yeatman

By: Donna C. Yeatman Executive Secretary

EXHIBIT A
Kansas
Board of Pharmacy

800 SW Jackson St., Suite 1414
Topeka, KS 66612

Phone (785) 296-4056
Fax (785) 296-8420
pharmacy@ks.gov
www.pharmacy.ks.gov

Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

October 5, 2021

ZO Skin Health Inc
7735 S 134th St. Suite 109
Omaha NE 68138

RE: Case No. 21-184

To Whom it May Concern:

Enclosed you will find a Summary Order issued by the Kansas Board of Pharmacy (Board) in the above-referenced matter. Please read the order in its entirety. In addition, a civil fine has been assessed totaling $1,000. Please submit a check or money order made payable to the Kansas Board of Pharmacy and include your case number in the check memo.

If you disagree with the findings of fact, you have the right to request a hearing. Instructions for filing a written request are included under the "Notices" section of the order. Hearings are held before the full Board during their regularly scheduled quarterly meetings.

According to KSA 65-1627h, the Board is required to recoup the costs of administrative hearings when the decision is adverse to the licensee. These costs may include charges for services rendered by the Board's disciplinary counsel, an administrative law judge, and, if applicable, a court reporter.

If you have any questions, feel free to contact the Board at Pharmacy.Compliance@ks.gov.

Sincerely,

Kansas Board of Pharmacy

Enclosure

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 21-184
ZO Skin Health, Inc.	)	
	)	
Registration No. 5-114611	)	

SUMMARY ORDER

NOW on this 5th day of October, 2021, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of ZO Skin Health, Inc. ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 5-114611 which entitles Respondent to operate as a wholesale distributor in the State of Kansas ("Respondent's Registration").

2. On October 15, 2020, the ownership of Respondent's facility changed.

3. On April 16, 2021, the Board received from Respondent a Form BA-05 Wholesale Distributor Registration Application, notifying of the change in ownership, effective October 15, 2020, and applying for a new wholesale distributor registration.

4. On August 26, 2021, the Board approved Respondent's Wholesale Distributor Application, effective immediately.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f)(6), the Board may take action against a registration of a wholesale distributor that has violated the Pharmacy Act of the State of Kansas or regulations adopted by the Board.

3. Pursuant to K.S.A. 68-14-4(c), each registrant must submit change in address information within 30 days after any change in that information.

4. Respondent's failure to submit the complete change of ownership application to the Board until April 16, 2021 – over six months past the November 15, 2020 deadline – is a violation of K.S.A. 68-14-4(c), and a basis to discipline Respondent's Registration pursuant to K.S.A. 65-1627(f)(6).

5. Pursuant to K.S.A. 65-1643, it shall be unlawful for any person to distribute at wholesale any drugs without first obtaining a registration as a wholesale distributor from the Board.

6. Pursuant to K.S.A. 65-1645(f), registrations issued pursuant to K.S.A. 65-1643 shall not be transferrable and shall expire every year.

7. By continuing to operate as a wholesale distributor under new ownership using the registration issued to the previous owner, Respondent violated K.S.A. 65-1643.

ORDER

The Board finds and concludes that Respondent's conduct, as described above, violates the Act and such conduct warrants the imposition of a fine pursuant to K.S.A. 65-1658, in the amount of $1,000. Respondent has 30 days from the date of this order to pay the full amount due.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

10/5/2021
Date

Alex Blasi
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 5th day of October, 2021 deposit in business mail a copy of the foregoing Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

ZO Skin Health, Inc.
7735 S 134th St, Suite 109
Omaha NE 68138

Alex Blasi
Kansas Board of Pharmacy Staff

EXHIBIT B

STATE OF MAINE
DEPARTMENT OF PROFESSIONAL
AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION
MAINE BOARD OF PHARMACY
35 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0035

Janet T. Mills
Governor

Anne L. Head
Commissioner

October 13, 2022

Via email: ross.mansbach@ZO.com; CNgo@ZOSkinHealth.com

ZO Skin Health, Inc.
Attn: Mark Williams, President & CEO
35292 N 72nd Place
Scottsdale, AZ 85266-1120

Re: Complaint No. 2022-PHA-18300

Dear Mr. Williams:

Enclosed please find the fully executed consent agreement between you, the Maine Board of Pharmacy, and the Office of the Attorney General in the above referenced matter.

If the consent agreement requires you to pay a fine that you have not already paid in full please send payment as directed in the consent agreement. Please include the complaint number above.

If you have any questions, please feel free to contact our office at (207) 624-8651.

Sincerely,

Jessica Gowell

Jessica Gowell, Professional Licensing Supervisor

Enclosure

cc: Jennifer Willis, Esq., Assistant Attorney General
Geraldine Betts, Board Administrator
Thomas Avery, Board Investigator

OFFICES LOCATED AT: 76 NORTHERN AVENUE GARDINER, MAINE
PHONE: (207)624-8651 (Voice) FAX: (207)624-8637
TTY users: call Maine relay 711

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
ZO SKIN HEALTH, INC	)	CONSENT AGREEMENT
	)	
Case No. 2022-PHA-18300	)	

PARTIES

This document is a Consent Agreement regarding the pending application of ZO Skin Health, Inc., for the renewal of its prescription drug wholesaler license. The parties to this Consent Agreement are: ZO Skin Health, Inc. ("ZO"), the Maine Board of Pharmacy ("the Board"), and the Office of the Maine Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

STATEMENT OF FACTS

1. Since June 29, 2021, ZO has been licensed in Maine as a prescription drug wholesaler with a registered location of 7735 S 134th Street, Suite 109, Omaha, Nebraska (license number **WH70003237**).

2. On October 5, 2021, the Kansas Board of Pharmacy imposed discipline against ZO's Kansas registration as a non-resident wholesaler (Registration # 5-114611) in Case No. 21-184.

3. ZO then failed to report the Kansas disciplinary action to the Board within 10 days as required by 10 M.R.S. § 8003-G(2)(C).

4. On November 1, 2021, ZO applied for renewal of its license and reported to the Board for the first time that it had been disciplined by the Kansas Board of Pharmacy.

5. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C), the Board may deny, refuse to renew, suspend, or revoke a license and impose other discipline for failing to report a license disciplinary action to the Board within 10 days of that action.

6. At its meeting on September 1, 2022, the Board reviewed the above information and voted to preliminarily deny ZO's application for renewal of its license to be a prescription drug wholesaler. In lieu of the denial, the Board also voted to offer ZO this Consent Agreement. Unless ZO either requests, in writing, a hearing regarding the appeal of the preliminary denial within thirty (30) days of receipt of the Notice of Preliminary Denial, or accepts this Consent Agreement by signing and dating it and returning it to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333, by **October 6, 2022,** the preliminary denial of ZO's application for licensure as a prescription drug wholesaler will become final.

COVENANTS

7. ZO admits to the facts above and admits that such conduct constitutes grounds for denial of or refusal to renew its license and for the imposition of discipline pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C) for failing to report disciplinary action taken in another jurisdiction against a professional license no later than 10 days after the action was taken.

8. As discipline for the violation admitted to in paragraph 7 above, ZO agrees to accept the following DISCIPLINARY ACTION:

a) A REPRIMAND; and

b) A CIVIL PENALTY in the amount of five hundred dollars ($500.00) payment of which shall be made payable to the "Treasurer, State of Maine" and delivered to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333, and must be submitted with the signed Consent Agreement.

9. Upon receipt of the signed Consent Agreement with the enclosed payment of the civil penalty from ZO, the Board will renew ZO's license contingent upon it meeting all other eligibility criteria.

10. Violation of any of the terms or conditions of this Consent Agreement by ZO shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

11. The Board and ZO agree that no further agency action will be initiated against its license by the Board based upon the specific violations admitted to herein, except or unless ZO fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct if other allegations are brought against ZO, and this Consent Agreement will be admitted into evidence in any future adjudicatory hearing involving ZO. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining appropriate discipline in any further complaints against ZO.

12. This Consent Agreement is not appealable and is effective until modified or terminated by the parties hereto.

13. The Board and the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

14. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

15. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

16. This Consent Agreement may be signed in counterparts, with all counterparts together constituting one original instrument. Signatures below may be applied and/or saved electronically, and such electronic signatures will be given the same effect as a paper document signed in ink.

17. ZO acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

DATED: October 10, 2022

ZO SKIN HEALTH, INC.

By: _____

Print Name: Drew Bordages

Title: EVP, General Counsel

DATED: 10-11-22

EDWARD J. KANE, Esq., President
MAINE BOARD OF PHARMACY

DATED: 10-12-22

JENNIFER A. WILLIS
Assistant Attorney General

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: PureTek Corporation
Address: 7900 Nelson Road City: Panorama City State: CA Zip: 91402

Name: N/A
Address: City: State: Zip:

Name: N/A
Address: City: State: Zip:

Name: N/A
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any): N/A
Corporation Name: N/A
Mailing Address: N/A
City: State: Zip:
Telephone: N/A Email: N/A
Contact Person Name: N/A

Date of SEC Registration:	SEC Registration Number: N/A	Stock Exchange Symbol: N/A

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California
Parent Company (if any): ZO SH Intermediate, Inc.
Corporation/Organization Name: ZO Skin Health, Inc.
Mailing Address: 9685 Research Drive
City: Irvine State: CA Zip: 92618
Telephone: 949-988-7524 Email: cngo@zoskinhealth.com
Contact Person Name: Christy Ngo

Section 6: Partnership

Partnership Name: N/A
Mailing Address: N/A
City: N/A State: N/A Zip: N/A
Telephone: N/A Email: N/A
Contact Person Name: N/A

Section 7: Sole Owner

Owner's Name: N/A
Business Name: N/A
Business Address: N/A
City: N/A State: Zip:
Telephone: N/A Email: N/A

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

ZO Skin Health, Inc.

Facility Name

Philip Andrew Bordages

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

7/22/2024

Date

Board Use Only	Date Received: 9/12/24	Amount: $1000 - ck 057387

An official website of the United States government Here's how you know

FDA

Home > Drug Databases > NDC > Search Result

Share | Tweet | LinkedIn | Email | Print

Current through May 30, 2024

You have searched Finished drug products

Search Results: *'ZO Skin'*

Back to Search Page

Keyword Search RESET

Showing 1 to 27 of 27 entries

Show 50 entries

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC	Non Propr Name
Sunscreen Plus Powder Broad-Spectrum SPF 45	42851-069-27	.675mg/2.7g	POWDER	TOPICAL	M020	ZO Skin Health, Inc.	42851-069	Zinc O
ZO Skin Health Acne Control Benzoyl Peroxide	42851-087-60	100mg/mL	CREAM	TOPICAL	part333D	ZO Skin Health, Inc.	42851-087	Benzo Peroxi
ZO Skin Health Astringent Solution	42851-090-06	4866mg/6g	POWDER	TOPICAL	part347	ZO Skin Health, Inc.	42851-090	Alumi Acetat

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC	Non Propr Name
ZO Skin Health Broad-Spectrum Sunscreen SPF 50	42851-064-04	7.552mg/118g, 17.7 mg/118g	CREAM	TOPICAL	part352	ZO Skin Health, Inc.	42851-064	Titaniu Dioxid Oxide
ZO Skin Health Daily Sheer Broad-Spectrum Sunscreen SPF 45	42851-094-45	1350mg/45mL, 3060 mg/45mL, 2250 mg/45mL, 4500 mg/45mL	LOTION	TOPICAL	M020	ZO Skin Health, Inc.	42851-094	Avobe Homo Octisa Octoci
ZO Skin Health Daily Sheer Broad-Spectrum Sunscreen SPF 50 Water Resistant (40 Minutes)	42851-095-45	1350mg/45mL, 3060 mg/45mL, 2250 mg/45mL, 4500 mg/45mL	CREAM	TOPICAL	M020	ZO Skin Health, Inc.	42851-095	Avobe Homo Octisa Octoci
ZO Skin Health Gel Sunscreen Broad-Spectrum SPF 50	42851-092-45	1.35g/45g, 2.25 g/45g, 4.5 g/45g	GEL	TOPICAL	M020	ZO Skin Health, Inc.	42851-092	Avobe Octisa Octoci
ZO Skin Health Oil Control Pads Acne Treatment	42851-085-30	20mg/mL	PATCH	TOPICAL	M006	ZO Skin Health, Inc.	42851-085	Salicyl
ZO Skin Health Oil Control Pads Acne Treatment	42851-085-60	20mg/mL	PATCH	TOPICAL	M006	ZO Skin Health, Inc.	42851-085	Salicyl
ZO Skin Health Pigment Control	42851-037-30	40mg/mL	EMULSION	TOPICAL	N/A	ZO Skin Health, Inc.	42851-037	Hydro

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC	Non Propr Name
Creme Hydroquinone								
ZO Skin Health Pigment Control Creme Hydroquinone	42851-037-80	40mg/mL	EMULSION	TOPICAL	N/A	ZO Skin Health, Inc.	42851-037	Hydro
ZO Skin Health Pigment Control Plus Blending Creme Hydroquinone	42851-036-30	.04g/mL	EMULSION	TOPICAL	N/A	ZO Skin Health, Inc.	42851-036	Hydro
ZO Skin Health Pigment Control Plus Blending Creme Hydroquinone	42851-036-80	.04g/mL	EMULSION	TOPICAL	N/A	ZO Skin Health, Inc.	42851-036	Hydro
ZO Skin Health Pigment Control plus Brightening Creme Hydroquinone plus Vitamin C	42851-035-81	.04mg/mL	EMULSION	TOPICAL	N/A	ZO Skin Health, Inc.	42851-035	Hydro

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC	Non Propr Name
ZO Skin Health Pigment Control Program Plus Hydroquinone	42851-184-60	N/A	KIT	N/A	N/A	ZO Skin Health, Inc.	42851-184	Hydro
ZO Skin Health Post Procedure Program	42851-187-06	N/A	KIT	N/A	M016	ZO Skin Health, Inc.	42851-187	ALUM ACET
ZO Skin Health Post Procedure Recovery System	42851-193-06	N/A	KIT	N/A	M016	ZO Skin Health, Inc.	42851-193	Alumi Acetat
ZO Skin Health Sheer Fluid Broad-Spectrum Sunscreen SPF 50	42851-091-50	.225g/50mL	LOTION	TOPICAL	M020	ZO Skin Health, Inc.	42851-091	Zinc O

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC	Non Propr Name
ZO Skin Health Smart Tone Broad-Spectrum Sunscreen SPF 50	42851-096-20	30mg/mL, 68 mg/mL, 50 mg/mL, 100 mg/mL	LOTION	TOPICAL	M020	ZO Skin Health, Inc.	42851-096	Avobe Homo Octisa Octoc
ZO Skin Health Smart Tone Broad-Spectrum Sunscreen SPF 50	42851-096-45	30mg/mL, 68 mg/mL, 50 mg/mL, 100 mg/mL	LOTION	TOPICAL	M020	ZO Skin Health, Inc.	42851-096	Avobe Homo Octisa Octoc
ZO Skin Health Smart Tone Broad-Spectrum Sunscreen SPF 50	42851-055-20	30mg/mL, 100 mg/mL, 50 mg/mL, 100 mg/mL	LOTION	TOPICAL	part352	ZO Skin Health, Inc.	42851-055	Avobe Homo Octisa Octoc
ZO Skin Health Smart Tone Broad-Spectrum Sunscreen SPF 50	42851-055-45	30mg/mL, 100 mg/mL, 50 mg/mL, 100 mg/mL	LOTION	TOPICAL	part352	ZO Skin Health, Inc.	42851-055	Avobe Homo Octisa Octoc
ZO Skin Health Sunscreen Plus Powder Broad-Spectrum SPF 45	42851-068-27	.675mg/2.7g	POWDER	TOPICAL	M020	ZO Skin Health, Inc.	42851-068	Zinc O
ZO Skin Health Sunscreen Plus Powder Broad-Spectrum SPF 45 (Light)	42851-049-27	.675mg/g	POWDER	TOPICAL	M020	ZO Skin Health, Inc.	42851-049	Zinc O
ZO Skin Health Sunscreen Plus Primer	42851-060-15	10mg/mL, 200 mg/mL	CREAM	TOPICAL	M020	ZO Skin Health, Inc.	42851-060	Titaniu Dioxid Zinc O

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC	Non Propr Name
Broad-Spectrum SPF 30								
ZO Skin Health Sunscreen Plus Primer Broad-Spectrum SPF 30	42851-060-30	10mg/mL, 200 mg/mL	CREAM	TOPICAL	M020	ZO Skin Health, Inc.	42851-060	Titaniu Dioxid Zinc O
ZO Skin Health Sunscreen Plus Primer Broad-Spectrum SPF 30	42851-060-75	10mg/mL, 200 mg/mL	CREAM	TOPICAL	M020	ZO Skin Health, Inc.	42851-060	Titaniu Dioxid Zinc O

Previous 1 Next

Background Information

Drug questions email: DRUGINFO@FDA.HHS.GOV

See also: Drug Registration and Listing Instructions
National Drug Code Directory Data Files

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration

ZO® SKIN HEALTH

ZO Skin Health, Inc.: Ownership & Officers

OVERVIEW

Ownership

ZO Skin Health, Inc.'s parent company, ZO SH Intermediate, Inc., holds 100% of the entity and is headquartered at 9685 Research Drive, Irvine, California 92618. The entity's Facility Establishment Identifier Number is 20-4686721.

Officers

ZO Skin Health, Inc.'s executive officer information follows.

Name:	Peter Justin Skala
Position:	Chief Executive Officer
Name:	Philip Bordages
Position:	Executive Vice President, General Counsel
Name:	Tanya Hayden
Position:	Chief Financial Officer

Other Contacts

ZO Skin Health, Inc.'s Designated Representative information follows.

Name:	Hector Serna
Position:	~~General Manager~~ / Designated Representative

Operations & Logistics Manager

CMO Information

- Name: PureTek Corporation
  Address: 7900 Nelson Road Panorama City, CA 91402 (USA)
  Contact Name: Linda Delatorre
  Email: ldelatorre@puretekcorp.com
  Phone Number: 818-837-5880

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	ZO SKIN HEALTH, INC.
Entity No.:	2858991
Registration Date:	03/16/2006
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of March 14, 2024.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 191101419

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.



Renewal License

Wholesale Drug Permit

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

LICENSE NO. WLS 7699
RECEIPT NO. 33450282

VALID UNTIL JANUARY 01, 2025

ZO SKIN HEALTH INC
9685 RESEARCH DR
IRVINE CA 92618

12/13/23
12/13/23

The official status of this license can be verified at www.pharmacy.ca.gov

In accordance with the provisions of section 4160 of the Business and Professions Code, the firm name hereon is issued a Wholesale Drug Permit.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) manager, vice president of operations, or designated representative-in-charge.

This permit is valid only at the address shown.

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHWLS (09/30/19) WLS

BOARD OF PHARMACY

LICENSING DETAILS FOR: WLS 7699

NAME: ZO SKIN HEALTH INC

LICENSE TYPE: WHOLESALER

LICENSE STATUS: CLEAR

ISSUANCE DATE

JANUARY 29, 2020

EXPIRATION DATE

JANUARY 1, 2025

CURRENT DATE / TIME

AUGUST 29, 2024
9:42:6 AM

CLEAR - A "CLEAR" LICENSE ENTITLES THE INDIVIDUAL OR FIRM TO PERFORM ALL DUTIES AUTHORIZED TO THE SPECIFIC TYPE OF LICENSE WITHIN THE LICENSE ISSUANCE DATE AND END OF DAY ON THE EXPIRATION DATE, UNLESS (1) A PHARMACIST HAS RENEWED HIS OR HER LICENSE ON INACTIVE STATUS, OR (2) UNLESS THE LICENSE HAS BEEN RESTRICTED BY A DISCIPLINARY ORDER OF THE BOARD. WHEN THE WORD "PROBATION" APPEARS UNDER "CLEAR" BOARD DISCIPLINARY RESTRICTIONS ARE LISTED AT THE BOTTOM OF THE SCREEN.

ADDRESS

9685 RESEARCH DR
IRVINE CA 92618
ORANGE COUNTY

LICENSE RELATIONSHIPS

NAME: SERNA, HECTOR

ADDRESS NOT DISCLOSED

LICENSE/REGISTRATION TYPE: DESIGNATED REPRESENTATIVE (WHOLESALER)

LICENSE NUMBER: 26256 **PRIMARY STATUS:** CLEAR

MarshMcLennan Agency

Marsh & McLennan Insurance Agency LLC
9171 Towne Centre Drive | Suite 100
San Diego | CA 92122
+1 800 321 4696
MarshMMA.com
CA Insurance Lic. 0H18131

9/23/2024

Ms. Christy Ngo
ZO Skin Health Inc.
9685 Research Drive
Irvine, CA 92618

RE: Nevada Pharmacy Wholesaler Bond
Bond #0754224

Dear Christy:

Please find enclosed the following:

( ) Bond

( ) Continuation Certificate

( ) Invoice

(X) Other – Rider

Please file the enclosed address change rider with the Nevada State Board of Pharmacy. Should you have any questions, please do not hesitate to call.

Sincerely,

Marsh McLennan Agency

Danielle Enriquez
Surety Associate, Business Insurance

Enclosure

BOND RIDER

To be attached to and form part of a Pharmaceutical Wholesaler Surety Bond

Bond No. 0754224, dated 2/25/2019

issued to ZO Skin Health, Inc.,

as Principal, and Harco National Insurance Company,

as Surety, in favor of Nevada State Board Pharmacy

, as Obligee.

It is understood and agreed that the Bond is changed or revised in the particulars as checked below:

( ) Name of Principal changed to:

( ) Amount of bond changed from:

($) DOLLARS,

to:

($) DOLLARS,

(X) Other: Address for purpose of service to be added for pharmaceutical wholesaler

9685 Research Drive, Irvine, CA 92618

Said Bond shall be subject to all its terms, conditions and limitations, except as herein expressly modified. This Bond Rider shall become effective as of 23rd day of September, 2024.

Signed, sealed and dated 9/23/2024

Harco National Insurance Company

By:

Danielle Enriquez Attorney-in-Fact

XDP

POWER OF ATTORNEY

Bond # 0754224

HARCO NATIONAL INSURANCE COMPANY
INTERNATIONAL FIDELITY INSURANCE COMPANY

Member companies of IAT Insurance Group, Headquartered: 4200 Six Forks Rd, Suite 1400, Raleigh, NC 27609

KNOW ALL MEN BY THESE PRESENTS: That **HARCO NATIONAL INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of Illinois, and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of New Jersey, and having their principal offices located respectively in the cities of Rolling Meadows, Illinois and Newark, New Jersey, do hereby constitute and appoint

PATRICIA WHITE, MARTA COLLETT, DANIELLE ENRIQUEZ, SANDRA CORONA, SHANNON ALVAREZ, KATHLEEN VANDERSLICE, TIMOTHY MCCLELLAN

San Diego, CA

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 13th day of December, 2018 and by the Board of Directors of **HARCO NATIONAL INSURANCE COMPANY** at a meeting held on the 13th day of December, 2018.

"**RESOLVED**, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** have each executed and attested these presents on this 31st day of December, 2023

INTERNATIONAL FIDELITY INSURANCE COMPANY CORPORATE SEAL 1904 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

STATE OF ILLINOIS
County of Cook

HARCO NATIONAL INSURANCE COMPANY CORPORATE SEAL 1994 ILLINOIS

Kenneth Chapman
Executive Vice President, Harco National Insurance Company
and International Fidelity Insurance Company

On this 31st day of December, 2023, before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**; that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

CATHY CRUZ NOTARY PUBLIC STATE OF NEW JERSEY MY COMMISSION EXPIRES 4-16-2024

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Cathy Cruz a Notary Public of New Jersey
My Commission Expires April 16, 2024

CERTIFICATION

I, the undersigned officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, September 23, 2024

A00874

Irene Martins, Assistant Secretary

NEVADA STATE BOARD OF PHARMACY
431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 0754224

Application/License No. _____

ZO Skin Health, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 7735 S. 134th St., Suite 109, Omaha, NE 68138 (Address of Applicant/Principal), as PRINCIPAL, and International Fidelity Insurance Company (Surety Company), a corporation organized under the laws of the state of New Jersey (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 2999 Oak Rd., #820, Walnut Creek, CA 94597 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 2/25/2019 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 25th day of February, 2019.

APPLICANT/PRINCIPAL
ZO Skin Health, Inc.

Authorized Representative

SURETY COMPANY
International Fidelity Insurance Company

Surety Company's Representative

Timothy McClellan, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

Aidan Kathleen Smock, 833180

POWER OF ATTORNEY

Bond # 0754224

INTERNATIONAL FIDELITY INSURANCE COMPANY
ALLEGHENY CASUALTY COMPANY

One Newark Center, 20th Floor, Newark, New Jersey 07102-5207 PHONE: (973) 624-7200

KNOW ALL MEN BY THESE PRESENTS: That **INTERNATIONAL FIDELITY INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of New Jersey, and **ALLEGHENY CASUALTY COMPANY** a corporation organized and existing under the laws of the State of New Jersey, having their principal office in the City of Newark, New Jersey, do hereby constitute and appoint

PAUL JEFFREY HERING, MARTA COLLETT, JOSE LEMUS, RICHARD HALLETT, AIDAN SMOCK, KATHLEEN VANDERSLICE, TIMOTHY MCCLELLAN

San Diego, CA

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **INTERNATIONAL FIDELITY INSURANCE COMPANY and ALLEGHENY CASUALTY COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **INTERNATIONAL FIDELITY INSURANCE COMPANY and ALLEGHENY CASUALTY COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 20th day of July, 2010 and by the Board of Directors of **ALLEGHENY CASUALTY COMPANY** at a meeting duly held on the 10th day of July, 2015 :

"**RESOLVED**, that (1) the Chief Executive Officer, President, Executive Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **INTERNATIONAL FIDELITY INSURANCE COMPANY** and **ALLEGHENY CASUALTY COMPANY** have each executed and attested these presents on this 31st day of December, 2017

INTERNATIONAL FIDELITY INSURANCE COMPANY CORPORATE SEAL 1904 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

George R. James
Executive Vice President (International Fidelity Insurance Company) and
Vice President (Allegheny Casualty Company)

ALLEGHENY CASUALTY COMPANY 1936 NEW JERSEY

On this 31st day of December, 2017 before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **INTERNATIONAL FIDELITY INSURANCE COMPANY and of ALLEGHENY CASUALTY COMPANY**; that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

CATHY CRUZ NOTARY PUBLIC MY COMMISSION EXPIRES 04-16-2019 STATE OF NEW JERSEY

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Cathy Cruz a Notary Public of New Jersey
My Commission Expires April 16, 2019

CERTIFICATION

I, the undersigned officer of **INTERNATIONAL FIDELITY INSURANCE COMPANY** and **ALLEGHENY CASUALTY COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, February 25, 2019

A00874

Maria H. Branco, Assistant Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Y

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler ZO Skin Health, Inc.

Pharmacy/Wholesaler License # (if applicable) Applying

Physical Address 9685 Research Drive

City Irvine State CA Zip 92618

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone 949-988-7524 Website http://www.zoskinhealth.com

Licensing Company Email cngo@zoskinhealth.com

Section 2: Personal Information

First Hector Middle Gomez Last Serna

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 9685 Research Drive

City Irvine State CA Zip 92618

Telephone [redacted] Email HSerna@zoskinhealth.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Golden West College			
Address	**City**	**State**	**Zip**
15744 Goldenwest Street	Huntington Beach	CA	92647
Diploma/Degree obtained, if any			
Criminal Justice			

School Name		From - To (MM/YY – MM/YY)	
Santiago High School			
Address	**City**	**State**	**Zip**
12342 Trask Ave	Garden Grove	CA	92840
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/22-04/24	[redacted]	Brea	CA	92821
05/17-09/22		Santa Ana	CA	92704
01/01-05/17		Norwalk,	CA	92704
From - To (MM/YY – MM/YY)	Address N/A	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)	
ZO Skin Health, Inc.		05/14 - current	
Business Address	**City**	**State**	**Zip**
9685 Research Drive	Irvine	CA	92833
Phone	**Title**	**Number of Employed Hours**	
949-988-7524	General Manager / Designated Representative	6,000+ hours	
Description of Duties			
please see attached			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Hector Serna

Objective
To obtain a challenging position where my knowledge, e erience and skills will contribute towards the development of your organization. My dynamic personality as well as innovative ideas should help me a lot in contributing to the growth of the company.

Experience
ZO Skin Health, Inc.
Operations & Logistics Manager
Irvine, CA 92618
hserna@ZOskinhealth.com
6/2019 – Present

International Logistics Functions
- Oversee the global movement of goods, ensuring compliance with regulations
- File export shipments data with the Automated Export System (AES) and manage FDA and HLS regulatory laws
- Develop & implement global sourcing strategies along with C-TPAT security programs
- Support strategy execution for logistics and warehousing
- Implement financial metrics and associated KPIs for supply-chain network and vendors
- Develop and implement global transportation cost-savings programs for year-over-year savings
- Identify project responsibilities, delegating phases and elements to appropriate personnel
- Maintain awareness of industry and global logistics trends that will benefit company in the marketplace
- Conduct root-cause analysis of failures and take corrective actions
- Provide oversight for budgetary, scheduling, and project database, and report regularly to senior management about progress, plans, and problems that could affect costs or schedules
- Consult with various internal business units and vendors to identify opportunities for improvements of the supply-chain network

Office Manager Functions
- Taking inventory of & purchasing office supplies
- Help maintain office equipment, areas, facilities, as well as a safe and secure working environment
- Partner with Human Resources, Infrastructure Technology, and other departments to coordinate/control office activities/events as well as maintain office policies
- Assist with managing contract and price negotiations with office vendors and service providers
- Provide friendly and professional support to all colleagues
- Oversee/record incoming as well as outgoing post and courier deliveries

Miscellaneous
- Serve as one of the onsite California Designated Representatives

5/2014 – 6/2019
- Plan, direct, and coordinate the warehouse operations.
- Formulate policies and manage daily operations.
- Oversee training processes for distribution center personnel.
- Managed the (OTC) Over-The-Counter Product inventory in accordance with the requirements of state and federal statutes and regulations.
- (QI) Document Quarantine Product for quality Inspection and final disposition.
- Develops necessary corrective action to resolve any deficiencies.
- Typically supervises 25 - 30 primarily nonexempt employees.
- Perform weekly, quarterly inventory counts and yearly internal audits.
- Forecasting stock levels, delivery times, transport costs and performance evaluation.
- Responsible for developing and implementing (SOP's) policies and procedures related to new drugs and pharmaceutical laws.
- Inspect pedigree verification/authentication for product being received, if applicable.
- Utilizes a Return Material Authorization (RMA) to coordinate vendors & customers returns.
- Report to the Executive Vice President of Operations, responsible for managing all aspects of operations for the company.
- Review vendor's pedigree for compliance with all states and federal regulations.

Health Essentials, LLC
Warehouse/Delivery Tech IV, Costa Mesa, CA 92626
3/2013- 5/2014

- Coordinates delivery/pick-up time with pharmacy, nursing and patient.
- Gathers supplies/equipment for patient orders in preparation for shipment/delivery.
- Assists in training and orientation of new employees.
- Documents supplies on Patient Delivery Record.
- Maintains delivery log of activities per policy and procedure.
- Transports and delivers medication supplies and equipment to patients in a safe and secure manner to prevent damage, spoilage or loss of such items.
- Takes responsibility for delivery vehicles on a daily basis, conforming to policies and

Procedures.

- Retrieves and returns supplies and equipment, upon discharge from patient service.
- Cleans and processes returned equipment and supplies in accordance with policies and procedures.
- Maintains professional appearance and attitude and serves as a liaison between the patient and other individuals encountered within the scope of employment.
- Performs general housekeeping duties in the warehouse and delivery vehicle.
- Assists with inventory control including purchasing, receiving, stocking and record keeping.
- Maintains and tracks pumps and other equipment including cleaning and testing functions.
- May assist in PI activities as directed.
- Become efficient in dispatch coordination, purchasing and asset tracking to be a backup when necessary.

Apria Healthcare Inc.
Branch Logistics Supervisor, Lake Forest, CA 92630
6/2011 - 1/2013

- We are committed to full-service home care solutions that give maximum independence to our patients.
- Ensures equipment and delivery order slips are completed accurately and preventative maintenance on vehicles is performed in accordance with D.O.T., F.D.A. and JCAHO regulations.
- Provides training sessions for staff to ensure their compliance.
- Maintains daily vehicle maintenance logs and documentation of incident reports.
- Supervises the scheduling of routes and dispatching of delivery employees on a daily and on-call basis.
- Resolves issues regarding staff shortages, routes, loading of equipment and delivery.
- Ensures routes and delivery of products are completed in a timely and accurate manner.
- Orders and maintains warehouse stock inventory levels.
- Responsible for hiring, coaching, performance appraisal and disciplining of subordinate staff.
- Supervises the activities of subordinate staff.
- Provides direction and guidance in work assignments.
- Ensures timely and accurate completion of tasks.
- Responds to telephone calls from patients, referral sources, vendors and delivery employees regarding equipment orders, patient problems and delivery employee incidents.
- Bi-Lingual in English/Spanish.

Novis Pharmaceuticals, LLC
Warehouse Manager, Santa Ana, CA 92705
1/2003 - 6/2010

Successfully managing a nationwide licensed and authorized distributor for some of the world's leading manufacturers of critical care products: plasma derivatives, albumin, immune globulins, coagulation factors and hyperimmunes.
As a remote distribution center included implementing automated distribution system; selecting, managing and training staff; establishing and monitoring productivity goals; and leading cross-functional team key projects.

- Have designed the layout organization, processes and procedures.
- Proven leadership skills gained from managing a remote distribution facility.
- Current with States Board of Pharmacy Licenses.
- Managed the logistics and accuracy (SAP) inventory system.
- (NDC) National Drug Code. Performed logistic, inventory stock control, warehousing to monitor the flow of medicine.
- Developed budgets based on detail forecast and operate effectively within the operating budget.
- Compliance to all safety regulations.
- Document all corrective action (NCR) Non Conformity Reports.
- Inspect all incoming shipments of medicine for damaged, counterfeit or compromised.
- Validate new vendors to adhere to state and federal regulations and company standards.
- Managed a 24/7 wholesale prescription drug facility.

- **Education**
- California, Board of Pharmacy, CDR, Designated Representative.
- Florida, Board of Pharmacy. CDR, Designated Representative.
- Golden West College, Criminal Justice.

- **Skills**
- MS Office, Spreadsheet Software, SAP, Data Processing Software.

- **Professional Development**
- Board of Pharmacy, Wholesale Distribution Licensing.
- FDA (US Food and Drug Administration)
- Pharmaceuticals Laws, Regulations and Implementation.

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1971/01/08		CA	Santa Ana	Orange
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		Agency Sheriff's Office Santa Ana CA/ Municipal Court Westminster		
Reason/Charge				
VC Hit and Run Property Damange				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				
N/A				

Provide explanation below: See attached explanation

Original Signature (electronic, copies or stamps not accepted)

7/18/24
Date

WESTMINSTER
COLORADO

WESTMINSTER MUNICIPAL COURT
3030 Turnpike Drive
Westminster, Colorado 80030
303-658-2250
Fax: 303-429-8684

Date: June 17, 2024

To Whom It May Concern:

After a review of our case management system, including potential name and date of birth combinations, we have found no record of information for the following individual:

Name: Hector Serna

[redacted]

The Westminster Municipal Court keeps copies of all court records for a period of seven years plus the current year. If you have requested a copy of a court record that falls outside that time period, we are unable to provide that information, as those records no longer exist. This is in accordance with the City of Westminster's Document Management and Retention Policy adopted by City Council pursuant to Resolution No. 17, Series 11.

If the requested record is for a juvenile, only the juvenile can request his/her own juvenile record.

If the requested record has been been expunged or sealed pursuant to statutory requirements, we are unable to provide that information, as it no longer exists.

Please contact the Clerk's Office at 303-658-2250 if you have any questions.

JS
Deputy Court Clerk

SEAL

I, Hector Serna, **certify that as the designated representative for**

ZO Skin Health, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. HS I am at least 21 years of age;
3. HS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. HS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. HS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. HS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. HS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Hector Serna

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/18/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hector Serna

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/18/24

Date

Please have this section completed in the presence of a Notary Public.

State of CALIFORNIA, ss. County of ORANGE

I, HECTOR JERNA, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/18/24

Date

Subscribed and Sworn to before me this 18th day of 2024.

Christy Ngo

Notary Public Signature

Please see enclosed california secretary of state notary public acknowledgement certificate. CN 07-18-2024

(Seal)

ZO® SKIN HEALTH

CALIFORNIA ALL-PURPOSE ACKNOWLEDGEMENT

A Notary Public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Orange }

On JULY 18th, 2024, before me, CHRISTY L NGO, Notary Public,

personally appeared HECTOR SERNA

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/~~are~~ subscribed to the within instrument and acknowledged to me that he/~~she~~/~~they~~ executed the same in his/~~her~~/~~their~~ authorized capacity(~~ies~~), and that by his/~~her~~/~~their~~ signature(s) on the instrument the person(~~s~~), or the entity upon behalf of which the person(~~s~~) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of State of California that the foregoing paragraph is true and correct.

CHRISTY LINH NGO
Notary Public - California
Orange County
Commission # 2480431
My Comm. Expires Feb 25, 2028

WITNESS my hand and official seal.

SIGNATURE christy ngo

PLACE NOTARY SEAL ABOVE

Though the information below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent removal and reattachment of this form to another document.

Description of attached document

Title or description of attached document: Nevada State Board of Pharmacy Designated Representative Application

Document Date: 07-18-2024 Number of Pages: 9

Capacity claimed by signer: ☐ Individual(s) ☐ Partner(s) ☐ Attorney-in-fact ☐ Trustee(s)

☐ Corporate officer (Title:)

☑ Other: operations & Logistics manager / Designated Representative

Employee List

Mary Anne Citrino

Jeremiah Harris

Scott Hirsch

Todd Hirsch

Ram Jagannath

Omar Kadro

Samar Obagi

Jessica Parry

P. Justin Skala

Tanya Hayden

Drew Bordages

Christy Ngo

Hector Serna

4EE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☑ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ☑ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 02098	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: INO Therapeutics LLC

Physical Address: 875 West Sandy Lake Road, Suite 300

City: Coppell State: TX Zip: 75019

Mailing Address (if different from physical address): 440 US HWY 22 East,

City: Bridgewater State: NJ Zip: 08807

Telephone: 469-496-3800 Website: https://www.mallinckrodt.com/

Name of Designated Representative (DR): Enrique Soria

Licensing Company Email: State.licensing@mnk.com DR Email: enrique.soria@mnk.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☑ Hospitals	☑ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☑ Others: Wholesale Distributor

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A				
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Jon Green (Jon Green) 08/07/2024

Original Signature (electronic, copies or stamps not accepted) Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: None. We serve as a backup facility for our California facility if needed.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Mallinckrodt Hospital Products Inc

Corporation/Organization Name: Mallinckrodt Hospital Products Inc

Mailing Address: 675 McDonnell Blvd, 20W, Suite 304

City: Hazelwood State: MO Zip: 63042

Telephone: 908-238-5587 Email: State.licensing@mnk.com

Contact Person Name: Jon Green

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

INO Therapeutics LLC

Facility Name

Jon Green

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

Date 08/07/2024

Board Use Only	Date Received: 8/20/24	Amount: $1000 ck 12949

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

National Drug Code Directory

Current through October 11, 2022

You have searched Finished drug products

Search Results: *'64693'*

Back to Search Page () | Search Again ()

CSV Excel

Display 50 **records per page**

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class
INOmax	64693-002-02	98 mg/L	GAS	RESPIRATORY (INHALATION)	NDA020845	INO THERAPEUTICS LLC	64693-002	nitric oxide	NITRIC OXIDE	HUMAN PRESCRIPTION DRUG	12/23/1999	N/A	NDA	1 CYLINDER in 1 CARTON (64693-002-02) > 1963 L in 1 CYLINDER	Vasodilation [PE], Vasodilator [EPC]
INOmax	64693-002-01	98 mg/L	GAS	RESPIRATORY (INHALATION)	NDA020845	INO THERAPEUTICS LLC	64693-002	nitric oxide	NITRIC OXIDE	HUMAN PRESCRIPTION DRUG	12/23/1999	N/A	NDA	1 CYLINDER in 1 CARTON (64693-002-01) > 353 L in 1 CYLINDER	Vasodilation [PE], Vasodilator [EPC]

Showing 1 to 2 of 2 entries

Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Current list of 5 NABP-Accredited Drug Distributors

Accreditation is valid for 3 years

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.

Name	Address	Accreditation Date
INO Therapeutics LLC	3600 Industrial Blvd, Ste C West Sacramento, CA 95691	Reaccreditation in process
INO Therapeutics LLC	1200 Northbrook Pkwy, Ste 60 Suwanee, GA 30024	Reaccreditation in process
INO Therapeutics, LLC	175 E Crossroads Pkwy, Ste C Bolingbrook, IL 60440	Reaccreditation in process
INO Therapeutics, LLC	875 W Sandy Lake Rd #300 Coppell, TX 75019	Reaccreditation in process
INO Therapeutics, LLC	22 World's Fair Dr, Ste J Somerset, NJ 08873	Reaccreditation in process

Mallinckrodt Pharmaceuticals

Business entity: **INO Therapeutics, LLC**
Corporate Business Address: 440 US HWY 22 East, Bridgewater, NJ 08807

Formation: Delaware

Executive Officers of INO Therapeutics, LLC are:

Name	Title	Business Address
Bryan Reasons	President	440 US HWY 22 East, Bridgewater, NJ 08807
Paul Coiante	Vice President	440 US HWY 22 East, Bridgewater, NJ 08807
Jon J. Green	Vice President, Secretary	440 US HWY 22 East, Bridgewater, NJ 08807

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "INO THERAPEUTICS LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINETEENTH DAY OF JANUARY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

3724403 8300

SR# 20240173879

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202624494

Date: 01-19-24

- Please contact this office immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **www.dshs.texas.gov**.
- Please submit written notice if you close or sell your business.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drug and Device Business Filing and Verification Unit at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

INO THERAPEUTICS LLC
53 FRONTAGE RD STE 300
HAMPTON NJ 08827

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

INO THERAPEUTICS LLC

875 W SANDY LAKE RD 300
COPPELL, TX 75019

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

WHOLESALE DISTRIBUTOR OF COMPRESSED MEDICAL GAS

DEVICE DISTRIBUTOR

License # 0065612
Expires: December 31, 2024

NON-TRANSFERABLE

Commissioner

513447

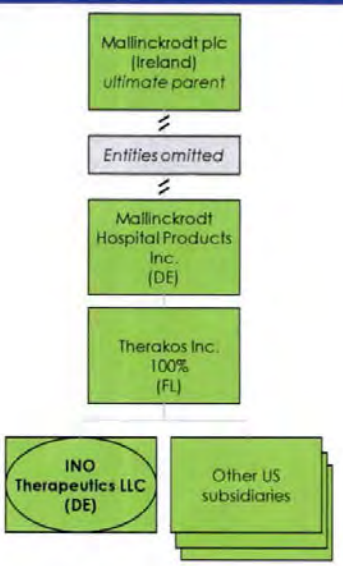
List of Licenses - Coppell

Jurisdiction	Requireme Details	Number	Expiration
US-AL	Private Label Distributor	195053	12/31/2024
US-AZ	Nonresident Wholesaler - Full Service	W002649	10/31/2025
US-CO	Wholesaler Out-of-State	WHO.0007383	10/31/2024
US-GA	Wholesaler	PHWH001810	6/30/2025
US-IL	Wholesale Drug Distributor	4002815	12/31/2024
US-IA	Medical Gas Distributor (Limited Distributor)	40458	12/31/2024
US-KS	Distributor	5-02419	6/30/2025
US-LA	Distributor Of Legend Drugs Or Devices	6099	12/31/2024
US-MN	Wholesaler License	363442	5/31/2025
US-MS	Wholesale Distributor	15772/16.5a	12/31/2024
US-MO	Drug Distributor License Out of State	2004003164	10/31/2025
US-NE	Wholesale Drug Distributor	979	7/1/2025
US-NV	Wholesaler	WH02098	10/31/2024
US-NJ	Wholesale	5002981	1/31/2025
US-NM	Wholesale Drug Distributor	WD00010377	12/31/2025
US-ND	Wholesaler or Distributor	WHOL1071	6/30/2025
US-OK	Wholesale Distributor	88-W-2045	7/31/2024
US-SD	Wholesale Drug Distributor	600-1771	12/31/2024
US-TN	Wholesale/Distributor	2978	3/31/2025
US-TX	Multi Products with Medical Gas	65612	12/31/2024
US-UT	Pharmacy: Distributor	9418731-1710	9/30/2025
US-WI	Wholesale Distributor of Prescription Drugs	2428-45	5/31/2026
US-AR	Wholesale Distributor	WD02430	12/31/2024
US-AL	Designated Enrique Soria	DR0691	12/31/2024

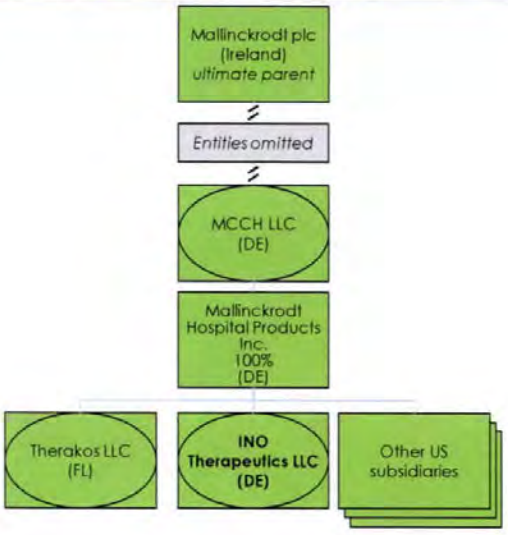
INO Therapeutics LLC (US) change of ownership

Supporting documentation

Current structure – Before ownership change



Future structure – After ownership change (Aug. 30th 2024)



CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 06/28/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. St. Louis MO Office 4220 Duncan Avenue Suite 401 St Louis MO 63110 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
MALLINCKRODT LLC 675 McDonnell Boulevard Hazelwood MO 63042 USA	INSURER A: National Union Fire Ins Co of Pittsburgh	19445
	INSURER B: AIU Insurance Company	19399
	INSURER C: Gemini Insurance Company	10833
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570106923285 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			GL9911771 General Liability SIR applies per policy terms & conditions	06/28/2024	06/28/2025	EACH OCCURRENCE	$2,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000
							MED EXP (Any one person)	$10,000
							PERSONAL & ADV INJURY	$2,000,000
							GENERAL AGGREGATE	$4,000,000
							PRODUCTS - COMP/OP AGG	Excluded
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			AL 7281212 AOS SIR applies per policy terms & conditions	06/28/2024	06/28/2025	COMBINED SINGLE LIMIT (Ea accident)	$3,000,000
							BODILY INJURY (Per person)	
B				AL 7281213 MA SIR applies per policy terms & conditions	06/28/2024	06/28/2025	BODILY INJURY (Per accident)	
							PROPERTY DAMAGE (Per accident)	
	UMBRELLA LIAB OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION						EACH OCCURRENCE	
							AGGREGATE	
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	Y / N: N	N / A	WC014111703 AOS	06/28/2024	06/28/2025	X PER STATUTE OTH-ER	
B				WC014111702 CA	06/28/2024	06/28/2025	E.L. EACH ACCIDENT	$1,000,000
				SIR applies per policy terms & conditions			E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000
C	Products Liability			GL177971 SIR applies per policy terms & conditions	06/28/2024	06/28/2025	SIR APPLIES	$5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: J. Green. Evidence of Insurance. Coverage evidenced under this certificate extends to include all Mallinckrodt subsidiaries including INO Therapeutics LLC and the locations at the following addresses: Illinois - 175 East Crossroad Parkway, Unit C, Bolingbrook, IL 60440 and New Jersey - 22 World's Fair Drive STE J, Somerset, NJ 08873 - 875 West Sandy Lake RD, Coppell, TX - 3600 Industrial Blvd, West Sacramento, CA

CERTIFICATE HOLDER

Mallinckrodt PLC
675 James S. McDonnell Blvd.
Hazelwood MO 63042 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central Inc.

Holder Identifier :

Certificate No : 570106923285

©1988-2015 ACORD CORPORATION. All rights reserved.

AGENCY CUSTOMER ID: 570000061378
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	MALLINCKRODT LLC
POLICY NUMBER: See Certificate Number: 570106923285	
CARRIER: See Certificate Number: 570106923285 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER	
INSURER	
INSURER	
INSURER	

ADDITIONAL POLICIES If a policy below does not include limit information, refer to the corresponding policy on the ACORD certificate form for policy limits.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	WORKERS COMPENSATION							
B		N/A		WC014111704 WI SIR applies per policy terms & conditions	06/28/2024	06/28/2025		

ACORD 101 (2008/01) © 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: 570000061378
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	MALLINCKRODT LLC
POLICY NUMBER: See Certificate Number: 570106923285	
CARRIER: See Certificate Number: 570106923285 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Excess Product Liability policies

Excess Products Liability 1st Layer
CARRIER: TDC Specialty Insurance Company
POLICY: LSX-00013-24-07
EFF: 6/28/24
EXP: 6/28/25
Limit: $5,000,000 xs $5,000000

ACORD 101 (2008/01)
© 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

VERIFICATION OF BOND IN FORCE
Form SB-3

Type of Bond: License/Permit Bond

Name of Principal: MALLINCKRODT ARD LLC / INO THERAPEUTICS LLC

Obligee: THE NEVADA STATE BOARD OF PHARMACY

Carrier: ATLANTIC SPECIALTY INSURANCE COMPANY

Bond Number: 800051035

Effective Date: October 26, 2024

Limit: $ 100,000.00

Premium: $ 1,000.00

This Bond is continuous with no definite expiration date. Sufficient Premium has been paid to satisfy the requirements of the Carrier for this bond to October 26, 2025.

ATLANTIC SPECIALTY INSURANCE COMPANY

By: _____
Nicholas Kertesz Attorney in Fact

Date: October 11, 2024

intact INSURANCE

Power of Attorney

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **Aaron D. Griffin, Aerie Walton, Barbara Pannier, Bartlomiej Siepierski, Christina L. Sandoval, Christopher P. Troha, Corinne Chapman, Dartonya Wright, Derek J. Elston, Jean Torres, Jennifer Williams, Judith A. Lucky-Eftimov, Kristin L Hannigan, Nicholas Kertesz, Nicholas Pantazis, Rachel Fore, Richard Casas, Roger Paraison, Salena Wood, Samantha Chierici, Sandra M. Winsted, Susan A. Welsh, Tara A Maquinto, Therese M. Jackson**, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this first day of January, 2023.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Sarah A. Kolar, Vice President and General Counsel

STATE OF MINNESOTA
HENNEPIN COUNTY

On this first day of January, 2023, before me personally came Sarah A. Kolar, Vice President and General Counsel of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and she acknowledged the execution of the same, and being by me duly sworn, that she is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON DWAN NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2025

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 11th day of October 2024

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

_____
Kara L.B. Barrow, Secretary

This Power of Attorney expires
January 31, 2025

Please direct bond verifications to surety@intactinsurance.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: INO Therapeutics LLC — MDEG License # (if applicable): WH02098

Physical Address: 875 West Sandy Lake Road, Ste 300

City: Coppell — State: TX — Zip: 75019

Mailing Address (if different from physical address): 440 US Highway 22 East

City: Bridgewater — State: NJ — Zip: 08807

Telephone: 469-496-3800 — Website: https://www.mallinckrodt.com

Licensing Company Email: state.licensing@mnk.com

Section 2: Personal Information

First: Enrique — Middle: M — Last: Soria

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Irving — State: TX — Zip: 75060

Telephone: [redacted] — Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Institute Las Casa		1983-1986	
Address	**City**	**State**	**Zip**
Prolongaci'on Santo Domingo 1, Zona Centro	San Miguel De Allende, Guanajuato	MX	37774
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/14/2000-present	[redacted]	Irving	TX	75060
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
INO Therapeutics LLC		11/2015-present	
Business Address	**City**	**State**	**Zip**
875 West Sandy Lake Road, Ste 300	Coppell	TX	75019
Phone	**Title**	**Number of Employed Hours**	
469-496-3800	RSC Distribution Operations/Service Lead	18,720	
Description of Duties			
Assist with all aspects of regional operations including distribution center management, transportation, and facilities			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

09/23/2024
Date

I, Enrique Soria, certify that as the MDEG Administrator for

INO Therapeutics LLC,

that I (initial that you have read and meet the following requirements):

1. ES Have a high school diploma or its equivalent;
2. ES Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. ES Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. ES Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Enrique Soria
Print Name (First, Last)


Original Signature (electronic, copies or stamps not accepted)

09/23/2024
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler INO Therapeutics LLC

Pharmacy/Wholesaler License # (if applicable) WH02098

Physical Address 875 West Sandy Lake Road, Suite 300

City Coppell State TX Zip 75019

Mailing Address (if different from physical address) 440 US HWY 22 East

City Bridgewater State NJ Zip 08807

Telephone 469-496-3800 Website https://www.mallinckrodt.com/

Licensing Company Email State.licensing@mnk.com

Section 2: Personal Information

First Enrique Middle M Last Soria

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☐ F ☐ X

Mailing Address [redacted]

City Irving State TX Zip 75060

Telephone [redacted] Email enrique.soria@mnk.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Institute Las Casa		1983 to 1986	
Address	**City**	**State**	**Zip**
Prolongación Santo Domingo 1, Zona Centro	San miguel de Allende,Guanajuato	MX	37774
Diploma/Degree obtained, if any			
HS diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/14/2000 to present	[redacted]	Irving	TX	75060
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
INO Therapeutics LLC			11/2015 to present
Business Address	**City**	**State**	**Zip**
875 West Sandy Lake Road, Suite 300	Coppell	TX	75019
Phone	**Title**	**Number of Employed Hours**	
469-496-3800	RSC Distribution Operations / Service Lead	18,720	

Description of Duties

Assist with all aspects of regional operations including distribution center management, transportation, and facilities

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

State of Texas
County of DALLAS
Sworn to and subscribed before me on the 8 day of Aug
Donald J Quiett
Notary Public

DONALD JOSEPH QUIETT
Notary Public, State of Texas
Comm. Expires 07-16-2028
Notary ID 134994434

Original Signature (electronic, copies or stamps not accepted)

08/08/2024
Date

I, Enrique Soria, **certify that as the designated representative for**

INO Therapeutics LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

State of Texas
County of DALLAS
Sworn to and subscribed before me on the 8th day of Aug

Donald J Quiett
Notary Public

DONALD JOSEPH QUIETT
Notary Public, State of Texas
Comm. Expires 07-16-2028
Notary ID 134994434

Enrique Soria
Print Name (First, Last)

E S
Original Signature (electronic, copies or stamps not accepted)

08/08/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Enrique Soria
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/08/2024
Date

Please have this section completed in the presence of a Notary Public.

State of TX, ss. County of DALLAS

I, Enrique M Soria, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

08/08/2024
Date

Subscribed and Sworn to before me this 8th day of August.

Notary Public Signature

DONALD JOSEPH QUIETT
Notary Public, State of Texas
Comm. Expires 07-16-2028
Notary ID 134994434

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site INO Therapeutics LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) WH02098

Physical Address 875 West Sandy Lake Road, Suite 300,

City Coppell State TX Zip 75019

Mailing Address (if different from physical address) 440 US HWY 22 East

City Bridgewater State NJ Zip 08807

Telephone 469-496-3800 Website https://www.mallinckrodt.com/

Licensing Company Email State.licensing@mnk.com

Section 2: Personal Information

First Jon Middle J Last Green

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Bridgewater State NJ Zip 08807

Telephone [redacted] Email jon.green@mnk.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Brentwood High School		09/1979 to 05/1983	
Address	**City**	**State**	**Zip**
2221 High School Drive	Brentwood	MO	63144
Diploma/Degree obtained, if any			
HS diploma			

School Name		From - To (MM/YY – MM/YY)	
Webster University		05/2006 to 05/2007	
Address	**City**	**State**	**Zip**
470 E Lockwood Ave	Webster Groves	MO	63119
Diploma/Degree obtained, if any			
Bachelor of Arts			

School Name		From - To (MM/YY – MM/YY)	
Webster University		05/2007 to 04/2009	
Address	**City**	**State**	**Zip**
470 E Lockwood Ave	Webster Groves	MO	63119
Diploma/Degree obtained, if any			
Master of Laws			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/2017 to present	[redacted]	Bedminster	NJ	07921
04/2010 to 02/2017		Kirkwood	MO	63122

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Mallinckrodt Pharmaceuticals			03/15/1991 to present
Business Address	**City**	**State**	**Zip**
440 US HWY 22 East	Bridgewater	NJ	08827
Phone	**Title**		
908-238-5587	Vice President		
Description of Duties			
Legal and Compliance Manager for Mallinckrodt Pharmaceuticals			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Jon Greer (Jon Greer)
Original Signature (electronic, copies or stamps not accepted)

08/07/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jon J Green
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/07/2024
Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Somerset

I, Jon J Green, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

08/07/2024
Date

Subscribed and Sworn to before me this 7th day of August.

Notary Public Signature

SUZANNE V DZULA-ADAMS
Commission # 50221776
Notary Public, State of New Jersey
My Commission Expires
May 09, 2029

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site INO Therapeutics LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) WH02098

Physical Address 875 West Sandy Lake Road, Suite 300,

City Coppell State TX Zip 75019

Mailing Address (if different from physical address) 440 US HWY 22 East

City Bridgewater State NJ Zip 08807

Telephone 469-496-3800 Website https://www.mallinckrodt.com/

Licensing Company Email State.licensing@mnk.com

Section 2: Personal Information

First Bryan Middle M Last Reasons

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Bridgewater State NJ Zip 08807

Telephone [redacted] Email bryan.reasons@mnk.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Widener University		08/1991 – 05/1993	
Address	City	State	Zip
One University Place	Chester	PA	19013
Diploma/Degree obtained, if any			
Masters in Business Administation			
School Name		From - To (MM/YY – MM/YY)	
Pennsylvania State University - Smeal College of Business		08/1986 – 05/1990	
Address	City	State	Zip
210 Business Building	University Park	PA	16802
Diploma/Degree obtained, if any			
Bachelor of Science			
School Name		From - To (MM/YY – MM/YY)	
Unionville High School		09/1982 – 06/1986	
Address	City	State	Zip
740 Unionville Road	Kennett Square	PA	19348
Diploma/Degree obtained, if any			
HS diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2022 to present	[redacted]	Wayne	PA	19087
From - To (MM/YY – MM/YY)		City	State	Zip
07/2021 – 07/2022		Chatham	NJ	07928
From - To (MM/YY – MM/YY)		City	State	Zip
08/2015 to 07/2021		Chatham	NJ	07928
From - To (MM/YY – MM/YY)		City	State	Zip
06/2013 to 08/2015		Danville	CA	94506
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Mallinckrodt Pharmaceuticals			03/2019 to present
Business Address	**City**	**State**	**Zip**
440 US HWY 22 East	Bridgewater	NJ	08807
Phone	**Title**		
908-997-9289	Vice President, CFO		
Description of Duties			
Accounting, Treasury, SEC Reporting, Management Reporting,Financial Planning and Analysis, Business Development, Investor Relations and Corporate Communications, Internal Audit and Information Technology (IT&S), Global Procurement			

Business Name			From - To (MM/YY – MM/YY)
Amneal Pharmaceuticals / Impax Laboratories			01/2012 to 02/2019
Business Address	**City**	**State**	**Zip**
400 Crossing Blvd	Bridgewater	NJ	08807
Phone	**Title**		
908- 947-3120	Senior Vice President Finance and Chief Financial Officer		
Description of Duties			
Accounting, Treasury, SEC Reporting, Management Reporting, Financial Planning and Analysis, Business Development, Investor Relations and Corporate Communications, Internal Audit and Information Technology (IT&S)			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

08/07/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bryan Reasons
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/07/24
Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Somerset

I, Bryan M Reasons, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

08/07/24
Date

Subscribed and Sworn to before me this 7th day of August.

Notary Public Signature

SUZANNE V DZULA-ADAMS
Commission # 50221776
Notary Public, State of New Jersey
My Commission Expires
May 09, 2029

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: INO Therapeutics LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WHO02098

Physical Address: 875 West Sandy Lake Road, Suite 300

City: Coppell State: TX Zip: 75019

Mailing Address (if different from physical address): 440 US HWY 22 East

City: Bridgewater State: NJ Zip: 08807

Telephone: 469-496-3800 Website: https://www.mallinckrodt.com/

Licensing Company Email: state.licensing@mnk.com

Section 2: Personal Information

First: Paul Middle: R Last: Coiante

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: Trenton, NJ SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 440 US HWY 22 East

City: Bridgewater State: NJ Zip: 08807

Telephone: [redacted] Email: paul.coiante@mnk.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Ewing High School		09/1985 to 06/1987	
Address	**City**	**State**	**Zip**
900 Parkway Ave	Ewing Twp	NJ	08618
Diploma/Degree obtained, if any			
HS diploma			

School Name		From - To (MM/YY – MM/YY)	
Eckerd College		09/1987 to 05/1991	
Address	**City**	**State**	**Zip**
4200 54th Ave S	St Petersburg	FL	33711
Diploma/Degree obtained, if any			
BA			

School Name		From - To (MM/YY – MM/YY)	
Rutgers University		09/1991 to 05/1994	
Address	**City**	**State**	**Zip**
190 University Ave	Newark	NJ	07102
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2004 to present	[redacted]	Ringoes	NJ	08551
11/2017 to 07/2004		Holgate	NJ	08008

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Mallinckrodt Pharmaceuticals			12/2010 to present
Business Address	**City**	**State**	**Zip**
440 US HWY 22 East	Bridgewater	NJ	08807
Phone	**Title**		
908-892-8116	Vice President of Sales		

Description of Duties

- Contracted over 500M across 600+ accounts
- 2020 sales volume of 523M (14% above plan) with 2 new market entrants
- Prepared 2 sales teams for 2 new product launches in critical care
- Successfully negotiated co-promote deal resulting in 6M

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A				
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

8-7-2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Paul R Coiante

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8-7-2024

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Somerset

I, Paul R Coiante, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8-7-2024

Date

Subscribed and Sworn to before me this 7th day of August.

Notary Public Signature

SUZANNE V DZULA-ADAMS
Commission # 50221776
Notary Public, State of New Jersey
My Commission Expires
May 09, 2029

(Seal)

Mallinckrodt Pharmaceuticals

List of Employees-INO Therapeutics-Coppell

Ernie Muniz: Manager, RSC Distribution Operations
Enrique Soria: RSC Distribution Operations/Service Lead
Jerry Nealy: Medical devices Service Technician
Terrell Henry: Medical devices Service Technician
Carlos Zuniga: Medical Delivery Associate
Michael Jennings: Medical Delivery Associate
Jeffrey Dow: Medical Delivery Associate
Luis Ortiz: Medical Delivery Associate
Andrew Njoroge: Medical Delivery Associate.
Chance Price: Wipe Down Associate

4FF

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☑ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ☑ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 01171	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: INO Therapeutics LLC

Physical Address: 3600 Industrial Blvd, Suite C

City: West Sacramento State: CA Zip: 95691

Mailing Address (if different from physical address): 440 US HWY 22 East

City: Bridgewater State: NJ Zip: 08807

Telephone: 916-894-9974 Website: https://www.mallinckrodt.com/

Name of Designated Representative (DR): Wilson Dale

Licensing Company Email: State.licensing@mnk.com DR Email: wilson.dale@mnk.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☑ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☑ Hospitals	☑ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☑ Others: Wholesaler Distributor

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

(Jon Green)
Original Signature (electronic, copies or stamps not accepted)

08/07/2024
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Sunrise Hospital and Medical Center
Address: 3186 South Maryland Parkway City: Las Vegas State: NV Zip: 89109

Name: St. Rose Dominican Hospital
Address: 3001 St. Rose Parkway City: Henderson State: NV Zip: 89052

Name: MountainView Hospital
Address: 3100 North Tenaya Way City: Las Vegas State: NV Zip: 89128

Name: Southern Hills Hospital
Address: 9300 West Sunset Road City: Las Vegas State: NV Zip: 89148

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): Mallinckrodt Hospital Products Inc
Corporation/Organization Name: INO Therapeutics LLC
Mailing Address: 440 US HWY 22 East
City: Bridgewater State: NJ Zip: 08807
Telephone: 916-894-9974 Email: State.licensing@mnk.com
Contact Person Name: Jon Green

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

INO Therapeutics LLC
Facility Name

Jon Green
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

08/07/2024
Date

Board Use Only	Date Received: 8/20/24	Amount: $1000-ck, 2950

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

National Drug Code Directory

Current through October 11, 2022

You have searched Finished drug products

Search Results: *'64693'*

Back to Search Page () | **Search Again ()**

CSV Excel

Display 50 **records per page**

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class
INOmax	64693-002-02	98 mg/L	GAS	RESPIRATORY (INHALATION)	NDA020845	INO THERAPEUTICS LLC	64693-002	nitric oxide	NITRIC OXIDE	HUMAN PRESCRIPTION DRUG	12/23/1999	N/A	NDA	1 CYLINDER in 1 CARTON (64693-002-02) > 1963 L in 1 CYLINDER	Vasodilation [PE], Vasodilator [EPC]
INOmax	64693-002-01	98 mg/L	GAS	RESPIRATORY (INHALATION)	NDA020845	INO THERAPEUTICS LLC	64693-002	nitric oxide	NITRIC OXIDE	HUMAN PRESCRIPTION DRUG	12/23/1999	N/A	NDA	1 CYLINDER in 1 CARTON (64693-002-01) > 353 L in 1 CYLINDER	Vasodilation [PE], Vasodilator [EPC]

Showing 1 to 2 of 2 entries

Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Current list of 5 NABP-Accredited Drug Distributors

Accreditation is valid for 3 years

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.

Name	Address	Accreditation Date
INO Therapeutics LLC	3600 Industrial Blvd, Ste C West Sacramento, CA 95691	Reaccreditation in process
INO Therapeutics LLC	1200 Northbrook Pkwy, Ste 60 Suwanee, GA 30024	Reaccreditation in process
INO Therapeutics, LLC	175 E Crossroads Pkwy, Ste C Bolingbrook, IL 60440	Reaccreditation in process
INO Therapeutics, LLC	875 W Sandy Lake Rd #300 Coppell, TX 75019	Reaccreditation in process
INO Therapeutics, LLC	22 World's Fair Dr, Ste J Somerset, NJ 08873	Reaccreditation in process

Mallinckrodt Pharmaceuticals

Business entity: **INO Therapeutics, LLC**
Corporate Business Address: 440 US HWY 22 East, Bridgewater, NJ 08807

Formation: Delaware

Executive Officers of INO Therapeutics, LLC are:

Name	Title	Business Address
Bryan Reasons	President	440 US HWY 22 East, Bridgewater, NJ 08807
Paul Coiante	Vice President	440 US HWY 22 East, Bridgewater, NJ 08807
Jon J. Green	Vice President, Secretary	440 US HWY 22 East, Bridgewater, NJ 08807

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "INO THERAPEUTICS LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINETEENTH DAY OF JANUARY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

3724403 8300

SR# 20240173879

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202624494

Date: 01-19-24





CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Renewal License

Wholesale Drug Permit

LICENSE NO. WLS 6541
RECEIPT NO. 32980427

VALID UNTIL DECEMBER 01, 2024

INO THERAPEUTICS LLC
3600 INDUSTRIAL BLVD SUITE C
WEST SACRAMENTO CA 95691

In accordance with the provisions of section 4160 of the Business and Professions Code, the firm name hereon is issued a Wholesale Drug Permit.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) manager, vice president of operations, or designated representative-in-charge.

This permit is valid only at the address shown.

10/27/23
10/27/23

The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHWLS (09/30/19) WLS

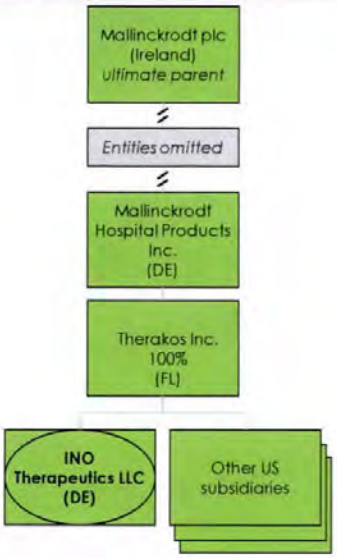
List of Licenses - Sacramento

State	Name	Number	Original Date	Expiration
AK	Non-Resident Wholesaler	179431	06-08-2021	09-30-2024
AR	Wholesale Distributor	WD05003	02-06-2018	12-31-2024
AZ	Wholesaler (Full Service)	W000964	07-29-2003	10-31-2024
CO	Wholesaler Out-of-State	WHO.0007809	04-25-2011	10-31-2024
DC	Non-Resident Wholesaler	DM1800070	03-07-2018	03-31-2025
FL	Non-resident Prescription Drug Manufacturer	26913	09-15-2008	09-30-2024
GA	Wholesaler	PHWH001942	01-02-2004	06-30-2025
ID	Wholesale Distributor	W36154	07-11-2014	12-31-2024
IL	Wholesale Drug Distributor	004002811	12-29-2008	12-31-2024
LA	Distributor Of Legend Drugs Or Devices	8133	01-05-2015	12-31-2024
MT	Wholesale Drug Distributor	PHA-WDD-LIC-28161	12-18-2014	11-30-2024
NC	Wholesale Distributor	1611	12-21-2021	12-31-2024
NJ	Wholesale	5002981	02-19-2003	01-31-2025
NM	Wholesale Drug Distributor	WD00010330	05-13-2003	12-31-2025
NV	Wholesaler	WH01171	06-24-2003	10-31-2024
NY	Non-Resident Wholesaler	036450	02-09-2018	01-31-2025
OH	Wholesaler - Category 2 - Full Service	0130000040	11-01-2008	06-30-2025
OK	Wholesale Distributor	88-W-5460	03-07-2018	03-31-2025
OR	Wholesaler I (With Prescription)	W1-0003645	10-14-2011	09-30-2024
PA	Distributor	3000009831	02-14-2008	02-28-2025
SC	Wholesale/Distributor/Manufacturer Out of State	18314	11-08-2018	06-30-2025
TX	Out-of-State Wholesale Distributor-RX	0072192	11-12-2003	12-31-2024
UT	Pharmacy: Class C Manufacturer, Wholesaler, Distributor	9140506-1710	09-03-2014	09-30-2025
VA	Non-resident Wholesale Distributor	0219001859	08-22-2018	02-28-2025
WA	Pharmaceutical Wholesaler License	PHWH.FX.60504643	01-01-2020	09-30-2024
WY	Wholesale Distributor of Prescription Drugs for Human Use Applica	WD-1269	05-26-2021	06-30-2025

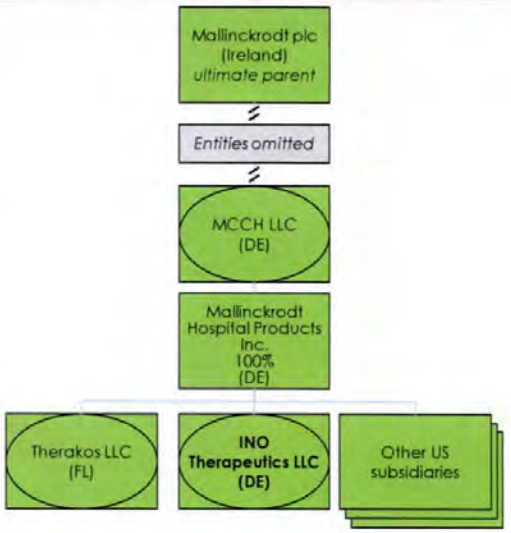
INO Therapeutics LLC (US) change of ownership

Supporting documentation

Current structure – Before ownership change



Future structure – After ownership change (Aug. 30th 2024)



CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 06/28/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. St. Louis MO Office 4220 Duncan Avenue Suite 401 St Louis MO 63110 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
MALLINCKRODT LLC 675 McDonnell Boulevard Hazelwood MO 63042 USA	INSURER A: National Union Fire Ins Co of Pittsburgh	19445
	INSURER B: AIU Insurance Company	19399
	INSURER C: Gemini Insurance Company	10833
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570106923285 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			GL9911771	06/28/2024	06/28/2025	EACH OCCURRENCE	$2,000,000
	CLAIMS-MADE [X] OCCUR			General Liability			DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000
				SIR applies per policy terms & conditions			MED EXP (Any one person)	$10,000
							PERSONAL & ADV INJURY	$2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$4,000,000
	X POLICY [ ] PRO-JECT [ ] LOC						PRODUCTS - COMP/OP AGG	Excluded
	OTHER:							
A	AUTOMOBILE LIABILITY			AL 7281212	06/28/2024	06/28/2025	COMBINED SINGLE LIMIT (Ea accident)	$3,000,000
	X ANY AUTO			AOS			BODILY INJURY (Per person)	
B	OWNED AUTOS ONLY / HIRED AUTOS ONLY / SCHEDULED AUTOS / NON-OWNED AUTOS ONLY			SIR applies per policy terms & conditions AL 7281213	06/28/2024	06/28/2025	BODILY INJURY (Per accident)	
				MA			PROPERTY DAMAGE (Per accident)	
				SIR applies per policy terms & conditions				
	UMBRELLA LIAB [ ] OCCUR						EACH OCCURRENCE	
	EXCESS LIAB [ ] CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			WC014111703	06/28/2024	06/28/2025	X PER STATUTE [ ] OTH-ER	
B	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [N] N/A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			AOS WC014111702	06/28/2024	06/28/2025	E.L. EACH ACCIDENT	$1,000,000
				CA			E.L. DISEASE-EA EMPLOYEE	$1,000,000
				SIR applies per policy terms & conditions			E.L. DISEASE-POLICY LIMIT	$1,000,000
C	Products Liability			GL177971	06/28/2024	06/28/2025	SIR APPLIES	$5,000,000
				SIR applies per policy terms & conditions				

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: J. Green. Evidence of Insurance. Coverage evidenced under this certificate extends to include all Mallinckrodt subsidiaries including INO Therapeutics LLC and the locations at the following addresses: Illinois - 175 East Crossroad Parkway, Unit C, Bolingbrook, IL 60440 and New Jersey - 22 World's Fair Drive STE J, Somerset, NJ 08873 - 875 West Sandy Lake RD, Coppell, TX - 3600 Industrial Blvd, West Sacramento, CA

CERTIFICATE HOLDER

Mallinckrodt PLC
675 James S. McDonnell Blvd.
Hazelwood MO 63042 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central Inc.

Holder Identifier :

Certificate No : 570106923285

©1988-2015 ACORD CORPORATION. All rights reserved.

AGENCY CUSTOMER ID: 570000061378
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	MALLINCKRODT LLC
POLICY NUMBER: See Certificate Number: 570106923285	
CARRIER: See Certificate Number: 570106923285 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER	
INSURER	
INSURER	
INSURER	

ADDITIONAL POLICIES If a policy below does not include limit information, refer to the corresponding policy on the ACORD certificate form for policy limits.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	WORKERS COMPENSATION							
B		N/A		WC014111704 WI SIR applies per policy terms & conditions	06/28/2024	06/28/2025		

ACORD 101 (2008/01) © 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: 570000061378
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	MALLINCKRODT LLC
POLICY NUMBER: See Certificate Number: 570106923285	
CARRIER: See Certificate Number: 570106923285 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Excess Product Liability policies

Excess Products Liability 1st Layer
CARRIER: TDC Specialty Insurance Company
POLICY: LSX-00013-24-07
EFF: 6/28/24
EXP: 6/28/25
Limit: $5,000,000 xs $5,000000

ACORD 101 (2008/01)
© 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

VERIFICATION OF BOND IN FORCE
Form SB-3

Type of Bond: License/Permit Bond

Name of Principal: MALLINCKRODT ARD LLC / INO THERAPEUTICS LLC

Obligee: THE NEVADA STATE BOARD OF PHARMACY

Carrier: ATLANTIC SPECIALTY INSURANCE COMPANY

Bond Number: 800051035

Effective Date: October 26, 2024

Limit: $ 100,000.00

Premium: $ 1,000.00

This Bond is continuous with no definite expiration date. Sufficient Premium has been paid to satisfy the requirements of the Carrier for this bond to October 26, 2025.

ATLANTIC SPECIALTY INSURANCE COMPANY

By: _____
Nicholas Kertesz Attorney in Fact

Date: October 11, 2024

intact INSURANCE

Power of Attorney

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **Aaron D. Griffin, Aerie Walton, Barbara Pannier, Bartlomiej Siepierski, Christina L. Sandoval, Christopher P. Troha, Corinne Chapman, Dartonya Wright, Derek J. Elston, Jean Torres, Jennifer Williams, Judith A. Lucky-Eftimov, Kristin L Hannigan, Nicholas Kertesz, Nicholas Pantazis, Rachel Fore, Richard Casas, Roger Paraison, Salena Wood, Samantha Chierici, Sandra M. Winsted, Susan A. Welsh, Tara A Maquinto, Therese M. Jackson**, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this first day of January, 2023.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Sarah A. Kolar, Vice President and General Counsel

STATE OF MINNESOTA
HENNEPIN COUNTY

On this first day of January, 2023, before me personally came Sarah A. Kolar, Vice President and General Counsel of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and she acknowledged the execution of the same, and being by me duly sworn, that she is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON DWAN NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2025

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 11th day of October 2024

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

_____
Kara L.B. Barrow, Secretary

This Power of Attorney expires
January 31, 2025

Please direct bond verifications to surety@intactinsurance.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG INO Therapeutics LLC MDEG License # (if applicable) WH01171

Physical Address 3600 Industrial Blvd Ste C

City West Sacramento State CA Zip 95691

Mailing Address (if different from physical address) 440 US Highway 22 East

City Bridgewater State NJ Zip 08807

Telephone 916-894-9974 Website www.inotherapeutics.com

Licensing Company Email state.licensing@mnk.com

Section 2: Personal Information

First Wilson Middle Collins Last Dale

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 3600 Industrial Blvd Ste C

City West Sacramento State CA Zip 95691

Telephone [redacted] Email state.licensing@mnk.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Tokay High School			
Address	**City**	**State**	**Zip**
1111 W. Century Blvd	Lodi	CA	95240
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/2019-present	[redacted]	Sacramento	CA	95833
11/2016-02/2019		Sacramento	CA	95826
06/2009-11/2016		Galt	CA	95632
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
INO Therapeutics LLC			12/2014-Present	
Business Address		City	State	Zip
3600 Industrial Blvd		West Sacramento	CA	95691
Phone	Title		Number of Employed Hours	
916-894-9970	RSC Distribution Operations/Service Lead		approx 18,720	

Description of Duties

Part of management team along with Customer Care to ensure customer needs for medical devices and pharmaceutical drug are met.
Part of management team to resolve exceptions on routes in SAP. Provide guidance to fellow employees on day to day operations.
Help ensure policies and procedures are followed per regulations. Manage distribution of pharmaceutical drug to customers via 3rd party logistics, and on pre-planned routes.
Designated Representative per FDA

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

09/19/2024
Date

I, Wilson Dale, **certify that as the MDEG Administrator for**

INO Therapeutics LLC,

that I (initial that you have read and meet the following requirements):

1. WD Have a high school diploma or its equivalent;
2. WD Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. WD Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. WD Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Wilson Dale
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

09/19/2024
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler INO Therapeutics LLC
Pharmacy/Wholesaler License # (if applicable) WH01171
Physical Address 3600 Industrial Blvd
City West Sacramento State CA Zip 95691
Mailing Address (if different from physical address) 440 US HWY 22 East
City Bridgewater State NJ Zip 08807
Telephone (916) 894-9974 Website www.inotherapeutics.com
Licensing Company Email state.licensing@mnk.com

Section 2: Personal Information

First Wilson Middle Collins Last Dale
Alias(es, nicknames, name changes, etc.)
Date of Birth [redacted] SSN or ITI [redacted] Sex ☑ M ☐ F ☐ X
Mailing Address 3600 Industrial Blvd
City West Sacramento State CA Zip 95691
Telephone (916) 894-9970 Email state.licensing@mnk.com
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Tokay High School		06/2001 to 06/2003	
Address	City	State	Zip
1111 W. Century Blvd	Lodi	CA	95240
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/2019- Present	[redacted]	Sacramento	CA	95833
11/2016-02/2019		Sacramento	CA	95826
06/2009-11/2016		Galt	CA	95632
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
INO Therapeutics LLC			December 2014 - Present
Business Address	**City**	**State**	**Zip**
3600 Industrial Blvd	West Sacramento	CA	95691
Phone	**Title**	**Number of Employed Hours**	
(916) 894-9970	RSC Distribution Operations/Service Lead	approx 18,720	

Description of Duties
Part of management team along with Customer Care to ensure customer needs for medical devices and pharmaceutical drug are met.
Part of management team to resolve exceptions on routes in SAP. Provide guidance to fellow employees on day to day operations.
Help ensure policies and procedures are followed per regulations. Manage distribution of pharmaceutical drug to customers via 3rd party logistics, and on pre-planned routes.
Designated Representative per FDA

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Wilson Dale

Original Signature (electronic, copies or stamps not accepted)

08/09/2024

Date

I, Wilson Dale, **certify that as the designated representative for**

INO Therapeutics LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. WCD I am at least 21 years of age;
3. WCD I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. WCD I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. WCD I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. WCD I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. WCD I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Wilson Dale

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/09/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Wilson Dale

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/09/2024

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, Wilson C Dale, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

MANIT PATEL
COMM. # 2394827
NOTARY PUBLIC - CALIFORNIA
YOLO COUNTY
COMM. EXPIRES FEB. 23, 2026

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California, County of YOLO
Subscribed and sworn to (or affirmed) before me on this 9TH day of AUGUST, 20 24, by WILSON COLLINS DALE, proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.
Signature _____ NOTARY PUBLIC

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site INO Therapeutics LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) WH01171

Physical Address 3600 Industrial Blvd, Suite C

City West Sacramento State CA Zip 95691

Mailing Address (if different from physical address) 440 US HWY 22 East

City Bridgewater State NJ Zip 08807

Telephone 916-894-9974 Website https://www.mallinckrodt.com/

Licensing Company Email State.licensing@mnk.com

Section 2: Personal Information

First Jon Middle J Last Green

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Bridgewater State NJ Zip 08807

Telephone [redacted] Email jon.green@mnk.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Brentwood High School		09/1979 to 05/1983	
Address	City	State	Zip
2221 High School Drive	Brentwood	MO	63144
Diploma/Degree obtained, if any			
HS diploma			

School Name		From - To (MM/YY – MM/YY)	
Webster University		05/2006 to 05/2007	
Address	City	State	Zip
470 E Lockwood Ave	Webster Groves	MO	63119
Diploma/Degree obtained, if any			
Bachelor of Arts			

School Name		From - To (MM/YY – MM/YY)	
Webster University		05/2007 to 04/2009	
Address	City	State	Zip
470 E Lockwood Ave	Webster Groves	MO	63119
Diploma/Degree obtained, if any			
Master of Laws			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/2017 to present	[redacted]	Bedminster	NJ	07921
04/2010 to 02/2017		Kirkwood	MO	63122
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Mallinckrodt Pharmaceuticals			03/15/1991 to present
Business Address	**City**	**State**	**Zip**
440 US HWY 22 East	Bridgewater	NJ	08827
Phone	**Title**		
908-238-5587	Vice President		
Description of Duties			
Legal and Compliance Manager for Mallinckrodt Pharmaceuticals			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

(Jon Green) 08/07/2024

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jon J Green
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/07/2024
Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Somerset

I, Jon J Green, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

08/07/2024
Date

Subscribed and Sworn to before me this 7th day of August.

Notary Public Signature

SUZANNE V DZULA-ADAMS
Commission # 50221776
Notary Public, State of New Jersey
My Commission Expires
May 09, 2029

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site INO Therapeutics LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) WH01171

Physical Address 3600 Industrial Blvd, Suite C

City West Sacramento State CA Zip 95691

Mailing Address (if different from physical address) 440 US HWY 22 East

City Bridgewater State NJ Zip 08807

Telephone 916-894-9974 Website https://www.mallinckrodt.com/

Licensing Company Email State.licensing@mnk.com

Section 2: Personal Information

First Bryan Middle N/A Last Reasons

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Bridgewater State NJ Zip 08807

Telephone [redacted] Email bryan.reasons@mnk.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Widener University		08/1991 – 05/1993	
Address	City	State	Zip
One University Place	Chester	PA	19013
Diploma/Degree obtained, if any			
Masters in Business Administation			

School Name		From - To (MM/YY – MM/YY)	
Pennsylvania State University - Smeal College of Business		08/1986 – 05/1990	
Address	City	State	Zip
210 Business Building	University Park	PA	16802
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name	Address	From - To (MM/YY – MM/YY)	
Unionville High School	225 Hickory Dri, #31D	09/1982 – 06/1986	
Address	City	State	Zip
740 Unionville Road	Kennett Square	PA	19348
Diploma/Degree obtained, if any			
HS diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2022 to present	[redacted]	Wayne	PA	19087
07/2021 – 07/2022		Chatham	NJ	07928
08/2015 to 07/2021		Chatham	NJ	07928
06/2013 to 08/2015		Danville	CA	94506
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Mallinckrodt Pharmaceuticals			03/2019 to present
Business Address	**City**	**State**	**Zip**
440 US HWY 22 East	Bridgewater	NJ	08807
Phone	**Title**		
908-997-9289	Vice President, CFO		
Description of Duties			
Accounting, Treasury, SEC Reporting, Management Reporting,Financial Planning and Analysis, Business Development, Investor Relations and Corporate Communications, Internal Audit and Information Technology (IT&S), Global Procurement			

Business Name			From - To (MM/YY – MM/YY)
Amneal Pharmaceuticals / Impax Laboratories			01/2012 to 02/2019
Business Address	**City**	**State**	**Zip**
400 Crossing Blvd	Bridgewater	NJ	08807
Phone	**Title**		
908- 947-3120	Senior Vice President Finance and Chief Financial Officer		
Description of Duties			
Accounting, Treasury, SEC Reporting, Management Reporting, Financial Planning and Analysis, Business Development, Investor Relations and Corporate Communications, Internal Audit and Information Technology (IT&S)			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

08/07/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bryan Reasons
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/27/24
Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Somerset

I, Bryan M Reasons, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/27/24
Date

Subscribed and Sworn to before me this 7th day of August.

Notary Public Signature

SUZANNE V DZULA-ADAMS
Commission # 50221776
Notary Public, State of New Jersey
My Commission Expires
May 09, 2029

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: INO Therapeutics LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WHO1171

Physical Address: 3600 Industrial Blvd, Suite 30

City: West Sacramento State: CA Zip: 95691

Mailing Address (if different from physical address): 440 US HWY 22 East

City: Bridgewater State: NJ Zip: 08807

Telephone: 916-894-9974 Website: https://www.mallinckrodt.com/

Licensing Company Email: state.licensing@mnk.com

Section 2: Personal Information

First: Paul Middle: R Last: Coiante

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: Trenton, NJ SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Bridgewater State: NJ Zip: 08807

Telephone: [redacted] Email: paul.coiante@mnk.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Ewing High School		09/1985 to 06/1987	
Address	**City**	**State**	**Zip**
900 Parkway Ave	Ewing Twp	NJ	08618
Diploma/Degree obtained, if any			
HS diploma			

School Name		From - To (MM/YY – MM/YY)	
Eckerd College		09/1987 to 05/1991	
Address	**City**	**State**	**Zip**
4200 54th Ave S	St Petersburg	FL	33711
Diploma/Degree obtained, if any			
BA			

School Name		From - To (MM/YY – MM/YY)	
Rutgers University		09/1991 to 05/1994	
Address	**City**	**State**	**Zip**
190 University Ave	Newark	NJ	07102
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2004 to present	[redacted]	Ringoes	NJ	08551
11/2017 to 07/2004		Holgate	NJ	08008
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Mallinckrodt Pharmaceuticals			12/2010 to present
Business Address	**City**	**State**	**Zip**
440 US HWY 22 East	Bridgewater	NJ	08807
Phone	**Title**		
908-892-8116	Vice President of Sales		

Description of Duties

- Contracted over 500M across 600+ accounts
- 2020 sales volume of 523M (14% above plan) with 2 new market entrants
- Prepared 2 sales teams for 2 new product launches in critical care
- Successfully negotiated co-promote deal resulting in 6M

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A				
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

8-7-2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Paul R Coiante

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8-7-2024

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Somerset

I, Paul R Coiante, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8-7-2024

Date

Subscribed and Sworn to before me this 7th day of August.

Notary Public Signature

SUZANNE V DZULA-ADAMS
Commission # 50221776
Notary Public, State of New Jersey
My Commission Expires
May 09, 2029

(Seal)

Mallinckrodt Pharmaceuticals

List of Employees-INO Therapeutics-Sacramento

Gregory Edwards: Manager, RSC Distribution Operations
Wilson Dale: Designated Representative, Medical Device Service Technician
Daniel Gonzalez: Medical Device Service Technician
Harman Jhajj: RSC Distribution Operations/Service Lead
Neal Hodge: Medical Delivery Associate
Don Spencer: Medical Delivery Associate
Chris Forwood: Medical Delivery Associate
Quentin Bonton: Medical Delivery Associate
Josh Rhoton: Medical Delivery Associate
Daniel DeLeon: Medical Delivery Associate

4GG

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Advanced Med Sales, Inc.

Physical Address: 2304 Seaborn Rd #100

City: Ponder State: TX Zip: 76259

Mailing Address (if different from physical address): 232 Avenida Fabricante, Suite 103/104

City: San Clemente State: CA Zip: 92672

Telephone: 949-348-7912 Website: ams-rx.com

Name of Designated Representative (DR): Dezmon Gonzalez

Licensing Company Email: compliance@ams-rx.com DR Email: dezmon@ams-rx.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A	N/A	N/A	N/A

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
N/A	N/A

Reason/Charge
N/A

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
N/A	N/A

Name of Business/Industry/Entity
N/A

Provide explanation below:
N/A

Original Signature (electronic, copies or stamps not accepted)

6/7/2024
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: McKesson Corp
Address: 16043 El Prado Avenue City: Chino State: CA Zip: 91708

Name: Masters Drug Company, Inc.
Address: 3600 Pharma Way City: Mason State: OH Zip: 45036

Name: Fresenius Kabi USA, LLC
Address: 5245 N. Solan Lane, Suite 100A City: North Las Vegas State: NV Zip: 89115

Name: Cardinal Health
Address: 27680 Avenue Mentry City: Valencia State: CA Zip: 91355

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any): N/A
Corporation Name: N/A
Mailing Address: N/A
City: N/A State: N/A Zip: N/A
Telephone: N/A Email: N/A
Contact Person Name: N/A

Date of SEC Registration: N/A | SEC Registration Number: N/A | Stock Exchange Symbol: N/A

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California
Parent Company (if any): N/A
Corporation/Organization Name: Advanced Medical Sales, Inc.
Mailing Address: 232 Avenida Fabricante, Suite 103/104
City: San Clemente State: CA Zip: 92672
Telephone: 949-348-7912 Email: Compliance@ams-rx.com
Contact Person Name: Michael Rocha

Section 6: Partnership

Partnership Name: N/A
Mailing Address: N/A
City: N/A State: N/A Zip: N/A
Telephone: N/A Email: N/A
Contact Person Name: N/A

Section 7: Sole Owner

Owner's Name: N/A
Business Name: N/A
Business Address: N/A
City: N/A State: N/A Zip: N/A
Telephone: N/A Email: N/A

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** ✓	✓	✓		
• ~~**List the top four corporation shareholders and their percent ownership.**~~	✓			
• **List of all corporation shareholders and their percent ownership.** ✓		✓		
• ~~**List of all partners and their percent ownership.**~~			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** ✓	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ ✓		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/ ✓		✓	✓	✓
• ~~**Copy of DEA certificate if handling controlled substances**~~	✓	✓	✓	✓
• ~~**Copy of current SEC 10K or 8K** (First 15 pages only)~~	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** ✓	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** ✓	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ ✓	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. ✓		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Advanced Medical Sales, Inc.

Facility Name

Michael Rocha

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

6/7/2024

Date

Board Use Only	Date Received: 6/6/24	Amount: $1000 ck 2923

Ownership & Corporate Structure

Advanced Medical Sales, Inc.

Dba Advanced Med Sales, Inc.

Owner:

- The Michael James Rocha and Shannon Janelle Rocha Family Trust DTD 12/03/14
  - [redacted] Ladera Ranch, CA 92694
  - Ownership Percentage: 100%
  - TIN: [redacted]

❖ Trustees:

- Michael Rocha
  - Home [redacted]
  - Business: 232 Avenida Fabricante #103/104, San Clemente, CA 92672
  - [redacted]
- Shannon Rocha
  - [redacted]
  - Business: 232 Avenida Fabricante #103/104, San Clemente, CA 92672
  - [redacted]

Executive Officers:

- Michael Rocha
  - CEO / CFO / Secretary / Treasurer
  - President / Vice President

Directors:

- Michael Rocha
- Shannon Rocha

Designated Representatives:

- Advanced Medical Sales, Inc.
  - 232 Avenida Fabricante #103/104, San Clemente, CA 92672
    - Michael Rocha
- Advanced Med Sales, Inc.
  - 2304 Seaborn Rd #100, Ponder, TX 76259
    - Dezmon Gonzalez

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Application for Registration for Advanced Medical Sales, Inc., authorized under the name Advanced Med Sales, Inc. (file number 804908230), a CALIFORNIA, USA, Foreign For-Profit Corporation, was filed in this office on February 01, 2023.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on January 31, 2024.

Jane Nelson
Secretary of State

TEXAS
Health and Human Services

Texas Department of State Health Services

Jennifer A. Shuford, M.D., M.P.H.
Commissioner

January 25, 2024

Ryan Moreau
Advanced Medical Sales, Inc.
ryan@ams-rx.com

CFN: 2112554
Lic.: 1003627
Type: 2501
File: 6839

Re: License Verification

Dear Ryan Moreau:

This letter shall serve as a verification of licensure for the following firm:
ADVANCED MED SALES INC
2304 SEABORN RD STE 100
PONDER, TX 76259

License No.	1003627
Type of license:	Prescription Drug Distributor
Status of license:	Current
Date license issued:	05/15/2023
Date license expires:	03/21/2025
Disciplinary action:	None

The firm is in good standing as of the date of this letter.

If you have questions or need additional information, please contact me at 512-834-4503, via fax at (512) 834-6759, or email me at *justin.arnold@dshs.texas.gov*.

Sincerely,

Justin Arnold, RS
Medical Research Specialist
Drugs and Medical Devices Unit
Consumer Protection Division

Mailing address:
Justin Arnold
Drugs and Medical Devices Unit, MC 1987
PO Box 149347
Austin, TX 78714-9347

- Please contact this office immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **www.dshs.texas.gov**.
- Please submit written notice if you close or sell your business.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drug and Device Business Filing and Verification Unit at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

ADVANCED MED SALES INC
2304 SEABORN RD STE 100
PONDER TX 76259

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

ADVANCED MEDICAL SALES INC DBA
ADVANCED MED SALES INC
2304 SEABORN RD STE 100
PONDER, TX 76259

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

WHOLESALE DISTRIBUTOR OF PRESCRIPTION DRUGS

License # 1003627
Expires: March 21, 2025

NON-TRANSFERABLE

Commissioner

516888

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 09/22/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Phone: (714) 973-1436 Fax: (714) 973-0811
ELMCO INSURANCE, INC.
636 E CHAPMAN AVENUE
ORANGE CA 92866
Agency Lic#: 0509747

CONTACT NAME: ELMCO INSURANCE, INC.
PHONE (A/C, No, Ext): (714) 973-1436 FAX (A/C, No): (714) 973-0811
E-MAIL ADDRESS: contact@Elmcoinsurance.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : LIBERTY SURPLUS INSURANCE CORPORATION	
INSURER B : MESA UNDERWRITERS SPECIALTY INSURANCE COMPANY	
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
ADVANCED MEDICAL SALES, INC
2304 SEABORNE ROAD, #100
PONDER, TX 76259

COVERAGES **CERTIFICATE NUMBER:** 77580 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			APU000258-06	05/01/24	05/01/25	EACH OCCURRENCE	$	1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	300,000
							MED. EXP (Any one person)	$	
							PERSONAL & ADV INJURY	$	INCLUDED
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$	INCLUDED
	OTHER:							$	
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$	
	ANY AUTO						BODILY INJURY (Per person)	$	
	ALL OWNED AUTOS / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS / NON-OWNED AUTOS						PROPERTY DAMAGE (per accident)	$	
								$	
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$	
	DED RETENTION $							$	
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY						PER STATUTE / OTH-ER		
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y / N	N / A					E.L. EACH ACCIDENT	$	
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	$	
							E.L. DISEASE-POLICY LIMIT	$	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

SEE SUPPLEMENTAL CERTIFICATE INFORMATION

CERTIFICATE HOLDER

Nevada State Board of Pharmacy

Attention:

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Veronica Acosta

ACORD 25 (2014/01)
© 1988-2014 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

SUPPLEMENT TO CERTIFICATE OF LIABILITY INS # 77580

DATE
SEP 22 2024

DESCRIPTION OF OPERATIONS, LOCATIONS, VEHICLES

2304 Seaborn Road, #100
Ponder, TX 76259

232 Avenida Frabricante Ste 103/104
San Clemente, CA 92672

Certificate # 77580

Western Surety Company

RIDER

To be attached to and form part of Bond No. 72644868

It is hereby mutually agreed and understood by and between Western Surety Company and **Advanced Medical Sales, Inc.**

that instead of as originally written; the bond is changed or revised in the particulars checked below:

- ☐ **Principal Name changed to:**
- ☐ **Principal Address changed to:**
- ☐ **Vehicle/Vessel/Hull Information changed to:**
- ☐ **Lost Instrument Information changed to:**
- ☐ **Identification Number changed to:**
- ☐ **Penalty Amount changed to:**
- ☒ **Additional or Event Location:** Addition Location: Advanced Medical Sales, Inc., 2304 Seaborn Rd, Ste 100, Ponder, TX 76259
- ☐ **Effective Date changed to:**
- ☐ **Expiration Date changed to:**
- ☐ **The following bond information changed:**

But in no event shall Western Surety Company's total liability for all locations exceed the aggregate amount set forth in the bond, regardless of the number of years this bond remains in force, the number of claims made, or the number of renewal premiums payable or paid.
It is further understood and agreed that all other terms and conditions of this bond shall remain unchanged.

This Rider becomes effective on the 14th day of May, 2024.

Signed this 29th day of May, 2024.

WESTERN SURETY COMPANY

By: _____
Larry Kasten, Vice President

Form F9586

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 72644868

Application/License No. _____

Advanced Medical Sales, Inc. (Applicant /Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is

Ste. 103-104 232 Avenida Fabricante, San Clemente, CA 92672 (Address of Applicant /Principal), as PRINCIPAL, and WESTERN SURETY COMPANY (Surety Company), a corporation organized under the laws of the state of South Dakota (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is

P. O. Box 5077, Sioux Falls, SD 57117-5077 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on May 14th, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

Western Surety Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS:

That WESTERN SURETY COMPANY, a corporation organized and existing under the laws of the State of South Dakota, and authorized and licensed to do business in the States of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming, and the United States of America, does hereby make, constitute and appoint

Larry Kasten of Sioux Falls,

State of South Dakota, *its regularly elected* Vice President,

as Attorney-in-Fact, with full power and authority hereby conferred upon him to sign, execute, acknowledge and deliver for and on its behalf as Surety and as its act and deed, the following bond:

One Prescription Drug Wholesale Distributor

bond with bond number 72644868

for Advanced Medical Sales, Inc.

as Principal in the penalty amount not to exceed: $100,000.00.

Western Surety Company further certifies that the following is a true and exact copy of Section 7 of the by-laws of Western Surety Company duly adopted and now in force, to-wit:

Section 7. All bonds, policies, undertakings, Powers of Attorney, or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, any Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys-in-Fact or agents who shall have authority to issue bonds, policies, or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile.

In Witness Whereof, the said WESTERN SURETY COMPANY has caused these presents to be executed by its Vice President with the corporate seal affixed this 29th day of May, 2024.

ATTEST

L. Bauder, Assistant Secretary

WESTERN SURETY COMPANY

By

Larry Kasten, Vice President

WESTERN SURETY COMPANY CORPORATE SEAL SOUTH DAKOTA

STATE OF SOUTH DAKOTA }
COUNTY OF MINNEHAHA } ss

On this 29th day of May, 2024, before me, a Notary Public, personally appeared Larry Kasten and L. Bauder who, being by me duly sworn, acknowledged that they signed the above Power of Attorney as Vice President and Assistant Secretary, respectively, of the said WESTERN SURETY COMPANY, and acknowledged said instrument to be the voluntary act and deed of said Corporation.

M. BENT NOTARY PUBLIC SOUTH DAKOTA SEAL SEAL

M. Bent

Notary Public

My Commission Expires March 2, 2026

To validate bond authenticity, go to www.cnasurety.com > Owner/Obligee Services > Validate Bond Coverage.

Form F1975-11-2022

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Advanced Medical Sales, Inc. MDEG License # (if applicable): N/A

Physical Address: 2304 Seaborn Rd. #100

City: Ponder State: TX Zip: 76259

Mailing Address (if different from physical address): 232 Avenida Fabricante, Suite 103/104

City: San Clemente State: CA Zip: 92672

Telephone: 949-348-7912 Website: ams-rx.com

Licensing Company Email: Compliance@ams-rx.com

Section 2: Personal Information

First: Dezmon Middle: Joseph Last: Gonzalez

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: 2304 Seaborn Rd. #100

City: Ponder State: TX Zip: 76259

Telephone: [redacted] Email: Compliance@ams-rx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Downey High School		2000-2004	
Address	**City**	**State**	**Zip**
11040 Brookshire Ave	Downey	CA	90241
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2/23 - Current	[redacted]	Northlake	TX	76226
03/18 - 02/23		Lake Elsinore	CA	92530
01/14 - 03/18		Lake Elsinore	CA	92530
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Advanced Med Sales, Inc.			02/23 - Current	
Business Address		**City**	**State**	**Zip**
2304 Seaborn Rd. #100		Ponder	TX	76259
Phone	**Title**		**Number of Employed Hours**	
949-348-7912	Director of Operations, Texas		2,400	
Description of Duties				
Running day to day operations, B2B Pharmaceutical, Shipping/Receiving, Administration work				

Business Name			From - To (MM/YY – MM/YY)	
Advanced Medical Sales, Inc.			04/11 - Current	
Business Address		**City**	**State**	**Zip**
216 Avenida Fabricante #110		San Clemente	CA	92672
Phone	**Title**		**Number of Employed Hours**	
949-348-7912	Purchasing Manager		22,880	
Description of Duties				
Purchasing Pharmaceuticals, Shipping/Receiving, B2B Pharmaceutical Sales, Managing Warehouse				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	
Description of Duties				
N/A				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
01/14/2005		CA	Fullerton	Orange
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		Fullerton Police Department		
Reason/Charge				
Possession of a Dangerous Weapon and Driving on a Suspended License				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Dezmon Gonzalez				
Name of Business/Industry/Entity				

Provide explanation below:

I was 18 years old and not taking life or anything serious at that time. Had just moved in with my father and was running with the wrong crowd and thought I was cool carrying butterfly knife around. My license was suspended because I did not pay a couple tickets I racked up. The expired tags on my uncle's car I was driving was the reason I was pulled over.

Original Signature (electronic, copies or stamps not accepted)

6/4/2024
Date

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
06/24/2005		CA	Fullerton	Orange

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2260593	Fullerton Police Department

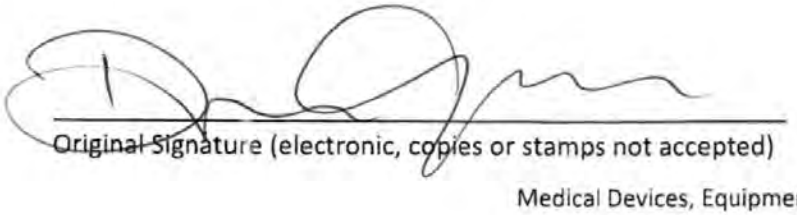
Reason/Charge
Possession of a Switchblade Knife and False ID to a Peace Officer

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Dezmon Gonzalez	

Name of Business/Industry/Entity

Provide explanation below:

I was hanging out with some friends at 1am outside my apartment complex that I lived in with my father. We had the cops called on us because it was late, and we were making a ton of noise and being obnoxious. A couple older guys in the group were drinking so the officer wanted to see everyone's ID/Driver's License. I had a warrant for not showing up to court for the previous offense on 01/14/2005 so I lied about my name to avoid getting caught. The officer found my ID in the car next to us and ran my name and took me in for lying to him about my name and again I had a butterfly knife on me. Needless to say, I never carried one again after that.



Original Signature (electronic, copies or stamps not accepted)

6/4/2024

Date

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
07/16/2010		CA	Whittier	Los Angeles

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
1365409	Whittier Police Department

Reason/Charge
Disorderly Conduct and Under the Influence of Alcohol

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Dezmon Gonzalez	

Name of Business/Industry/Entity

Provide explanation below:

I was at my aunt's house drinking with friends and family. Had too much to drink and went outside to smoke a cigarette after an arguement with my wife (then girlfriend) and was locked out of the house. I started causing a scene banging on the door to be let in. I started walking down the street after I realized I needed to cool off. I assume a neighbor called the cops because I was picked up walking down the street. The police officer could tell I was intoxicated and put me in a holding cell till I sobered up. I was released the next morning. One of a few embarrassing moments in my life.

Original Signature (electronic, copies or stamps not accepted)

6/4/2024
Date

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
04/09/2009		CA	Rancho Cucamonga	San Bernardino
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
90301866		San Bernardino Sheriff's Station		
Reason/Charge				
Drunk in Public				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Dezmon Gonzalez				
Name of Business/Industry/Entity				

Provide explanation below:

I was 22 years old at a local bar with friends and decided to walk home with a buddy instead of drive. We were drunk and making quite a bit of noise and was pulled over and cited for being drunk in public and released.

Original Signature (electronic, copies or stamps not accepted)

6/4/2024
Date

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
03/18/2013		CA	Ontario	San Bernardino

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
MWV1302033-3	Ontario Police Department

Reason/Charge
Fight/Challenge to Fight in a Public Place

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Dezmon Gonzalez	

Name of Business/Industry/Entity

Provide explanation below:

I went to a bar with friends and family for St. Patrick's Day. Near the end of the night, a guy was harassing my wife (fiance at the time) so I confronted him, and we got into a fight that poured outside. Cops were called and was broken up by onlookers. The bar ended up pressing charges on everyone involved. I had to be taken away by ambulance and spent part of the night in the hospital for observation.

Original Signature (electronic, copies or stamps not accepted)

6/4/2024
Date

I, Dezmon Gonzalez, **certify that as the MDEG Administrator for**

Advanced Medical Sales, Inc. dba Advanced Med Sales, Inc.,

that I (initial that you have read and meet the following requirements):

1. DG Have a high school diploma or its equivalent;
2. DG Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. DG Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. DG Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

DEZMON GONZALEZ

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/4/2024

Date

Board Use Only	Date Received: 8/6/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

y

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Advanced Medical Sales, Inc.

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 2304 Seaborn Rd. #100

City: Ponder State: TX Zip: 76259

Mailing Address (if different from physical address): 232 Avenida Fabricante #103/104

City: San Clemente State: CA Zip: 92672

Telephone: 949-348-7912 Website: ams-rx.com

Licensing Company Email: compliance@ams-rx.com

Section 2: Personal Information

First: Dezmon Middle: Joseph Last: Gonzalez

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: 2304 Seaborn Rd. #100

City: Ponder State: TX Zip: 76259

Telephone: [redacted] Email: compliance@ams-rx.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Downey High School		2000-2004	
Address	**City**	**State**	**Zip**
11040 Brookshire Ave.	Downey	CA	90241
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/23 - Current	[redacted]	Northlake	TX	76226
03-18 - 02/23		Lake Elsinore	CA	92530
1/14 - 03/18		Lake Elsinore	CA	92530
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Advanced Med Sales, Inc			02/23 - Current	
Business Address	**City**		**State**	**Zip**
2304 Seaborn Rd #100	Ponder		TX	76259
Phone	**Title**		**Number of Employed Hours**	
949-348-7912	Director of Operations, Texas		2,400	
Description of Duties				
Running day to day operations, B2B Pharmaceutical , Shipping/ Receiving, Administration work.				

Business Name			From - To (MM/YY – MM/YY)	
Advanced Medical Sales, Inc			04/11 - Current	
Business Address	**City**		**State**	**Zip**
216 Avenida Fabricante #110	San Clemente		CA	92672
Phone	**Title**		**Number of Employed Hours**	
949-348-7912	Purchasing Manager		22,880	
Description of Duties				
Purchasing Pharmaceuticals, Shipping/Receiving, B2B Pharmaceutical Sales, Managing Warehouse				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Advanced Med Sales, Inc			02/23 - Current	
Business Address		**City**	**State**	**Zip**
2304 Seaborn Rd #100		Ponder	TX	76259
Phone	**Title**		**Number of Employed Hours**	
949-348-7912	Director of Operations, Texas		2,400	
Description of Duties				
Running day to day operations, B2B Pharmaceutical , Shipping/ Receiving, Administration work.				

Business Name			From - To (MM/YY – MM/YY)	
Advanced Medical Sales, Inc			04/11 - Current	
Business Address		**City**	**State**	**Zip**
216 Avenida Fabricante #110		San Clemente	CA	92672
Phone	**Title**		**Number of Employed Hours**	
949-348-7912	Purchasing Manager		22,880	
Description of Duties				
Purchasing Pharmaceuticals, Shipping/Receiving, B2B Pharmaceutical Sales, Managing Warehouse				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✔	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
1/14/2005		CA	Fullerton	Orange
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		Fullerton Police Department		
Reason/Charge				
Possession of a Dangerous Weapon and Driving on a Suspended License				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Dezmon Gonzalez				
Name of Business/Industry/Entity				

Provide explanation below:

I was 18 years old and not taking life or anything serious at that time. Had just moved in with my father and was running with the wrong crowd and thought I was cool carrying butterfly knife around. My license was suspended because I did not pay a couple tickets I racked up. The expired tags on my uncle's car I was driving was the reason I was pulled over.

Original Signature (electronic, copies or stamps not accepted)

3/24/24
Date

Applicant's initials

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
6/24/2005		CA	Fullerton	Orange

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2260593	Fullerton Police Department

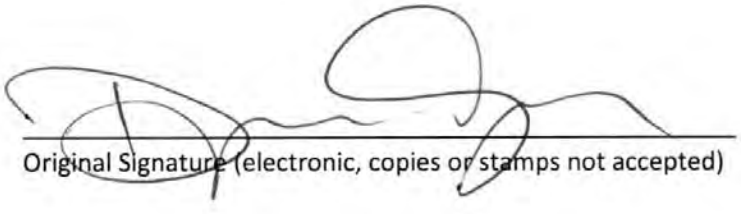
Reason/Charge
Possession of a Switchblade Knife and False ID to a Peace Officer

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Dezmon Gonzalez	

Name of Business/Industry/Entity

Provide explanation below:

I was hanging out with some friends at 1am outside my apartment complex that I lived in with my father. We had the cops called on us because it was late, and we were making a ton of noise and being obnoxious. A couple older guys in the group were drinking so the officer wanted to see everyone's ID/ Driver's License. I had a warrant for not showing up top court for the previous offense eon 1/14/2005 so I lied about my name to avoid getting caught. The Officer found my ID in the car next to us and ran my name and took me in for lying to him about my name and again I had a butterfly knife on me. Needless to say, I never carried one again after that.



Original Signature (electronic, copies or stamps not accepted)

3/26/24

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
4/9/2009		CA	Rancho Cucamonga	San Bernardino

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
90301866	San Bernardino Sheriff's Station

Reason/Charge
Drunk In Public

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Dezmon Gonzalez	

Name of Business/Industry/Entity

Provide explanation below:

I was 22 years old at a local bar with friends and decided to walk home with a buddy instead of drive. We were drunk and making quite a bit of noise and was pulled over and cited for being drunk in public and released.

Original Signature (electronic, copies or stamps not accepted)

3/26/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
7/16/2010		CA	Whittier	Los Angeles
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
1365409		Whittier Police Department		
Reason/Charge				
Disorderly Conduct and Under the Influence of Alcohol				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Dezmon Gonzalez				
Name of Business/Industry/Entity				

Provide explanation below:

I was at my aunt's house drinking with friends and family. Had too much to drink and went outside to smoke a cigarette after an argument with my wife(then girlfriend) and was locked out of the house. I started causing a scene banging on the door to be let in. I started walking down the street after I realized I need to cool off. I assume a neighbor called the cops because i was picked up walking down the street. The police officer could tell I was intoxicated and put me in a holding cell till I sobered up. I was released the next morning. One of a few embarrassing moments in my life.

Original Signature (electronic, copies or stamps not accepted)

3/20/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
3/18/2013		CA	Ontario	San Bernardino

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
MWV1302033-3	Ontario Police Department

Reason/Charge
Fight/Challenge to Fight in a Public Place

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Dezmon Gonzalez	

Name of Business/Industry/Entity

Provide explanation below:

I went to a bar with friends and family for St Patrick's Day. Near the end of the night, a guy was harassing my wife (fiancé at the time) so I confronted him, and we got into a fight that poured outside. Cops were called and was broken up by onlookers. The bar ended up pressing charges on everyone involved. I had to be taken away by ambulance and spent part of the night in the hospital for observation.

Original Signature (electronic, copies or stamps not accepted)

3/26/24
Date

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Suite 206
Reno, NV 89521

Nevada State Board of Pharmacy,

I, Dezmon Joseph Gonzalez, in keeping with Section 8, Question 1 of the Designated Representative Application, have provided statements pertaining to my past history of legal transgressions. In addition to these statements, I have provided a current copy of my FBI background check, obtained via www.fbi.gov and submitted with a valid FD-258 Fingerprint Card. Due to the amount of time passed since these incidents, records of court appearances, rulings and fees are not currently available or would be difficult to acquire.

Sincerely,



Dezmon J. Gonzalez
Director of Operations, Texas
Advanced Med Sales, Inc
[redacted]

7/29/2024

DEZMON JOSEPH GONZALEZ
[redacted]
NORTHLAKE, TX 76226

1-787a (Rev. [illegible])

U.S. Department of Justice
Federal Bureau of Investigation
Criminal Justice Information Services Division
Clarksburg, WV 26306

DEZMON JOSEPH GONZALEZ
[redacted]
NORTHLAKE, TX 76226

Date: 11-10-2023

The Criminal Justice Information Services (CJIS) Division of the Federal Bureau of Investigation (FBI) has completed the following fingerprint submission:

Subject Name

DEZMON JOSEPH GONZALEZ

Search Completed Result 11-10-2023 E20233140000000196287

A SEARCH OF THE FINGERPRINTS PROVIDED BY THIS INDIVIDUAL HAS REVEALED PRIOR ARREST DATA AT THE FBI. THIS DOES NOT PRECLUDE FURTHER CRIMINAL HISTORY AT THE STATE OR LOCAL LEVEL.

Date of Birth: [redacted]

Social Security number: XXX-XX-[redacted]

The result of the above response is only effective for the date the submission was originally completed. For more updated information, please submit new fingerprints of the Subject.

In order to protect Personally Identifiable Information, as of August 17, 2009, FBI policy has changed to no longer return the fingerprint cards. This form will serve as the FBI's official response.

This Identity History Summary (IdHS) is provided pursuant to 28 CFR 16.30-16.34 solely for you to conduct a personal review and/or obtain a change, correction, or updating of your record. **This IdHS is not provided for the purpose of licensing or employment or any other purpose enumerated in 28 CFR 20.33.**

Any questions may be addressed to the Customer Service Group at 304-625-5590. You may also visit the website at www.fbi.gov/checks for further instructions.

Chris Ormerod
Section Chief
Biometric Services Section
Criminal Justice Information
Services Division

UNITED STATES DEPARTMENT OF JUSTICE
FEDERAL BUREAU OF INVESTIGATION
CRIMINAL JUSTICE INFORMATION SERVICES DIVISION
CLARKSBURG, WV 26306

DC000001Z NCN E2023314000000196287

DC000001Z
DO 556-73 REQ
FBI-CJIS-WV
BIOMETRIC TECHNOLOGY CTR
1000 CUSTER HOLLOW RD
CLARKSBURG,WV 26306

UNITED STATES DEPARTMENT OF JUSTICE
FEDERAL BUREAU OF INVESTIGATION
CRIMINAL JUSTICE INFORMATION SERVICES DIVISION
CLARKSBURG, WV 26306

DC000001Z NCN E2023314000000196287

BECAUSE ADDITIONS OR DELETIONS MAY BE MADE AT ANY TIME, A NEW COPY SHOULD BE REQUESTED WHEN NEEDED FOR SUBSEQUENT USE.
- FBI IDENTIFICATION RECORD -

WHEN EXPLANATION OF A CHARGE OR DISPOSITION IS NEEDED, COMMUNICATE DIRECTLY WITH THE AGENCY THAT FURNISHED THE DATA TO THE FBI.

NAME	FBI UCN	DATE REQUESTED
GONZALEZ,DEZMON JOSEPH	[redacted]	2023/11/10

SEX	RACE	BIRTH DATE	HEIGHT	WEIGHT	EYES	HAIR
M	W	[redacted]				

BIRTH PLACE
CALIFORNIA

PATTERN CLASS
LS LS LS LS LS LS LS LS LS LS

CITIZENSHIP
UNITED STATES

1-ARRESTED OR RECEIVED 2003/04/17 SID- CA24554437
AGENCY-POLICE DEPARTMENT DOWNEY (CA0192000)
AGENCY CASE-7660941

FINGERPRINT INFORMATION
BSI/2000129662192
PRINT DATE/2003/04/17

CHARGE 1-00 COUNTS OF JUVENILE,MINOR UNDER 18 YEARS, PETTY THEFT

COURT-POLICE DEPARTMENT DOWNEY (CA0192000)
CHARGE-484 PC-PETTY THEFT
RELEASED TO PARENT/GUARD -JUVENILE

END OF PART 1 - PART 2 TO FOLLOW

UNITED STATES DEPARTMENT OF JUSTICE
FEDERAL BUREAU OF INVESTIGATION
CRIMINAL JUSTICE INFORMATION SERVICES DIVISION
CLARKSBURG, WV 26306

DC000001Z NCN E2023314000000196287
PART 2
- FBI IDENTIFICATION RECORD - FBI UCN-615259AC2
2-ARRESTED OR RECEIVED 2005/01/14 SID- CA24554437
AGENCY-POLICE DEPARTMENT FULLERTON (CA0300800)
AGENCY CASE-05-102FL

FINGERPRINT INFORMATION
BSI/2000129662921
PRINT DATE/2005/01/14

CHARGE 1-0[illegible] COUNTS OF MFG/SELL/POS DANG WPN/ETC
CHARGE 2-0[illegible] COUNTS OF FTA,VEHICLE CODE VIOLATION, DRIVE W/O LICENS
E

COURT-POLICE DEPARTMENT FULLERTON (CA0300800)
CHARGE-5204(A) VC-EXPIRED TABS/FAIL TO DISPLALY
NO DISPOSITION AVAILABLE - WARRANT
CHARGE-12020(A)(1) PC-MANUFACTURE/POS DANG WPN/ETC
NO DISPOSITION AVAILABLE
CHARGE-12500(A) VC-DRIVE W/O LICENSE
NO DISPOSITION AVAILABLE - FTA:VEHICLE CODE VIOLATION - WARRANT

3-ARRESTED OR RECEIVED 2005/06/24 SID- CA24554437
AGENCY-SHERIFF'S OFFICE SANTA ANA (CA0300000)
AGENCY CASE-2860593

FINGERPRINT INFORMATION
BSI/2000129662386
PRINT DATE/2005/06/24

CHARGE 1-0[illegible] COUNTS OF POSSESS SWITCHBLADE KNIF
CHARGE 2-0[illegible] COUNTS OF FALSE ID TO PEACE OFFICE

COURT-MUNICIPAL COURT FULLERTON (CA030073J)
CHARGE-653K PC-POSSESS/SELL SWITCH-BLADE KNIFE
CONVICTED-PROB/JAIL
CHARGE-148.9(A) PC-FALSE ID TO SPECIFIC PEACE OFICERS
CONVICTED-PROB/JAIL - 3 YEARS PROBATION - 15 DAYS JAIL

END OF PART 2 - PART 3 TO FOLLOW

UNITED STATES DEPARTMENT OF JUSTICE
FEDERAL BUREAU OF INVESTIGATION
CRIMINAL JUSTICE INFORMATION SERVICES DIVISION
CLARKSBURG, WV 26306

DC000001Z NCN E2023314000000196287
PART 3
- FBI IDENTIFICATION RECORD - FBI UCN-615259AC2
4-ARRESTED OR RECEIVED 2005/11/27 SID- CA24554437
AGENCY-POLICE DEPARTMENT ANAHEIM (CA0300100)
AGENCY CASE-050210549

FINGERPRINT INFORMATION
BSI/2000129662452
PRINT DATE/2005/11/27

CHARGE 1-0[illegible] COUNTS OF FALSE ID TO SPECIFIC PO S
CHARGE 2-0[illegible] COUNTS OF POSSESS SWITCHBLADE KNIFE

5-ARRESTED OR RECEIVED 2005/11/27A SID- CA24554437
AGENCY-SHERIFF'S OFFICE SANTA ANA (CA0300000)
AGENCY CASE-2289631

FINGERPRINT INFORMATION
BSI/2000129661477
PRINT DATE/2005/11/27

CHARGE 1-0[illegible] COUNTS OF PROB VIOL,REARREST/REVOKE

6-ARRESTED OR RECEIVED 2007/01/26 SID- CA24554437
AGENCY-SHERIFF'S OFFICE SANTA ANA (CA0300000)
AGENCY CASE-[illegible]57003

FINGERPRINT INFORMATION
BSI/2000129662409
PRINT DATE/2007/01/26

CHARGE 1-0[illegible] COUNTS OF LIC. SUSPEND/REVOKED

END OF PART 3 - PART 4 TO FOLLOW

UNITED STATES DEPARTMENT OF JUSTICE
FEDERAL BUREAU OF INVESTIGATION
CRIMINAL JUSTICE INFORMATION SERVICES DIVISION
CLARKSBURG, WV 26306

DC000001Z NCN E2023314000000196287
PART 4
- FBI IDENTIFICATION RECORD - FBI UCN-615259AC2
7-ARRESTED OR RECEIVED 2007/08/23 SID- CA24554437
AGENCY-SHERIFF'S OFFICE SANTA ANA (CA0300000)
AGENCY CASE-2406021

FINGERPRINT INFORMATION
BSI/2000129661153
PRINT DATE/2007/08/23

CHARGE 1-001 COUNTS OF PROB VIOL,REARREST/REVOKE

8-ARRESTED OR RECEIVED 2009/03/28 SID- CA24554437
AGENCY-POLICE DEPARTMENT ONTARIO (CA0360700)
AGENCY CASE-090301866

FINGERPRINT INFORMATION
BSI/2000129663894
PRINT DATE/2009/03/28

CHARGE 1-001 COUNTS OF DISORD CONDUCT,UI/DRUG

COURT-MUNICIPAL COURT RANCHO CUCAMONGA (CA036043J)
CHARGE-647(F) PC-DISORDERLY CONDUCT:INTOX DRUG/ALCOH
CONVICTED-FINE - FINE

9-ARRESTED OR RECEIVED 2010/07/16 SID- CA24554437
AGENCY-POLICE DEPARTMENT WHITTIER (CA0197600)
AGENCY CASE-1365409

FINGERPRINT INFORMATION
BSI/2000129661946
PRINT DATE/2010/07/16

CHARGE 1-001 COUNTS OF DISORD CONDUCT,UI/DRUG
CHARGE 2-001 COUNTS OF DISORD CONDUCT,UI/DRUG

COURT- ()
CHARGE- MRD 647(F) PC-DISORDERLY CONDUCT:INTOX DRUG/ALCOH
MRD/DISMISSED/FURTHERANCE OF JUSTICE

END OF PART 4 - PART 5 TO FOLLOW

UNITED STATES DEPARTMENT OF JUSTICE
FEDERAL BUREAU OF INVESTIGATION
CRIMINAL JUSTICE INFORMATION SERVICES DIVISION
CLARKSBURG, WV 26306

DC000001Z NCN E2023314000000196287
PART 5

- FBI IDENTIFICATION RECORD - FBI UCN-615259AC2

RECORD UPDATED 2023/11/10

ALL ENTRIES CONTAINED IN THIS FBI RECORD ARE BASED ON FINGERPRINT COMPARISONS AND PERTAIN TO THE SAME INDIVIDUAL.

THE USE OF THIS RECORD IS REGULATED BY LAW. IT IS PROVIDED FOR OFFICIAL USE ONLY AND MAY BE USED ONLY FOR THE PURPOSE REQUESTED.

I, Dezmon Gonzalez, **certify that as the designated representative for**

Advanced Medical Sales, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. DG I am at least 21 years of age;
3. DG I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DG I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DG I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DG I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DG I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Dezmon Gonzalez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/25/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

DELMON GONZALEZ

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/26/24

Date

Please have this section completed in the presence of a Notary Public.

State of TEXAS, ss. County of DENTON

I, DELMON GONZALEZ, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/26/24

Date

Subscribed and Sworn to before me this 26 day of March, 2024.

Notary Public Signature

ANTHONY ZURITA
Notary Public, State of Texas
Comm. Expires 08-18-2024
Notary ID 132684674
(Seal)

Applicant's initials DK

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Advanced Medical Sales, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 2304 Seaborn Rd. #100

City: Ponder State: TX Zip: 76259

Mailing Address (if different from physical address): 232 Avenida Fabricante, Suite 103/104

City: San Clemente State: CA Zip: 92672

Telephone: 949-348-7912 Website: Ams-rx.com

Licensing Company Email: Compliance@ams-rx.com

Section 2: Personal Information

First: Michael Middle: James Last: Rocha

Alias(es, nicknames, name changes, etc.): Michael James Roache, Mike Roache, Mike Rocha

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: 232 Avenida Fabricante, Suite 103/104

City: San Clemente State: CA Zip: 92672

Telephone: [redacted] Email: Compliance@ams-rx.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Southern California		09/98 - 05/02	
Address	**City**	**State**	**Zip**
3551 Trousdale Pkwy	Los Angeles	CA	90089
Diploma/Degree obtained, if any			
B.A., College of Letters, Arts, and Sciences emphasis Economics			

School Name		From - To (MM/YY – MM/YY)	
Santa Margarita Catholic High School		09/94 - 06/98	
Address	**City**	**State**	**Zip**
22062 Antonio Pkwy	Rancho Santa Margarita	CA	92688
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/23 - Current	[redacted]	Ladera Ranch	CA	92694
From - To (MM/YY – MM/YY)		City	State	Zip
06/18 - 03/23		Laguna Niguel	CA	92677
From - To (MM/YY – MM/YY)		City	State	Zip
02/10 - 06/18		San Clemente	CA	92673
From - To (MM/YY – MM/YY)		City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Advanced Medical Sales, Inc.			03/03 - Current	
Business Address		**City**	**State**	**Zip**
232 Avenida Fabricante, Suite 103/104		San Clemente	CA	92672
Phone	**Title**			
949-348-7912	President / CEO			
Description of Duties				
Responsible for general management of all aspects of business operations for a national pharmaceutical distributor.				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address	**City**		**State**	**Zip**
N/A	N/A		N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address	**City**		**State**	**Zip**
N/A	N/A		N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address	**City**		**State**	**Zip**
N/A	N/A		N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address	**City**		**State**	**Zip**
N/A	N/A		N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address	**City**		**State**	**Zip**
N/A	N/A		N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A	N/A	N/A	N/A
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A		N/A		
Reason/Charge				
N/A				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
N/A			N/A	
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

6/18/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Rocha

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/18/24

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Orange

I, Michael Rocha, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/18/24

Date

Subscribed and Sworn to before me this 18th day of June 2024

Notary Public Signature

RYAN PATRICK MOREAU
Notary Public - California
Orange County
Commission # 2402485
My Comm. Expires Apr 28, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Advanced Medical Sales, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 2304 Seaborn Rd. #100

City: Ponder State: TX Zip: 92672

Mailing Address (if different from physical address): 232 Avenida Fabricante, Suite 103/104

City: San Clemente State: CA Zip: 92672

Telephone: 949-348-7912 Website: Ams-rx.com

Licensing Company Email: Compliance@ams-rx.com

Section 2: Personal Information

First: Shannon Middle: Janelle Last: Rocha

Alias(es, nicknames, name changes, etc.): Shannon Roache, Shannon Voigt

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: 232 Avenida Fabricante, Suite 103/104

City: San Clemente State: CA Zip: 92672

Telephone: 949-348-7912 Email: Compliance@ams-rx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Southern California		09/98 - 06/02	
Address	**City**	**State**	**Zip**
3551 Trousdale Pkwy	Los Angeles	CA	90089
Diploma/Degree obtained, if any			
B.A., College of Letters, Arts, and Sciences			

School Name		From - To (MM/YY – MM/YY)	
Huntington Beach High School		09/94 - 06/98	
Address	**City**	**State**	**Zip**
1905 Main St.	Huntington Beach	CA	92648
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY	
N/A		N/A	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
N/A			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/23 - Current	[redacted]	Ladera Ranch	CA	92694
From - To (MM/YY – MM/YY)		City	State	Zip
06/18 - 03/23		Laguna Niguel	CA	92677
From - To (MM/YY – MM/YY)		City	State	Zip
02/10 - 06/18		San Clemente	CA	92673
From - To (MM/YY – MM/YY)		City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A	N/A	N/A	N/A	N/A

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Advanced Medical Sales, Inc.			06/14 - Current
Business Address	**City**	**State**	**Zip**
232 Avenida Fabricante, Suite 103/104	San Clemente	CA	92672
Phone	**Title**		
949-348-7912	Director		
Description of Duties			
Annual corporate meetings and general consultation.			

Business Name			From - To (MM/YY – MM/YY)
N/A			N/A
Business Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Phone	**Title**		
N/A	N/A		
Description of Duties			
N/A			

Business Name			From - To (MM/YY – MM/YY)
N/A			N/A
Business Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Phone	**Title**		
N/A	N/A		
Description of Duties			
N/A			

Business Name			From - To (MM/YY – MM/YY)
N/A			N/A
Business Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Phone	**Title**		
N/A	N/A		
Description of Duties			
N/A			

Business Name			From - To (MM/YY – MM/YY)
N/A			N/A
Business Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Phone	**Title**		
N/A	N/A		
Description of Duties			
N/A			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**			
N/A	N/A			
Description of Duties				
N/A				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A	N/A	N/A	N/A
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A		N/A		
Reason/Charge				
N/A				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
N/A			N/A	
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

6/1/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shannon Rocha

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-1-24

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Orange

I, Shannon Rocha, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6-1-24

Date

Subscribed and Sworn to before me this 1st day of June 2024

Notary Public Signature

RYAN PATRICK MOREAU
Notary Public - California
Orange County
Commission # 2402485
My Comm. Expires Apr 28, 2026

(Seal)

Employee Roster

Advanced Medical Sales, Inc.

Dba Advanced Med Sales, Inc.

❖ Location: 232 Avenida Fabricante, Suite 103/104, San Clemente, CA 92672

- **Executive Management / Designated Representative**
  - Michael Rocha
- **Sales Department**
  - Joshua Baisley
  - Cole Vietor
  - Mason Paine
  - Brianne Yepiz
  - Conor Good
  - Michele Rudin
  - Laurinho Walch
- **Acquisitions Department**
  - Jay Warren
  - Sarah Lattouf
  - Samantha Westgate
  - Alena Duffill
- **Administration**
  - Stephanie Rondini
  - Ryan Moreau
  - Nichole Anders
  - Christian Felix
- **Warehouse**
  - Stephen Radigan
  - Javier Hernandez
  - Robert Chapa

❖ Location: 2304 Seaborn Road #100, Ponder, TX, 76259

- **Management / Designated Representative**
  - Dezmon Gonzalez
- **Warehouse**
  - Gabriel Gonzales

4HH

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: CARDIO PARTNERS, INC.

Physical Address: 1033 COLLINS RD, SUITE B

City: GREENWOOD State: IN Zip: 46143

Mailing Address (if different from physical address): 5000 TUTTLE CROSSING BLVD

City: DUBLIN State: OH Zip: 43016

Telephone: 614-760-5000 Website: WWW.AED.COM

Name of Designated Representative (DR): KYLE FRIERMOOD

Licensing Company Email: REGULATORY@SARNOVA.COM DR Email: REGULATORY@SARNOVA.COM

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Darrell Hughes, Secretary

4/17/24

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: CARDIO PARTNERS, INC. DOES NOT SELL OR DISTRIBUTE PHARMACEUTICALS

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: OH

Parent Company (if any): SARNOVA HC, LLC

Corporation/Organization Name: CARDIO PARTNERS, INC.

Mailing Address: 5000 TUTTLE CROSSING BLVD

City: DUBLIN State: OH Zip: 43016

Telephone: 614-760-5000 Email: REGULATORY@SARNOVA.COM

Contact Person Name: JILL VENNEKOTTER

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

CARDIO PARTNERS, INC.

Facility Name

DARRELL HUGHES, CORPORATE SECRETARY

Print Name of Authorized Person Submitting Application



Original signature of Authorized Person (copies or stamps not accepted)

4/17/24

Date

Board Use Only	Date Received: _____	Amount: _____

Sarnova HC, LLC
(100% Owner of Cardio Partners, Inc.)

PO Box 8023, Dublin, Ohio 43016

State of Organization: DE Date of Organization: 05/01/2008 EIN: 26-2549813
File No. 4540843

Officers	
NAME	**TITLE**
Brian LaDuke	President
Shawn Saylor	CFO
Darrell Hughes	Secretary

Cardio Partners, Inc.
(Owned 100% by Sarnova HC, LLC)

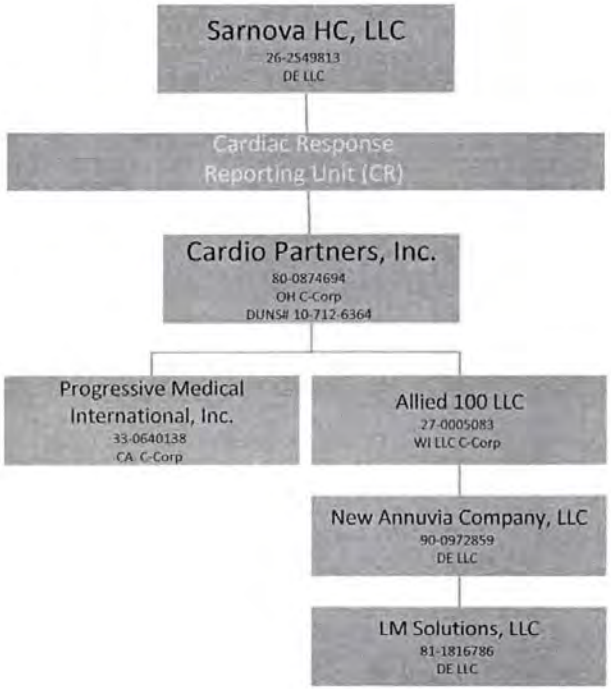
State of Incorporation: OH Date of Incorporation: 12/03/2012 EIN: 80-0874694
Charter No. 2155064

Officers	
NAME	**TITLE**
Brian LaDuke	CEO
Lawrence Franchetti	President
Shawn Saylor	CFO
Darrell Hughes	Secretary

d/b/a Sarnova, Inc.

Cardio Partners Org Chart

As of September 27, 2021



UNITED STATES OF AMERICA
STATE OF OHIO
OFFICE OF THE SECRETARY OF STATE

I, Frank LaRose, do hereby certify that I am the duly elected, qualified and present acting Secretary of State for the State of Ohio, and as such have custody of the records of Ohio and Foreign business entities; that said records show CARDIO PARTNERS, INC., an Ohio corporation, Charter No. 2155064, having its principal location in Dublin, County of Franklin, was incorporated on December 3, 2012 and is currently in GOOD STANDING upon the records of this office.

Witness my hand and the seal of the Secretary of State at Columbus, Ohio this 18th day of April, A.D. 2024.

Ohio Secretary of State

Validation Number: 202410901412

Cardio Partners

Statement of Explanation for Wholesale Distributor License Documentation Requests

Applicant: Cardio Partners, Inc.
1033 Collins Road, Suite B
Greenwood, Indiana 46143

Explanation for not having Home State License:

Cardio Partners, Inc. is a national leader in providing emergency preparedness solutions for public access. Cardio Partners, Inc. offers a proven and complete suite of products and services including employee CPR training, AED deployments, and AED program management to help organizations of all sizes be heart safe.

Cardio Partners, Inc. is not required to be licensed to operate as wholesale device distributor in Indiana. Indiana does not regulate the distribution of legend devices unless sold direct-to-consumer for home medical/personal use. Cardio Partner's customer base does not include customers purchasing devices for residential use; therefore, a license is not required. (See **IC 25-26-21-4"Home Medical Equipment Provider**) Furthermore, Cardio Partners, Inc. does not sell prescription drugs and therefore is not required by Indiana to obtain a wholesale drug distributor license. In fact, Indiana does not define Wholesale Distribution to include device distribution at all. (See **IC 25-26-14-11 "Wholesale distribution"**)

Indiana Code Citations:
IC 25-26-21-4"Home Medical Equipment Provider"

Sec. 4. As used in this chapter, "provider" means a person engaged in the business of providing home medical equipment services to an unrelated individual in the individual's residence.
As added by P.L.122-2005, SEC.1.

IC 25-26-14-11"Wholesale distribution"
Sec. 11. As used in this chapter, "wholesale distribution" means to distribute legend drugs to persons other than a consumer or patient.

Explanation for not having a recent Inspection Report:

Wholesale device distributors are not regulated by the state of Indiana unless the distribution is to residential customers. Cardio Partners, Inc. does not sell to residential customers as explained in the statements above. Therefore, Cardio Partners, Inc. is not subject to Indiana Board of Pharmacy inspections and does not have a recent home state inspection report.

Sincerely,

Michael Cooke
Senior Regulatory Counsel, Compliance Manager

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY): 04/09/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Northeast, Inc. Columbus OH Office 8940 Lyra Drive Suite 250 Columbus OH 43240 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Cardio Partners, Inc. 5000 Tuttle Crossing Blvd. P.O. Box 8023 Dublin OH 43016 USA	INSURER A: Federal Insurance Company	20281
	INSURER B: ProAssurance Specialty Insurance Company	17400
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570105025395 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS.

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY X PRO-JECT X LOC OTHER:			36073395	12/01/2023	12/01/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $1,000,000 $10,000 $1,000,000 $2,000,000 Excluded
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY SCHEDULED AUTOS HIRED AUTOS ONLY NON-OWNED AUTOS ONLY			7363-09-65	12/01/2023	12/01/2024	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$1,000,000
A	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION $10,000			78197881	12/01/2023	12/01/2024	EACH OCCURRENCE AGGREGATE	$10,000,000 $10,000,000
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/ PARTNER/ EXECUTIVE OFFICER/MEMBER (Mandatory in NH) Y/N N/A If yes, describe under DESCRIPTION OF OPERATIONS below						PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	
B	Products Liability			N23OH380021 Claims Made	12/01/2023	12/01/2024	Aggregate Limit Agg Deductible Per Occ Comp/Op	$10,000,000 $150,000 $10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Evidence of Coverage. Facility Address: 1033 Collins Rd, Suite B, Greenwood, IN 46143.

CERTIFICATE HOLDER

Cardio Partners, Inc.
5000 Tuttle Crossing Blvd.
PO Box 8023
Dublin OH 43016 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast, Inc.

Holder Identifier :

Certificate No : 570105025395

©1988-2015 ACORD CORPORATION. All rights reserved

AGENCY CUSTOMER ID: 570000037575

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Cardio Partners, Inc.
POLICY NUMBER: See Certificate Numbe 570105025395	
CARRIER: See Certificate Numbe 570105025395 / NAIC CODE:	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 FORM TITLE: Certificate of Liability Insurance

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER	
INSURER	
INSURER	
INSURER	

ADDITIONAL POLICIES If a policy below does not include limit information, refer to the corresponding policy on the ACORD certificate form for policy limits.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	OTHER							
B	Products Liability			N23OH380021 Claims Made	12/01/2023	12/01/2024	Per Occ Deductible	$50,000

© 2008 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

RIDER

To be attached to and form part of:

Bond Number 107403303

originally dated November 24, 2021

issued by the TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA

originally
in the amount of $ 100,000.00

originally
on behalf of CARDIO PARTNERS, INC.
(Principal)
and in favor of THE STATE OF NEVADA
(Obligee)

Now therefore, it is agreed that in consideration of the premium charged, the attached bond shall be amended as follows:

The Locations shall be amended to:

1800 US Highway 51 N, Woodruff, WI 54568
1033 Collins Rd, Suite B, Greenwood, IN 46143

It is further understood and agreed that all other terms and conditions of this bond shall remain unchanged.

This Rider is to be Effective this 16th day of April, 2024.

Signed, Sealed & Dated this 16th day of April, 2024.

CARDIO PARTNERS, INC.
(Principal)

By: _____

TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA
(Surety)

By: _____
Richard Casas, Attorney-in-Fact

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **Richard Casas** of **CHICAGO**, **Illinois**, their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **21st** day of **April**, **2021**.

State of Connecticut

City of Hartford ss.

By: _____
Robert L. Raney, Senior Vice President

On this the **21st** day of **April**, **2021**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of **each of the Companies**, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of **said Companies** by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June**, **2026**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of **each of the Companies**, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of **each of the Companies**, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this **16th** day of **April** **2024**

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG CARDIO PARTNERS, INC. MDEG License # (if applicable) _____

Physical Address 1033 COLLINS RD, SUITE B

City GREENWOOD State IN Zip 46143

Mailing Address (if different from physical address) 5000 TUTTLE CROSSING BLVD

City DUBLIN State OH Zip 43016

Telephone 614-760-5000 Website WWW.AED.COM

Licensing Company Email REGULATORY@SARNOVA.COM

Section 2: Personal Information

First KYLE Middle _____ Last FRIERMOOD

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 1033 COLLINS RD, STE B

City GREENWOOD State IN Zip 46143

Telephone 614-760-5000 Email REGULATORY@SARNOVA.COM

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
SOUTHWOOD JUNIOR		2003-2007	
Address	**City**	**State**	**Zip**
564 E STATE ROAD 124	WABASH	IN	46992
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2021-PRESENT	[redacted]	PITTSBORO	IN	46167
08/2017-12/2020		INDIANAPOLIS	IN	46234
07/2015-07/2017		PLAINFIELD	IN	46168
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
BOUND TREE MEDICAL, LLC (moving to the Cardio Partners, Inc. suite)			09/2022-PRESENT
Business Address	**City**	**State**	**Zip**
1033 COLLINS RD, SUITE A (Cardio will be Ste B)	GREENWOOD	IN	46143
Phone	**Title**	**Number of Employed Hours**	
614-760-5000	OPERATIONS MANAGER	1,200	
Description of Duties			
SEE ATTACHED JOB DESCRIPTION			

Business Name			From - To (MM/YY – MM/YY)
IDS, LLC			04/2017-08/2022
Business Address	**City**	**State**	**Zip**
931 ALLPOINTS PKWY	PLAINFIELD	IN	46168
Phone	**Title**	**Number of Employed Hours**	
866-232-6533	OPERATIONS SUPERVISOR	11,000	
Description of Duties			
SEE ATTACHED RESUME			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

4/1F/24
Date

I, KYLE FRIERMOOD, **certify that as the MDEG Administrator for**

CARDIO PARTNERS, INC.,

that I (initial that you have read and meet the following requirements):

1. KF Have a high school diploma or its equivalent;
2. KF Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. KF Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. KF Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

KYLE FRIERMOOD
Print Name (First, Last)

Kyle Friermood
Original Signature (electronic, copies or stamps not accepted)

4/18/24
Date

Board Use Only	Date Received:

Kyle Friermood

[redacted]

PROFESSIONAL SUMMARY

I'm an experienced manager and team leader with 5+ years of warehousing and logistics experience, with a demonstrated ability to work in a fast-paced, goal oriented environment. My goal is to obtain a leadership position that is focused on internal promotion and advancement opportunities.

EXPERIENCE

Warehouse Manager, Emergency Medical Products, Inc.
Greenwood, IN; September 2022-Present

- Document and maintain, in proper form, all records required relating to the purchase and distribution of all prescription drugs, including controlled substances and devices.
- Manage staff to ensure timely distribution and receipt of product while meeting standards of budget, policies, procedures and quality.
- Monitor the unloading of all materials into the Receiving Department; ensure materials are staged for counting and inspection and reports accurately reflect material received.
- Implement and maintain a program for inventory control--receiving, documenting, and adjusting product
- Assure complete compliance with the Prescription Drug Marketing Act of 1987 (Federal) and with all Federal and State laws and regulation applicable to the conduct of a wholesaler.
- Provide for the proper storage of drugs in order to prevent loss or deterioration.
- Assure security and limited access to all areas holding prescription drugs and devices.

Operations Supervisor, IDS
Plainfield, IN; March 2021-September 2022

- Schedule labor and supervise the workforce
- Conduct daily shift meetings
- Coach employees, provide performance feedback, and administer discipline accordingly
- Ensure proper utilization of space, equipment, and resources
- Oversee receiving and shipping activities, including timeliness, accuracy, and productivity
- Ensure inventory accuracy, adherence to policies and procedures, sanitation guidelines, and security protocols
- Process all paperwork associated with customer orders and maintains the corresponding files
- Generate all related paperwork and necessary information required for customer orders, check all orders for special requests and maintain inventory levels
- Compute and analyze daily, weekly production metrics
- Handle returned merchandise in an efficient manner and ensure proper credit is given to the customer
- Maintain a current and accurate procedure manual that details processing for each fulfillment account

Inventory Control Supervisor, IDS
Plainfield, IN; May 2019-March 2021

- Oversaw and supervised inventory control department for the entire company.
- Designed, implemented, and maintained cycle count programs for multiple accounts.
- Created account specific inventory SOP's for standardization purposes
- Trained, coached, and developed cycle counts as needed
- Maintained updated and accurate inventories of multiple accounts
- Created and maintained labor plans on a weekly/monthly basis
- Enforced floor processes to promote accurate inventory

- Maintained an open line of communication with customers on all inventory related issues
- Scheduled, planned, and coordinated yearly physical inventories for multiple accounts

Floor Lead, Inventory, IDS
Plainfield, IN; April 2017-May 2019
- Oversaw daily operations of inventory audits
- Maintained updated and accurate records of all inventory
- Researched orders systematically to correct errors
- Adjusted inventory quantities as needed
- Identified and corrected process breakdowns leading to inventory discrepancies
- Created daily inventory reports
- Trained staff in cycle counting procedure
- Oversaw and facilitated order picking and staging
- Assisted in all floor activities as needed
- Coordinated special projects as needed

Operations Manager, LA Fitness
Avon, IN; August 2015-October 2016
- Ensured all members checked-in properly
- Greeted all guests and transferred to the appropriate membership sales associate
- Managed all aspects of the front desk
- Lead all front desk, baby sitter, and janitorial personnel
- Hired and trained new personnel as needed
- Processed all new hire paperwork
- Oversaw the overall cleanliness and maintenance of the gym
- Coordinated with outside vendors for repairs as needed
- Serviced members accounts and processed all billing
- Placed bi-weekly orders for various supplies
- Published weekly schedules for all operations personnel
- Addressed all customer service issues in a friendly and timely manner

General Manager, Sky Zone Indoor Trampoline Park
Plainfield, IN; April 2014-August 2015
- Created, promoted, and embodied a culture of healthy, active, fun with focus on amazing customer experience
- Acted as the face of the organization and represented values to team members, guests, and the public
- Developed and implemented plans to meet monthly sales goals
- Drove external sales strategies around corporate events, youth organizations, and more
- Oversaw all functions of the management team
- Oversaw and manage all daily functions of the facility
- Resolved any operational issues that may present themselves in an efficient manner
- Continued performing all functions of the Operations Manager

Operations Manager, Sky Zone Indoor Trampoline Park
Plainfield, IN; September 2012-April 2014
- Supervised all day to day functions of the facility
- Supervised weekly court inspections (maintenance) and cleaning
- Replaced damaged court parts during operating hours
- Placed orders as needed for replacement parts and retail merchandise
- Placed weekly Pepsi order for concession stand needs
- Hired and trained all hourly employees
- Supervised all hourly employees.
- Published weekly schedules for all hourly employees (approx. 60)

- Approved all employee time off, shift trade, shift drop, and shift pick-up requests.
- Coordinated various special events throughout the year.
- Scheduled birthday parties and group events as needed.
- Provided customer service to any and all patrons during operating hours.
- Ensured all hourly employees adhered to any and all Sky Zone standards.

EDUCATION

Bachelor of Science, July 2011
Ball State University, Muncie, Indiana
- Major: Sports Administration
- Minor: Foundations of Management

Global Logistics Associate Certificate, March 2017
Vincennes University (Logistics Training Education Center), Plainfield, Indiana
- GLA APICS Certificate (In-progress)
- OSHA 10 Certificate
- Fork Lift Certificate
- Lean Six Sigma, Yellow Belt (In-progess)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler CARDIO PARTNERS, INC.

Pharmacy/Wholesaler License # (if applicable) PENDING

Physical Address 1033 COLLINS RD, SUITE B

City GREENWOOD State IN Zip 46143

Mailing Address (if different from physical address) 5000 TUTTLE CROSSING BLVD

City DUBLIN State OH Zip 43016

Telephone 614-760-5000 Website WWW.AED.COM

Licensing Company Email REGULATORY@SARNOVA.COM

Section 2: Personal Information

First KYLE Middle _____ Last FRIERMOOD

Alias(es, nicknames, name changes, etc.) NONE

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City PITTSBORO State OH Zip 46168

Telephone 614-760-5000 Email REGULATORY@SARNOVA.COM

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
SOUTHWOOD JUNIOR		2003-2007	
Address	**City**	**State**	**Zip**
18635 LEE ST	COUNTRY CLUB HILLS	IL	60478
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2021-PRESENT	[redacted]	PITTSBORO	IN	46167
08/2017-12/2020		INDIANAPOLIS	IN	46234
07/2015-07/2017		PLAINFIELD	IN	46168
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
BOUND TREE MEDICAL, LLC (moving to the Cardio Partners, Inc. suite)			09/2022-PRESENT	
Business Address		City	State	Zip
1033 COLLINS RD, SUITE A (Cardio will be Suite B)		GREENWOOD	IN	46143
Phone	Title		Number of Employed Hours	
614-760-5000	OPERATIONS MANAGER		1,200	
Description of Duties				
SEE ATTACHED JOB DESCRIPTION				

Business Name			From - To (MM/YY – MM/YY)	
IDS, LLC			04/2017-08/2022	
Business Address		City	State	Zip
9431 ALLPOINTS PKWY		PLAINFIELD	IN	46168
Phone	Title		Number of Employed Hours	
866-232-6533	OPERATIONS SUPERVISOR		11,000	
Description of Duties				
SEE ATTACHED RESUME				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

4/30/24
Date

I, KYLE FRIERMOOD, **certify that as the designated representative for**

CARDIO PARTNERS, INC.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. KF I am at least 21 years of age;
3. KF I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. KF I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. KF I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. KF I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. KF I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

KYLE FRIERMOOD, OPERATIONS MANAGER
Print Name (First, Last)

Kyle Friermood
Original Signature (electronic, copies or stamps not accepted)

4/30/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

KYLE FRIERMOOD

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/30/24

Date

Please have this section completed in the presence of a Notary Public.

State of Indiana, ss. County of Marion

I, KYLE FRIERMOOD, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/30/24

Date

Subscribed and Sworn to before me this 30 day of April, 2024

Athena K Houston

Notary Public Signature

SEAL

ATHENA K. HOUSTON
My Commission Expires
November 22, 2028
Commission Number NP0730087
Marion County

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site CARDIO PARTNERS, INC.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PENDING

Physical Address 1033 COLLINS RD, SUITE B

City GREENWOOD State IN Zip 46143

Mailing Address (if different from physical address) 5000 TUTTLE CROSSING BLVD

City DUBLIN State OH Zip 43016

Telephone 614-760-5000 Website WWW.CARDIOPARTNERS.COM

Licensing Company Email REGULATORY@SARNOVA.COM

Section 2: Personal Information

First BRIAN Middle _____ Last LADUKE

Alias(es, nicknames, name changes, etc.) N/A

Date of Birt[redacted] SSN or ITIN[redacted] Sex ☒ M ☐ F ☐ X

Mailing Addres[redacted]

City PLAIN CITY State OH Zip 43064

Telephone 614-760-5000 Email REGULATORY@SARNOVA.COM

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY - MM/YY)	
XAVIER UNIVERSITY		2009-2011	
Address	**City**	**State**	**Zip**
3000 VICTORY PKWY	CINCINNATI	OH	45207
Diploma/Degree obtained, if any			
MBA, BUSINESS			

School Name		From - To (MM/YY - MM/YY)	
POINT LOMA NAZARENE UNIVERSITY		1994-2000	
Address	**City**	**State**	**Zip**
3900 LOALAND	SAN DIEGO	CA	92106
Diploma/Degree obtained, if any			
B.A., BUSINESS COMMUNICATIONS			

School Name		From - To (MM/YY - MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY - MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY - MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY - MM/YY)	Address	City	State	Zip
07/2018-PRESENT	[redacted]	PLAIN CITY	OH	43064
06/2013-07/2018	[redacted]	STRONGSVILLE	OH	44136

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
CARDIO PARTNERS, INC.			10/2017-PRESENT
Business Address	**City**	**State**	**Zip**
5000 TUTTLE CROSSING BLVD	DUBLIN	OH	43016
Phone	**Title**		
614-760-5000	CEO		
Description of Duties			
SEE ATTACHED			

Business Name			From - To (MM/YY – MM/YY)
INVACARE CORPORATION			01/2013-10/2017
Business Address	**City**	**State**	**Zip**
ONE INVACARE WAY	ELYRIA	OH	44035
Phone	**Title**		
--	VP, NORTH AMERICA REHAB CHANNEL & PRODUCT MARKETING		
Description of Duties			
SEE ATTACHED			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

BRIAN LADUKE

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/27/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Franklin.

I, Brian LaDuke, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/27/2024

Date

Subscribed and Sworn to before me this 27th day of September 2024

Notary Public Signature

JILL VENNEKOTTER
NOTARY PUBLIC • STATE OF OHIO
Comm. No. 2023-RE-869823
My Commission Expires Oct. 23, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site CARDIO PARTNERS, INC.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PENDING

Physical Address 1033 COLLINS RD, SUITE B

City GREENWOOD State IN Zip 46143

Mailing Address (if different from physical address) 5000 TUTTLE CROSSING BLVD

City DUBLIN State OH Zip 43016

Telephone 614-760-5000 Website WWW.CARDIOPARTNERS.COM

Licensing Company Email REGULATORY@SARNOVA.COM

Section 2: Personal Information

First DARRELL Middle _____ Last HUGHES

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City UPPER ARLINGTON State OH Zip 43220

Telephone 614-760-5000 Email REGULATORY@SARNOVA.COM

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
CAPITAL UNIVERSITY LAW SCHOOL		1996-1999	
Address	**City**	**State**	**Zip**
303 EAST BROAD ST	COLUMBUS	OH	43215
Diploma/Degree obtained, if any			
J.D.			

School Name		From - To (MM/YY – MM/YY)	
INDIANA UNIVERSITY, BLOOMINGTON		1991-1995	
Address	**City**	**State**	**Zip**
107 S INDIANA AVE	BLOOMINGTON	IN	47405
Diploma/Degree obtained, if any			
B.A. PSYCHOLOGY			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2003-PRESENT	[redacted]	UPPER ARLINGTON	OH	43220
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
CARDIO PARTNERS, INC.			2012-PRESENT
Business Address	**City**	**State**	**Zip**
5000 TUTTLE CROSSING BLVD	DUBLIN	OH	43016
Phone	**Title**		
614-760-5000	SECRETARY		
Description of Duties			
SEE ATTACHED			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or no o contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

DARRELL HUGHES

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/24/24

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Franklin

I, Darrell Hughes, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/24/24

Date

Subscribed and Sworn to before me this 24 day of September 2024

Notary Public Signature

JILL VENNEKOTTER
NOTARY PUBLIC • STATE OF OHIO
Comm. No. 2023-RE-869823
My Commission Expires Oct. 23, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775 850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site CARDIO PARTNERS, INC.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PENDING

Physical Address 1033 COLLINS RD. SUITE B

City GREENWOOD State IN Zip 46143

Mailing Address (if different from physical address) 5000 TUTTLE CROSSING BLVD

City DUBLIN State OH Zip 43016

Telephone 614-760-5000 Website WWW.CARDIOPARTNERS.COM

Licensing Company Email REGULATORY@SARNOVA.COM

Section 2: Personal Information

First LAWRENCE Middle _____ Last FRANCHETTI

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted]

City MIAMI State FL Zip 33138

Telephone 614-760-5000 Email REGULATORY@SARNOVA.COM

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF DELAWARE		1999-2001	
Address	**City**	**State**	**Zip**
210 SOUTH COLLEGE AVE	NEWARK	DE	19716
Diploma/Degree obtained, if any			
BACHELORS			

School Name		From - To (MM/YY – MM/YY)	
TULANE UNIVERSITY		1997-1999	
Address	**City**	**State**	**Zip**
6823 ST CHARLES AVE	NEW ORLEANS	LA	70118
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
SALESIANUM SCHOOL		1993-1997	
Address	**City**	**State**	**Zip**
1801 N BROOM ST	WILMINGTON	DE	19802
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2019-PRESENT	[redacted]	MIAMI	FL	33138
01/2019-05/2019		MIAMI	FL	33131
04/2011-01/2019		NEW YORK	NY	10001

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
ONE BEAT CPR LEARNING CENTER, LLC			01/2019- PRESENT
Business Address	**City**	**State**	**Zip**
3151 EXECUTIVE WAY	MIRAMAR	FL	33025
Phone	**Title**		
614-760-5000	CEO		
Description of Duties			
SEE ATTACHED			

Business Name			From - To (MM/YY – MM/YY)
CARDIO PARTNERS, INC.			08/2024-PRESENT
Business Address	**City**	**State**	**Zip**
5000 TUTTLE CROSSING BLVD	DUBLIN	OH	43016
Phone	**Title**		
614-760-5000	PRESIDENT		
Description of Duties			
SEE ATTACHED			

Business Name			From - To (MM/YY – MM/YY)
CIGNET, LLC			04/2014-01/2019
Business Address	**City**	**State**	**Zip**
24601 CAPITAL BLVD	CLINTON TOWNSHIP	MI	48036
Phone	**Title**		
586-307-3790	PRESIDENT		
Description of Duties			
CIGNET IS NO LONGER A COMPANY			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

LAWRENCE FRANCHETTI

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9-25-24

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Franklin

I, Lawrence Franchetti, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9-25-24

Date

Subscribed and Sworn to before me this 25 day of September 2024

Notary Public Signature

JILL VENNEKOTTER
NOTARY PUBLIC • STATE OF OHIO
Comm. No. 2023-RE-869823
My Commission Expires Oct. 23, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application
Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site CARDIO PARTNERS, INC.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PENDING

Physical Address 1033 COLLINS RD, SUITE B

City GREENWOOD State IN Zip 46143

Mailing Address (if different from physical address) 5000 TUTTLE CROSSING BLVD

City DUBLIN State OH Zip 43016

Telephone 614-760-5000 Website WWW.CARDIOPARTNERS.COM

Licensing Company Email REGULATORY@SARNOVA.COM

Section 2: Personal Information

First SHAWN Middle _____ Last SAYLOR

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City POWELL State OH Zip 43065

Telephone 614-760-5000 Email REGULATORY@SARNOVA.COM

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
THE OHIO STATE UNIVERSITY		2002-2004	
Address	**City**	**State**	**Zip**
281 W LANE AVE	COLUMBUS	OH	43210
Diploma/Degree obtained, if any			
MASTERS OF ACCOUNTING/CPA			

School Name		From - To (MM/YY – MM/YY)	
OHIO UNIVERSITY		2003	
Address	**City**	**State**	**Zip**
1 OHIO UNIVERSITY	ATHENS	OH	45701
Diploma/Degree obtained, if any			
BACHELOR OF BUSINESS ADMINISTRATION			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2008-PRESENT	[redacted]	POWELL	OH	43065
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
CARDIO PARTNERS, INC.			2009-PRESENT
Business Address	**City**	**State**	**Zip**
5000 TUTTLE CROSSING BLVD	DUBLIN	OH	43016
Phone	**Title**		
614-760-5000	CFO		
Description of Duties			
SEE ATTACHED			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SHAWN SAYLOR

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/25/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Franklin.

I, Shawn Saylor, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/25/2024

Date

Subscribed and Sworn to before me this 25 day of September 2024

Notary Public Signature

JILL VENNEKOTTER
NOTARY PUBLIC • STATE OF OHIO
Comm. No. 2023-RE-869823
My Commission Expires Oct. 23, 2028

(Seal)

Employee number	Name	Job	GL Location	BusinessUnit	Supervisor
[redacted]	Ewing, Wendy K.	Warehouse Associate	WH Greenwood (13)	Cardio Partners	Friermood, Kyle
	Foster Jr., Mike M.	Inbound Invtry Cntrl Sup	WH Greenwood (13)	Cardio Partners	Friermood, Kyle
	Friermood, Kyle G.	Operations Manager	WH Greenwood (13)	Cardio Partners	Flaugher, Ryan
	Gardner, Melvin	Equipment Operator	WH Greenwood (13)	Cardio Partners	Friermood, Kyle
	Hassell, Madreicus D.	Warehouse Supervisor	WH Greenwood (13)	Cardio Partners	Friermood, Kyle
	Peck, Devonte	Equipment Operator	WH Greenwood (13)	Cardio Partners	Friermood, Kyle
	Perez, Guadalupe	Warehouse Clerk	WH Greenwood (13)	Cardio Partners	Friermood, Kyle
	Ray Sr., Scottie D.	Warehouse Associate	WH Greenwood (13)	Cardio Partners	Friermood, Kyle
	Smallstey, Justin M.	Equipment Operator	WH Greenwood (13)	Cardio Partners	Friermood, Kyle
	Tinhlawnsung, Anao	Warehouse Associate	WH Greenwood (13)	Cardio Partners	Friermood, Kyle
	Villalobos, Kenya M.	Warehouse Associate	WH Greenwood (13)	Cardio Partners	Friermood, Kyle
	Whitlow, Iesha	Equipment Operator	WH Greenwood (13)	Cardio Partners	Friermood, Kyle
	Woods Jr., Trumell M.	Warehouse Associate	WH Greenwood (13)	Cardio Partners	Friermood, Kyle
	Zi, Van B.	Warehouse Associate	WH Greenwood (13)	Cardio Partners	Friermood, Kyle

411

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Fisher BioServices Inc.

Physical Address: 20439 Seneca Meadows Parkway

City: Germantown State: MD Zip: 20876

Mailing Address (if different from physical address): c/o State License Servicing, 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: www.thermofisher.com

Name of Designated Representative (DR): Dennis Albert Eyler

Licensing Company Email: FBS@slsny.com DR Email: dennis.eyler@thermofisher.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☒ Others: Drugs (Human OTC, Biologics) Devices (Containing a drug, RX Convenience Kit, Containing a drug component)	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: US Government		☒ Others: 3PL

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
07/26/22		AL	Birmingham	Shelby

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
21-L-0023	Alabama State Board of Pharmacy

Reason/Charge
Fine

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity
Fisher BioServices Inc.

Provide explanation below:

Please see attached letter of explanation.

Deanna Marie Connors

Original Signature (electronic, copies or stamps not accepted)

12 Aug 2024

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
03/11/15		KY	Frankfort	Franklin
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
14-0403A		Kentucky Board of Pharmacy		
Reason/Charge				
Fine				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Fisher BioServices Inc.				
Name of Business/Industry/Entity				

Provide explanation below:

Please see attached.

Deanna Marie Connors

Original Signature (electronic, copies or stamps not accepted)

12 Aug 2024

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
11/17/21		LA	Baton Rouge	East Baton Rouge Parish
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
21-0384		Louisiana Board of Pharmacy		
Reason/Charge				
Fine				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Fisher BioServices Inc.				
Name of Business/Industry/Entity				

Provide explanation below:

Please see attached

Deanna Marie Connors

Original Signature (electronic, copies or stamps not accepted)

12Aug2024

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
02/16/24		MD	Baltimore	Baltimore County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
24-153		Maryland Board of Pharmacy		
Reason/Charge				
Letter of Admonishment				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Fisher BioServices Inc.				
Name of Business/Industry/Entity				

Provide explanation below:

Please see attached

Deanna Marie Connors

Original Signature (electronic, copies or stamps not accepted)

12/19/2024

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
06/30/23		PA	Harrisburg	Dauphin
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
21-54-019642		Commonwealth of Pennsylvania Department of State before the State Board of Pharmacy		
Reason/Charge				
Fine				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Fisher BioServices Inc.				
Name of Business/Industry/Entity				

Provide explanation below:

Please see attached

Deanna Marie Connors

Original Signature (electronic, copies or stamps not accepted)

12 Aug 2024

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
05/16/22		TX	Austin	Travis
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2022-01874		Texas State Board of Pharmacy		
Reason/Charge				
Fine				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Fisher BioServices Inc.				
Name of Business/Industry/Entity				

Provide explanation below:

Please see attached.

Deanna Marie Connors

Original Signature (electronic, copies or stamps not accepted)

12 Aug 2024

Date

Discipline - KY

DocuSign Envelope ID C7005CAF-494F-4B68-90B7-90EE74D4029D

EXHIBIT "A"

COMMONWEALTH OF KENTUCKY
KENTUCKY BOARD OF PHARMACY
Case No. 14-0403A

IN RE: PHARMACY PERMIT NO. MD1153 HELD BY FISHER BIOSERVICES INC.

Agreed Order

Come the parties, the Kentucky Board of Pharmacy ("the Board") and Fisher Bioservices Inc. ("Respondent"), and both having been fully informed regarding the matter set forth herein, state as follows:

(1) Pursuant to Chapter 315 of the Kentucky Revised Statutes, the Board is authorized to regulate and control all matters related to pharmacists and pharmacies not delegated to another agency of the Commonwealth. The matter herein has not been delegated to another agency of the Commonwealth.

(2) Respondent is a pharmacy in the Commonwealth of Kentucky, having been assigned pharmacy permit no. MD1153.

(3) (a) A board investigation revealed that Respondent sent 38 shipments into the Commonwealth of Kentucky between March 1 and June 27, 2014, without a named Kentucky licensed Pharmacist-in-Charge.
(b) Consequently, the Respondent is subject to discipline pursuant to KRS 315.0351(7) and KRS 315.121(1)(h).

(4) The Board and Respondent have agreed to address this matter by entering into this Agreed Order, in lieu of the filing of a formal Complaint.

WHEREFORE, IT IS HEREBY AGREED AND ORDERED THAT:

(A) Respondent shall be fined $2000 payable by February 23, 2015. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky Board of Pharmacy, State Office Bldg. Annex, Ste. 300, 125 Holmes St., Frankfort, Kentucky 40601.

(B) By entering into this Agreed Order, Respondent expressly acknowledges that Respondent was fully and completely informed of Respondent's right to due process, that the Respondent

Discipline- AL

DocuSign Envelope ID: C7005CAF-494F-4B68-90B7-90EE74D4029D

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
FISHER BIOSERVICES INC.	)	
	)	
Non-Resident Pharmacy Permit Number: 112698	)	**CASE NO: 21-L-0023**
	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Fisher Bioservices Inc. which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975), § 41-22-12(f), the Board through its counsel and Fisher Bioservices Inc., through its counsel, engaged in negotiations and as a result, the matters at issue were resolved informally by the parties who agreed to the entry of this Consent Order which includes the following terms:

1. The Board finds that Fisher Bioservices Inc. has violated the provisions of law based upon the conduct set out in Counts One through Four of the Statement. Count Five shall be dismissed.

2. Fisher Bioservices Inc. shall pay an administrative fine in the amount of Four Thousand Dollars ($4,000.00) within thirty (30) days of the effective date of this Consent Order, that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall Fisher Bioservices Inc. attempt to discharge the same.

3. Fisher Bioservices Inc. expressly waives its rights pursuant to the Alabama

DocuSign Envelope ID C7005CAF-494F-4B68-90B7-90EE74D4029D

COUNT TWO

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of the preceding Count.

COUNT THREE

Violating Code of Alabama (1975), § 34-23-33(2) based upon the entry of a Consent Order by the Louisiana State Board of Pharmacy on November 17, 2021 attached hereto as Exhibit "B" and/or your failure to disclose when required to do so on your Application for Renewal of Pharmacy Permit for Year 2016 the Kentucky discipline set out in Count One above.

COUNT FOUR

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of Count Three above.

Further, pursuant to the provisions of Code of Alabama, (1975), §20-2-53 and §41-22-12, you are hereby notified and requested to appear before the Board at the aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture, dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), §20-2-1, et. seq., issued pursuant to Code of Alabama (1975), §20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

COUNT FIVE

Violating Code of Alabama (1975), §20-2-54(a)(4) by violating the provisions of

DONE this the 26 of [illegible], 2022.

FISHER BIOSERVICES INC

BY: [illegible]

ITS: [illegible]

[illegible]

Allison Fulton, Attorney for Fisher Bioservices Inc.

DONE this the 27 of July, 2022.

ALABAMA STATE BOARD OF PHARMACY

By: [illegible]

Chris Phung, R.Ph., President

By: [illegible]

James S. Ward,
Attorney for the Alabama State Board of Pharmacy

OF COUNSEL:
WARD & COOPER, LLC
2100A Southbridge Parkway
Suite 645
Birmingham, AL 35209
(205) 871-5404

Discipline - LA

DocuSign Envelope ID C7005CAF-494F-4B68-90B7-90EE74D4029D

EXHIBIT "B"

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

FISHER BIOSERVICES, INC.

LOUISIANA PHARMACY PERMIT NO. 5649 **Case No. 21-0384**

CONSENT AGREEMENT

WHEREAS, FISHER BIOSERVICES, INC. (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 5649, 14665 Rothgeb Drive, Rockville, Maryland 20850, was disciplined by Board Order issued by the Kentucky Board of Pharmacy on or about March 11, 2015 for dispensing 38 prescriptions into Kentucky from March 1 to June 27, 2014, without a licensed pharmacist-in-charge.

WHEREAS, Respondent failed to report this disciplinary action to the Board as part of its Application for Renewal of Pharmacy Permit for Year 2016.

WHEREAS, such action constitutes a violation of the following:

La. R.S. 37:1241(A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

La. R.S. 37:1241(A)(2): Has attempted to or obtained a license by misrepresentation.

LA. R.S. 37:1241(A)(6) Has had his license, permit, certification, registration or any other designations deemed necessary to engage in the practice of pharmacy revoked or suspended, or has had other disciplinary action taken, or has had his application for licensure refused, revoked, or suspended by the proper authorities of another state, territory, or country based upon conduct by the licensee similar to conduct that would constitute grounds for action as defined in this Section.

La. R.S. 37:1241(A)(7): Has failed to report to the board any adverse action taken by another government agency, law enforcement agency, or court that would constitute grounds for action as defined in this Section.

La. R.S. 37:1241(A)(22): Has failed to furnish to the board or representatives any information legally requested by the board.

To facilitate the submission of this Consent Agreement, Respondent agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

DocuSign Envelope ID C7005CAF-494F-4B68-90B7-90EE74D4029D

SIGNED, AGREED TO AND ENTERED ON THIS 2nd DAY OF December, 2021

FISHER BIOSERVICES, INC.
Louisiana Pharmacy Permit No. 5649

Cheryl L Robinson, witness

BY Authorized Representative

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on November 17, 2021, the Board hereby adopts said Agreement as a Final Order of the Board

FOR THE BOARD

Hearing Officer for the Board

Discipline - MD

Maryland
DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

Maryland Board of Pharmacy
Neil Leikach, RPh, M.Sc., Board President
Deena Speights-Napata, M.A., Executive Director
4201 Patterson Avenue
Baltimore, MD 21215-2299

February 16, 2024

BY REGULAR AND CERTIFIED MAIL
RETURN RECEIPT REQUESTED
ARTICLE # 7019 2280 0000 6567 8171

Fisher Bioservices
Attn: Cheryl Robinson
14665 Rothgeb Drive
Rockville, MD 20850

RE: Letter of Admonishment – Case #24-153
Permit #D01827, P04312

Dear Ms Robinson:

The Maryland Board of Pharmacy (the "Board") has received reports of disciplinary actions which were taken against Fisher Bioservices by the Texas, Pennsylvania, Louisiana, and Kentucky Boards of Pharmacy. The Board has determined that you did not answer correctly on your application for a distributor registration and pharmacy permit when asked about prior disciplinary actions, and had failed to report the Kentucky and Louisiana actions. Therefore, the Board is issuing this Letter of Admonishment.

The Board would like to remind you that all licensed permit holders are required to provide accurate information in order to remain in good standing with the Board. In accordance with COMAR 10.34.11.06(B)(1):

"a permit holder withholding required information on an application is submitting a false application."

The failure to provide the Board with complete, up-to-date, and accurate information shall constitute a violation on the grounds for action under the Health Occupations Article § 12-6C-05 (7)(v), Annotated Code of Maryland.

This Letter of Admonishment will form a part of the permanent record for your file with the Board. However, this Letter will not be revealed to any person and will not be obtainable by any person under the Public Information Act, General Provisions Article, section 4-101, *et seq.*

unless otherwise authorized. ***This Letter of Admonishment is not considered disciplinary action by the Board***. You need not reveal this letter to any person and is not required to report the letter if asked if the Board has taken any disciplinary action against this license.

If you have questions about this Letter of Admonishment, or would like the opportunity to address the Board regarding this matter, please contact Jered Pasay, M.S. Laboratory Scientist Surveyor at (443) 220-9821.

Sincerely,

Deena Speights-Napata, M.A.
Executive Director

cc: Linda Bethman, Board Counsel
Jered Pasay, M.S. Laboratory Scientist Surveyor

Discipline - PA

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania Bureau of Professional and Occupational Affairs	
vs.	**Case No. 21-54-019642**
Fisher BioServices Inc. t/d/b/a Fisher BioServices **Respondent**	

CONSENT AGREEMENT AND ORDER

PARTIES

The Commonwealth of Pennsylvania, Department of State, Bureau of Professional and Occupational Affairs ("Commonwealth") and **Fisher BioServices Inc. t/d/b/a Fisher BioServices** ("Respondent") stipulate as follows in settlement of the above-captioned case.

APPLICABLE LAW

1. This matter is before the Pennsylvania State Board of Pharmacy ("Pennsylvania Board") pursuant to the Pharmacy Act, act of September 27, 1961, P.L. 1700, ("Act"), *as amended*, 63 P.S. §§ 390-1 to 390-13; and/or 63 Pa.C.S. Chapter 31 ("Chapter 31").

LICENSURE STATUS

2. At all relevant and material times, Respondent held the following registration to practice as a nonresident pharmacy in the Commonwealth of Pennsylvania: registration no. NP001519, which was originally issued on December 11, 2019, and which is currently set to expire on August 31, 2023.

STIPULATED FACTS

3. Respondent admits the following:

a. Absent additional Pennsylvania Board action, Respondent's registration may be continually reactivated or reinstated upon the filing of the required documentation and payment of the applicable fees.

b. Respondent's address is: 14665 Rothgeb Drive, Rockville, MD 20850.

c. At all relevant and material times, Respondent was authorized to practice as a nonresident pharmacy in the Commonwealth of Kentucky.

d. On or about March 11, 2015, the Commonwealth of Kentucky's Board of Pharmacy ("Kentucky Board"), by way of Agreed Order at Kentucky Board Case Number 14-0403A, found Respondent to be in violation of the laws, rules, code and/or regulations of the Commonwealth of Kentucky because Respondent shipped approximately thirty-eight (38) prescription medications into Kentucky during a time Respondent did not have an actively licensed pharmacist in charge.

e. In the March 15, 2015 Agreed Order, the Kentucky Board imposed a two thousand dollar ($2,000.00) fine upon Respondent.

f. A true and correct copy of the Kentucky Board's March 11, 2015 Agreed Order, Kentucky Board Case Number 14-0403A, is attached as **EXHIBIT A** and is incorporated by reference.

g. On or about November 21, 2019, Respondent submitted an Initial Application to the Pennsylvania Board for registration as a nonresident pharmacy.

h. On the November 21, 2019 Initial Application, Respondent answered "No" to the question, "Has the nonresident pharmacy named in this application been subject to suspension or revocation or otherwise disciplined by the proper licensing authority of another state?"

DOS Prothonotary
Jun 30 2023

i. A true and correct cope of the November 21, 2019 Initial Application is attached as **EXHIBIT B** and is incorporated by reference.

j. At all relevant and material times, Respondent was authorized to practice as a nonresident pharmacy in the State of Louisiana.

k. On or about November 17, 2021, the State of Louisiana's Board of Pharmacy ("Louisiana Board"), by way of Consent Agreement at Louisiana Board Case Number 21-0384, found Respondent to be in violation of the laws, rules, code and/or regulations of the State of Louisiana because Respondent failed to report the March 11, 2015 Kentucky discipline on its 2016 Louisiana renewal application.

l. In the November 17, 2021 Consent Agreement, the Louisiana Board imposed a five thousand dollar ($5,000.00) fine, two hundred fifty dollars ($250.00) in costs, and a letter of reprimand upon Respondent.

m. A true and correct copy of the Louisiana Board's November 17, 2021 Consent Agreement, Louisiana Board Case Number 21-0384, is attached as **EXHIBIT C** and is incorporated by reference.

AUTHORITY OF THE BOARD

4. The Pennsylvania Board is authorized to suspend or revoke, or otherwise restrict Respondent's registration under section 4.1(e) of the Act, 63 P.S. §§ 390-4.1(e); impose a civil penalty under 63 Pa.C.S. § 3108(b)(4); and/or impose the costs of investigation upon Respondent under section 63 Pa.C.S. § 3108(b)(5).

PROPOSED ORDER

5. The parties, intending to be legally bound, consent to the issuance of the following Order in settlement of this matter:

a. **VIOLATIONS:** Respondent violated the Act at:

GDS Preliminary
Jun 30 2023

(1) Section 4.1(g), 63 P.S. § 390-4.1(g), in that Respondent had a permit to conduct a pharmacy suspended or revoked or the nonresident pharmacy was otherwise disciplined by the proper licensing authority of another state;

(2) Section 8(1), 63 P.S. § 390-8(1), in that Respondent procured a its nonresident pharmacy registration by making a false representation, as evidenced by Respondent incorrectly stating it had not been disciplined by another state on its initial application.

b. **PUBLIC REPRIMAND:** A public reprimand shall be placed on Respondent's permanent disciplinary record with the Pennsylvania Board.

c **CIVIL PENALTY:** Respondent shall pay a civil penalty of two thousand five hundred dollars ($2,500.00).

d. Payment of the civil penalty is subject to the following terms:

(1) The full civil penalty shall be tendered to the prosecution division of the Department of State with the executed consent agreement;

(2) The civil penalty shall be **paid by certified check, cashier's check, attorney's check, or money order** issued by a usual, customary, and reputable issuer (e.g. U.S. Postal Money Order, Western Union Money Order, etc.);

DOS Prothonotary
Jun 30 2023

(3) Payment shall be valid for a period of at least 180 days and shall be **made payable to the "Commonwealth of Pennsylvania"**; and

(4) Respondent agrees that payment shall only be made by one of the methods indicated and shall not be made by uncertified personal or corporate check.

e. This Order constitutes disciplinary action by the Pennsylvania Board. This Order will be reported to other licensing authorities and any applicable national licensing databank as a disciplinary action by the Pennsylvania Board.

f. This case shall be deemed settled and discontinued upon the Pennsylvania Board issuing an order adopting this Consent Agreement.

ADMISSIBILITY OF CONSENT AGREEMENT IN FUTURE PROCEEDINGS

6. Respondent agrees that this Consent Agreement and Order shall be admitted into evidence, without objection, in any proceeding before the Department of State.

ACKNOWLEDGMENT OF NOTICE AND WAIVER OF HEARING

7. Respondent acknowledges receipt of an Order to Show Cause in this matter. Respondent knowingly and voluntarily waives the right to an administrative hearing in this matter and the following rights related to that hearing: to be represented by counsel; to present witnesses and testimony in defense or in mitigation of any sanction that may be imposed for a violation; to cross-examine witnesses and to challenge evidence presented by the Commonwealth; to present legal arguments by means of a brief; and to take an appeal from any adverse final decision.

ACKNOWLEDGMENT OF RIGHT TO ATTORNEY

8. Respondent acknowledges the right to consult with and be represented by private legal counsel of Respondent's choosing and at Respondent's expense when reviewing, considering, and

DOS Penitentiary
Jun 30 2023

accepting the terms of this Consent Agreement. To the extent that Respondent is not represented by legal counsel, Respondent has knowingly elected to proceed without the assistance of legal counsel.

WAIVER OF CLAIMS

9. Should the Pennsylvania Board vote not to adopt the Order proposed in this Consent Agreement, the presentation and consideration of this Consent Agreement shall not prejudice the Pennsylvania Board or any of its members from further participation in the adjudication of this matter. Respondent expressly waives the right to raise any claims or issues, including any and all constitutional claims or issues, which may arise or have arisen during the review, presentation and deliberation of this Consent Agreement. These claims or issues include, but are not limited to, bias, the commingling of prosecutorial and adjudicative functions by the Pennsylvania Board or its counsel, and the Pennsylvania Board, in its discretion, recommending a different sanction based upon the facts set forth in the Consent Agreement. If a hearing is subsequently held, neither this Consent Agreement nor the proposed terms of settlement may be admitted into evidence and any facts, averments, and allegations contained in the Consent Agreement must be proven at a hearing unless otherwise separately stipulated.

LIMITS ON MODIFICATION OF ORDER

10. Respondent agrees not to seek modification of the Order adopting and implementing this Consent Agreement without first obtaining the express written permission from the prosecution division. Any modification is at the sole discretion of the Pennsylvania Board.

AGREEMENT NOT BINDING UNTIL APPROVED

11. This Consent Agreement is between the Commonwealth and Respondent. The Office of General Counsel has approved this Consent Agreement as to form and legality. The disciplinary

DOS Prothonotary
Jun 30 2023

provisions of this Consent Agreement do not take effect unless and until the Pennsylvania Board issues an order adopting this Consent Agreement.

ENTIRE AGREEMENT

12. This Consent Agreement contains the entire agreement between the parties. There are no other terms, obligations, covenants, representations, statements, or conditions, oral or otherwise, of any kind whatsoever concerning this agreement.

AGREEMENT DOES NOT PREVENT FUTURE DISCIPLINE

13. Nothing in this Order shall preclude the prosecution division of the Department of State from filing charges, or the Pennsylvania Board from imposing disciplinary or corrective measures, for violations or facts not contained in this Consent Agreement.

VERIFICATION OF FACTS AND STATEMENTS

14. Respondent verifies that the facts and statements set forth in this Consent Agreement are true and correct to the best of Respondent's knowledge, information, and belief. Respondent understands that statements in this Consent Agreement are made subject to the criminal penalties of 18 Pa.C.S.A. §4904 relating to unsworn falsification to authorities.

/s/ Glenn P. Masser

Glenn P. Masser

Prosecuting Attorney

DATED: 6/5/2023

William E. Turner ~~Kathleen Mulholland, President~~

Fisher BioServices Inc.
t/d/b/a Fisher BioServices
Respondent

DATED: 31 May 2023

DOS Prothonotary
Jun 30 2023

Andy Beshear
Governor

KENTUCKY BOARD OF PHARMACY

State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601
Phone (502) 564-7910
Fax (502) 696-3806
http://pharmacy.ky.gov

Board Members
Jason Belcher, Consumer
Peter P. Cohron, R.Ph.
Meredith Figg, Pharm.D.
John Fuller, R.Ph.
Anthony B. Tagavi, Pharm.D.
Jonathan Van Lahr, R.Ph.

Executive Director
Christopher P. Harlow, Pharm.D.

Pennsylvania Department of State
Office of Chief Counsel
Professional Compliance Office
Attn: Laura Dickinson
P.O. Box 69522
Harrisburg, PA 17106

April 12, 2023

Ms. Dickinson,

Please find enclosed the certified records requested from the Kentucky Board of Pharmacy. This is the only disciplinary action we have against Fisher Bioservices, MD1151. Their current address on file is 14665 Rothgeb Dr., Rockville, Maryland, 20850. If you have further questions, please do not hesitate to contact me.

Thanks,

Eden S Davis

Eden S. Davis, General Counsel
Kentucky Board of Pharmacy
Eden.davis@ky.gov
(502) 564-8078

EXHIBIT A

Kentucky

005 Prothonotary
Jun 30 2023

KENTUCKY BOARD OF PHARMACY
CERTIFICATION OF ADMINISTRATIVE CASE RECORDS

Case Number: 14-0403A

I, Christopher Harlow, as custodian of records for the Kentucky Board of Pharmacy, do hereby certify that the attached copies are true and correct copies of the originals and are official records of the Kentucky Board of Pharmacy.

Christopher Harlow Custodian of Records

Signature

4-12-2023 Date

DOS Prothonotary
Jun 30 2023

COMMONWEALTH OF KENTUCKY
KENTUCKY BOARD OF PHARMACY
Case No. 14-0403A

IN RE: PHARMACY PERMIT NO. MD1153 HELD BY FISHER BIOSERVICES INC.

Agreed Order

Come the parties, the Kentucky Board of Pharmacy ("the Board") and Fisher Bioservices Inc. ("Respondent"), and both having been fully informed regarding the matter set forth herein, state as follows:

(1) Pursuant to Chapter 315 of the Kentucky Revised Statutes, the Board is authorized to regulate and control all matters related to pharmacists and pharmacies not delegated to another agency of the Commonwealth. The matter herein has not been delegated to another agency of the Commonwealth.

(2) Respondent is a pharmacy in the Commonwealth of Kentucky, having been assigned pharmacy permit no. MD1153.

(3) (a) A board investigation revealed that Respondent sent 38 shipments into the Commonwealth of Kentucky between March 1 and June 27, 2014, without a named Kentucky licensed Pharmacist-in-Charge.
(b) Consequently, the Respondent is subject to discipline pursuant to KRS 315.0351(7) and KRS 315.121(1)(h).

(4) The Board and Respondent have agreed to address this matter by entering into this Agreed Order, in lieu of the filing of a formal Complaint.

WHEREFORE, IT IS HEREBY AGREED AND ORDERED THAT:

(A) Respondent shall be fined $2000 payable by February 23, 2015. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky Board of Pharmacy, State Office Bldg. Annex, Ste. 300, 125 Holmes St., Frankfort, Kentucky 40601.

(B) By entering into this Agreed Order, Respondent expressly acknowledges that Respondent was fully and completely informed of Respondent's right to due process, that the Respondent

DOS Preliminary
Jun 30 2023

fully understands those rights, and that Respondent knowingly, voluntarily, and willingly agrees to waive those rights and to enter into this Agreed Order.

(C) The above information shall be reported to the National Association of Boards of Pharmacy ("NABP"), and is subject to disclosure under the Kentucky Open Records Act.

Joel Thornbury, President
Kentucky Board of Pharmacy

3/11/15
Date

Fisher Bioservices INC
Respondent

JAN 30, 2015
Date

DOS Prothonotary
Jun 30 2023

Steven L. Beshear
Governor

KENTUCKY BOARD OF PHARMACY

State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601
Phone (502) 564-7910
Fax (502) 696-3806
http://pharmacy.ky.gov

Board Members
Deborah L. Brewer, R.Ph.
Brian C. DeWire, DC, Consumer
Scott A. Greenwell, Pharm.D.
Larry Hadley, R.Ph.
Anne Policastri, Pharm.D., MBA
Joel C. Thornbury R.Ph.

Executive Director
Michael Burleson, R.Ph.

CERTIFICATE OF SERVICE

I hereby certify that a copy of Agreed Order 14-0403A was mailed to you on this the 2nd day of April, 2015 to:

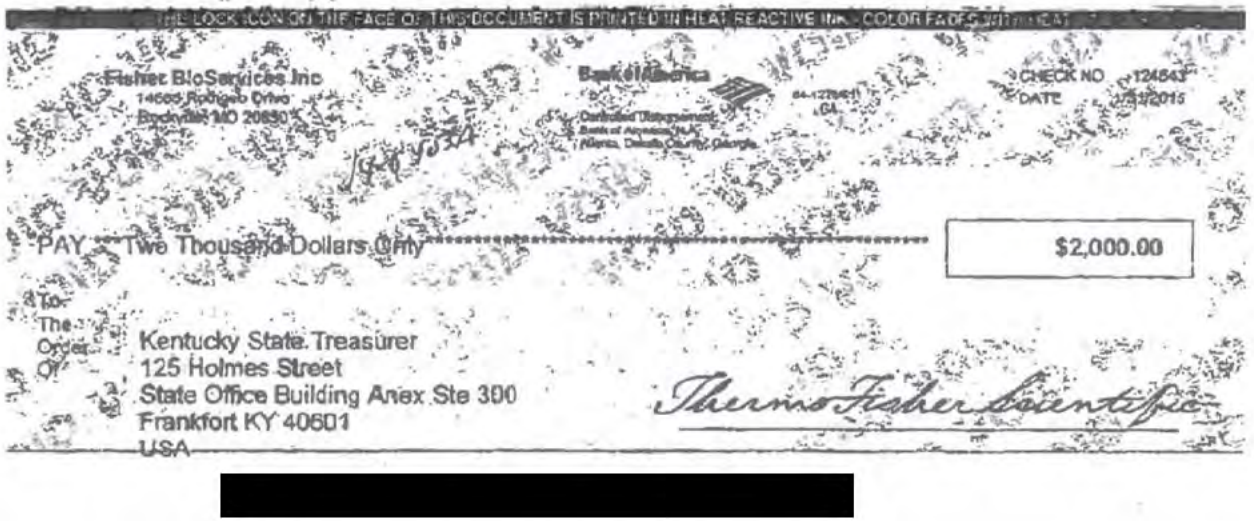
Fisher Bioservices, Inc
14665 Rothgeb Dr
Rockville MD 20850

This copy of your Agreed Order is for your records.

Lisa Atha

Lisa Atha
Executive Secretary

DDS Prothonotary
JUN 30 2023



THE LOCK ICON ON THE FACE OF THIS DOCUMENT IS PRINTED IN HEAT REACTIVE INK - COLOR FADES WITH HEAT

Fisher BioServices Inc
14565 Rothgeb Drive
Rockville MD 20850

Bank of America

CHECK NO 124543
DATE 2/5/2015

PAY ***Two Thousand Dollars Only*** $2,000.00

To The Order Of
Kentucky State Treasurer
125 Holmes Street
State Office Building Anex Ste 300
Frankfort KY 40601
USA

ThermoFisher Scientific

[redacted]

Kentucky Board of Pharmacy
Frankfort, KY
October 2, 2014

CASE: 14-0403

RE: Fisher Bioservices Inc. MD1153
14665 Rothgeb Drive
Rockville, MD 20850

ALLEGATION: Non-resident pharmacy shipped prescriptions into the Commonwealth without a Kentucky licensed pharmacist in charge from March 1, 2014 until June 27, 2014.

ALLEGED VIOLATION OF LAW: 315.0351 (7) Each out-of-state pharmacy shall have a pharmacist in charge who is licensed to engage in the practice of pharmacy by the Commonwealth that shall be responsible for compliance by the pharmacy with the provisions of this section

INVESTIGATIVE FINDINGS: On March 18, 2014, Fisher Bioservices Inc. was notified by certified mail that Teicher Haney, pharmacist in charge, license had lapsed The permit status was placed in a pending status and the pharmacy was advised to refrain from shipping into Kentucky until the issue was resolved. The pharmacy renewed it's permit on June 27, 2014 and included Linda Antonishek as the pharmacist in charge. Ms Antonishek became licensed in Kentucky on June 26, 2014. On July 23, 2014 a request was made for records of any prescriptions that were shipped into Kentucky during the period March 1, 2014 and June 27, 2014. On August 26, 2014 a report was received that indicates that 38 shipments took place during the period without a pharmacist in charge.

INVESTIGATIVE DOCUMENTATION:

1. March 18, 2014 letter
2. Pharmacy renewal 6/27/2014
3. Pharmacist L. A. profile
4. July 23, 2014 letter
5. Shipping records for March 1, 2014 through June 27, 2014

Submitted by:

Steve Hart, R.Ph

DOS Prothonotary
Jun 30 2023

KENTUCKY BOARD OF PHARMACY

Steven L. Beshear
Governor

State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601
Phone (502) 564-7910
Fax (502) 696-3806
http://pharmacy.ky.gov

Board Members
Deborah L. Brewer, R.Ph.
Brian C. DeWire, DC, Consumer
Scott A. Greenwell, Pharm.D.
Larry Hadley, R.Ph.
Cathy Hanna, Pharm.D.
Joel C. Thornbury R.Ph.

Executive Director
Michael Burleson, R.Ph.

March 18, 2014

FISHER BIOSERVICES INC
14665 ROTHGEB DRIVE
ROCKVILLE MD 20850

RE: Non-Resident Pharmacy Permit – MD1153

Dear Sir or Madam:

The pharmacist in charge on your Kentucky permit, TEICHER HANEY, has been removed. This pharmacist has not renewed their Kentucky pharmacist license which expired on February 28, 2014. Upon renewal, please notify the Board office to reinstate this pharmacist as your PIC.

Thank you for your attention regarding this matter. Please note your pharmacy permit has been placed in PENDING status. You should refrain from shipping any prescriptions into Kentucky until this has been resolved.

Sincerely,

Michael Burleson, R.Ph.
Executive Director

2

Permit Number: MD1153, Renewal Date: 06/27/2014

Contact Information:

Pharmacy Name:	FISHER BIOSERVICES INC
Address 1:	14665 ROTHGEB DRIVE
City:	ROCKVILLE
County:	Out Of State
State:	MD
Zip Code:	20850

Contact Numbers:

Pharmacy Telephone Number:	(301) 315-8426
Pharmacy Fax Number:	(301) 294-4795

Controlled Substance/DEA Information:

DEA Registration Number: BF9547324 Expiration Date: 09/30/2014

Pharmacy Ownership:

Corporation

Pharmacy Owner/Officer Information:

CHERYL ROBINSON, DIRECTOR OF PHARMACY OPERATIONS
14665 Rothgeb Drive , Rockville, MD 20850
JAMES BRUNI, Asst Secretary
171 Industry Drive , Pittsburgh, PA 15275

Pharmacy Hours:

Monday	8:00:00AM to 5:00:00PM
Tuesday	8:00:00AM to 5:00:00PM
Wednesday	8:00:00AM to 5:00:00PM
Thursday	8:00:00AM to 5:00:00PM
Friday	8:00:00AM to 5:00:00PM
Saturday	
Sunday	

Lunch Time: to

Type of Pharmacy:

Primary type of pharmacy: Out-of-State
Additional type: Mail Order

Data Processing System:

Does this pharmacy currently utilize an automated data processing system? If yes, please identify the hardware and software: Yes
Hardware: Dell
Software: In-House/Custom

Shipping Information:

Does this pharmacy ship any prescriptions to the citizens of the Commonwealth of Kentucky under any name or return address other than the information of the pharmacy provided in this application? No

Delivery Services Utilized	Percentage of Time Utilized
FedEx	100

Pharmacist Employment Information:

First and Last Name: LINDA ANTONISHEK

BOS Prothonotary
Jun 30 2023

License Number: 017161

Position: Pharmacist In Charge

Status: Active

Does the pharmacy employ, contract with, or compensate directly or indirectly physicians to authorize prescriptions for citizens of the Commonwealth of Kentucky?

Signature of Owner:

Cheryl A Robinson

DOS Prothonotary
Jun 30 2023

Pharmacy- Nonresident Pharmacy-
Application
Initial
AA0002003555

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
P. O. Box 2649
Harrisburg, PA 17105-2649

APPLICANT INFORMATION

FACILITY INFORMATION			
Facility Name	FISHER BIOSERVICES		
ADDRESS DETAILS			
Street Address	14665 ROTHGEB DR		
City/State/Zip	ROCKVILLE MD 20850		
County	MONTGOMERY	Country	United States

CHECKLIST ITEMS

Checklist name	Status	Submitted Date	Expiration Date
Affidavit	Pending Review	11/21/2019	
Application	Pending Review	11/21/2019	11/20/2020
Application Fee	Completed	11/21/2019	11/20/2020
Databank Report	Pending Review	11/21/2019	
Letters of Good Standing (LOGS)	Not Received	11/20/2019	
Ownership	Pending Review	11/20/2019	
Pharmacy Permit	Pending Review	11/21/2019	
Resident Inspection Report	Pending Review	11/21/2019	

LEGAL QUESTIONS

	Questions	Answer	Document Uploaded	File Name
6	Has the nonresident pharmacy named in this application been subject to suspension or revocation or otherwise disciplined by the proper licensing authority of another state?	N	No	
7	Upload a letter of explanation along with copies of the disciplinary action.		No	

STANDARD QUESTIONS

	Questions	Answer
1	Identify the type of entity that directly owns the pharmacy:	Corporation
2	Provide an explanation regarding the nonstandard ownership.	
3	Full Name of Corporation:	Fisher BioServices Inc.
4	Name of Owner	
5	Full Name of Partnership:	
6	Full Name of Limited Liability Company:	
7	Federal Employer Identification Number (FEIN) (Do NOT use a hyphen)	541348241

EXHIBIT B

DOS Prothonotary
Jun 30 2023

OTHER LICENSE

State	Registration Number	Registration Date	Obtained By
Maryland	P04312		

PRINCIPAL OFFICER DETAILS

Name	Address	Title	Percentage	License Number	Member of Board	Other Information
DAVID MEADOWS	[redacted]	President & Secretary				
MICHAEL MICHAUD		Asst. Secretary				
JAMES BRUN		Asst. Secretary				
CHERYL ROBINSON		Treasurer				

RELATIONSHIP/ASSOCIATION REQUEST

License Number	Name	Relationship Type	Address	License Expiration Date
14806	CHERYL ROBINSON	Pharmacist Manager		

CONTACT PERSON DETAILS

Last Name	First Name	Address	City	State Name	Zip Code	Phone Number	Email
ROBINSON	CHERYL						
ROBINSON	CHERYL	14665 ROTHGEB DR	Rockville	Maryland	20850	[redacted]	cheryl.robinson@thermofisher.com

CONFIRMATION

☑ All fees are non-refundable. Please check to continue with your transaction (11/21/2019 10:12:51)

DOS Probationary
Jun 30 2023

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

FISHER BIOSERVICES, INC.

LOUISIANA PHARMACY PERMIT NO. 5649 **Case No. 21-0384**

****

CONSENT AGREEMENT

WHEREAS, FISHER BIOSERVICES, INC. (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 5649, 14665 Rothgeb Drive, Rockville, Maryland 20850, was disciplined by Board Order issued by the Kentucky Board of Pharmacy on or about March 11, 2015 for dispensing 38 prescriptions into Kentucky from March 1 to June 27, 2014, without a licensed pharmacist-in-charge.

WHEREAS, Respondent failed to report this disciplinary action to the Board as part of its Application for Renewal of Pharmacy Permit for Year 2016.

WHEREAS, such action constitutes a violation of the following:

La. R.S. 37:1241(A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

La. R.S. 37:1241(A)(2): Has attempted to or obtained a license by misrepresentation.

LA. R.S. 37:1241(A)(6) Has had his license, permit, certification, registration or any other designations deemed necessary to engage in the practice of pharmacy revoked or suspended, or has had other disciplinary action taken, or has had his application for licensure refused, revoked, or suspended by the proper authorities of another state, territory, or country based upon conduct by the licensee similar to conduct that would constitute grounds for action as defined in this Section.

La. R.S. 37:1241(A)(7): Has failed to report to the board any adverse action taken by another government agency, law enforcement agency, or court that would constitute grounds for action as defined in this Section.

La. R.S. 37:1241(A)(22): Has failed to furnish to the board or representatives any information legally requested by the board.

To facilitate the submission of this Consent Agreement, Respondent agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

EXHIBIT C

DOE Penitentiary
Jun 30 2025

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

1. **Louisiana Pharmacy Permit No. 5649 belonging to FISHER BIOSERVICES, INC. is issued a LETTER OF REPRIMAND.**

2. **FISHER BIOSERVICES, INC. is ordered to pay a fine of $5,000.00 and to reimburse the Board $250.00 for administrative costs, with total payment due the Board of $5,250.00, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.**

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter and waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing, and to judicial review of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, _____, authorized to act on behalf of and acting on behalf of FISHER BIOSERVICES, INC., understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

[Remainder of page intentionally left blank; signature page to follow.]

DOS Postbusiness
JUN 30 2025

SIGNED, AGREED TO AND ENTERED ON THIS 8 DAY OF December, 2021.

FISHER BIOSERVICES, INC.
Louisiana Pharmacy Permit No. 5649

BY: Authorized Representative

Cheryl A Robinson, witness

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY.

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on November 17, 2021, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Hearing Officer for the Board

DOS Prothonotary
Jun 30 2023

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania Bureau of Professional and Occupational Affairs	
vs.	**Case No. 21-54-019642**
Fisher BioServices Inc. t/d/b/a Fisher BioServices **Respondent**	

ORDER

AND NOW, this 30th day of June 2023, the **STATE BOARD OF PHARMACY** ("Board") approves and adopts the foregoing Consent Agreement and incorporates the terms of paragraph 5, which shall constitute the Board's Order and is now issued in resolution of this matter.

This Order shall take effect immediately.

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

Arion R. Claggett

Arion R. Claggett
Acting Commissioner

BY ORDER:
STATE BOARD OF PHARMACY

Theresa Talbott, R.Ph.
Chairperson

For the Commonwealth:

Glenn P. Masser, Esquire
2601 North Third Street
P.O. Box 69521
Harrisburg, PA 17106-9521

For the Respondent:

Fisher BioServices
14665 Rothgeb Drive
Rockville, MD 20850

Date of mailing:

June 30, 2023

OOI Prothonotary
Jun 30 2023

Discipline - TX

ThermoFisher
SCIENTIFIC

Thermo Fisher Scientific
Fisher BioServices
14665 Rothgeb Drive
Rockville, MD 20850
www.thermofisher.com

May 2022

Dear Board of Pharmacy Representative:

This letter is to inform you of a fine received by Fisher BioServices, Inc. ("Fisher BioServices") from the Texas State Board of Pharmacy. This fine is not related to a new action or inaction but is instead related to an Inadvertent Nondisclosure from 2015. The details are as follows:

In November 2015, upon completing Louisiana's pharmacy permit renewal form, the applicant inadvertently stated that Fisher BioServices had not received discipline from any other state that year. However, Fisher BioServices received and paid a fine due to a violation of Kentucky pharmacy law that calendar year. After paying the fine, Fisher BioServices mailed a notification letter *to each state where it was licensed*. Despite mailing a notification letter Fisher Bioservices failed to re-disclose the fine on the pharmacy permit renewal forms ("Inadvertent Nondisclosure") , which was required by law in the State of Louisiana. As a result of Fisher BioServices' Inadvertent Nondisclosure, it received a fine from Louisiana's Board of Pharmacy and paid the required fine.

In December 2021, upon signature of the Louisiana order, Fisher BioServices notified each state of the fine it paid to the Louisiana Board of Pharmacy. After receipt of such notification, the Texas State Board of Pharmacy reviewed Fisher BioServices' file and identified that in 2016 Fisher Bioservices failed to include on its renewal application reference to the Kentucky disciplinary action, which it was required to do under Texas state law. Thus, Fisher BioServices made the same Inadvertent Nondisclosure to Texas, as it had made to Louisiana. Attached are the documents related to the Texas fine.

Fisher BioServices would like to reiterate that these fines from Louisiana and Texas result from the Inadvertent Nondisclosure that occurred in the 2015/2016 renewal season. While the Inadvertent Nondisclosure occurred, such fines stem from a single violation of Kentucky pharmacy law that occurred in 2015 and do not arise from a new action or inaction by Fisher BioServices.

If you have any questions, please do not hesitate to contact me at the phone number or email listed below.

Kind regards,

Cheryl A. Robinson, RPh, MS
[redacted]
cheryl.robinson@thermofisher.com

AGREED BOARD ORDER #2022-01874

RE: IN THE MATTER OF
FISHER BIOSERVICES INC.
(PHARMACY LICENSE #25011)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 25011 issued to Fisher BioServices Inc. (Respondent), 14665 Rothgeb Drive, Rockville, Maryland 20850.

By letter dated April 14, 2022, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

Sections 565.002(a)(3) and (10); and 565.002(c) of the Texas Pharmacy Act, TEX OCC. CODE ANN. Title 3, Subtitle J (2015); and

Section 281.8(c)(3) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2016), in that allegedly:

COUNT

On or about March 11, 2015, the Kentucky Board of Pharmacy (Kentucky Board) entered an Agreed Order against the Kentucky pharmacy permit number MD1153 held by Fisher BioServices Inc. The Order was based on allegations that between March 1, 2014, and June 27, 2014, the pharmacy shipped thirty-eight prescriptions into Kentucky without a Kentucky-licensed pharmacist-in-charge. The Order imposed a $2,000 fine.

On or about April 1, 2016, Fisher BioServices Inc. submitted an application for license renewal as a nonresident pharmacy to the Texas State Board of Pharmacy. On the application, it was falsely indicated that the pharmacy had not been subject to any professional disciplinary action by a regulatory authority within the last 36 months, when the pharmacy was subject to the disciplinary action of the Kentucky Board previously described.

By letter dated April 14, 2022, Respondent was notified that the matters previously set out in this Order could be disposed of without the scheduling of an informal conference or a formal administrative hearing. By signing this Order, William Edward Turner, President, Fisher BioServices, Inc., on behalf of Respondent, neither admits nor denies the truth of the matters previously set out in this Order, and agrees that the Board has jurisdiction in this matter and waives the right to an informal conference, notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

(1) Respondent shall pay an administrative penalty of one thousand dollars ($1,000) due one hundred twenty (120) days after the entry of this Order.

(2) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2021), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2022).

And it is so Ordered.

THIS ORDER IS A PUBLIC RECORD.

Signed and entered by the Executive Director on behalf of the Texas State Board of Pharmacy on this 16th day of May, 2022.

Tim Tucker, Pharm.D.
Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

William Edward Turner, President, Fisher BioServices, Inc.
On behalf of Fisher BioServices Inc.

APPROVED AS TO FORM:

Megan G. Holloway, General Counsel
Texas State Board of Pharmacy

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: CONSENT ORDER

FISHER BIOSERVICES, INC.

LOUISIANA PHARMACY PERMIT NO. 5649 Case No. 21-0384

CONSENT AGREEMENT

WHEREAS, FISHER BIOSERVICES, INC. (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 5649, 14665 Rothgeb Drive, Rockville, Maryland 20850, was disciplined by Board Order issued by the Kentucky Board of Pharmacy on or about March 11, 2015 for dispensing 38 prescriptions into Kentucky from March 1 to June 27, 2014, without a licensed pharmacist-in-charge.

WHEREAS, Respondent failed to report this disciplinary action to the Board as part of its Application for Renewal of Pharmacy Permit for Year 2016.

WHEREAS, such action constitutes a violation of the following:

La. R.S. 37:1241(A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

La. R.S. 37:1241(A)(2): Has attempted to or obtained a license by misrepresentation.

LA. R.S. 37:1241(A)(6): Has had his license, permit, certification, registration or any other designations deemed necessary to engage in the practice of pharmacy revoked or suspended, or has had other disciplinary action taken, or has had his application for licensure refused, revoked, or suspended by the proper authorities of another state, territory, or country based upon conduct by the licensee similar to conduct that would constitute grounds for action as defined in this Section.

La. R.S. 37:1241(A)(7): Has failed to report to the board any adverse action taken by another government agency, law enforcement agency, or court that would constitute grounds for action as defined in this Section.

La. R.S. 37:1241(A)(22): Has failed to furnish to the board or representatives any information legally requested by the board.

To facilitate the submission of this Consent Agreement, Respondent agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

1. **Louisiana Pharmacy Permit No. 5649 belonging to FISHER BIOSERVICES, INC. is issued a LETTER OF REPRIMAND.**

2. **FISHER BIOSERVICES, INC. is ordered to pay a fine of $5,000.00 and to reimburse the Board $250.00 for administrative costs, with total payment due the Board of $5,250.00, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.**

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter and waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing, and to judicial review of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, Bill Turner, authorized to act on behalf of and acting on behalf of FISHER BIOSERVICES, INC., understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

[Remainder of page intentionally left blank; signature page to follow.]

SIGNED, AGREED TO AND ENTERED ON THIS DAY OF 2021

FISHER BIOSERVICES, INC.
Louisiana Pharmacy Permit No. 5649

BY: Authorized Representative

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on November 17, 2021, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Hearing Officer for the Board

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: PRN
Address: 15809 Crabbs Branch Way City: Rockville State: MD Zip: 20850

Name: Drug Depot
Address: 7025 Brookville Road City: Chevy Chase State: MD Zip: 20815

Name: McKesson Medical Surgical
Address: Lockbox 634404 City: Cincinnati State: OH Zip: 45274

Name: Fisher Scientific
Address: 168 3rd Avenue City: Waltham State: MA Zip: 02451

N/A

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: VA
Parent Company (if any): Fisher Clinical Services, Inc.
Corporation/Organization Name: Fisher BioServices Inc.
Mailing Address: c/o State License Servicing 1751 State Route 17A, Suite 3
City: Florida State: NY Zip: 10921
Telephone: (845) 544-2482 Email: FBS@slsny.com
Contact Person Name: Christine Cannon

N/A

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

N/A

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		X
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Fisher BioServices Inc.

Facility Name

Deanna Marie Connors

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

12 Aug 2024

Date

Board Use Only	Date Received: 9/19/24	Amount: $1,000 - ck 36824

List of officers

Fisher BioServices
A Thermo Fisher Scientific Brand

Corporate Officers

James E. Bruni- Assistant Secretary

Michael K. Michaud- Assistant Secretary

William Edward Turner- President & Secretary

Stephen Eric Benson- Treasurer

Deanna Connors- Assistant Secretary

Company Particulars

Fisher BioServices Inc.

Corporate Address: 14665 Rothgeb Drive, Rockville, MD 20850 USA
FEIN: 54-1348241
www.thermofisher.com

Drug Labeler Code: N/A
Incorporation State: VA
Incorporation Date: 12/19/1985

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
DMID	20439 Seneca Meadows Parkway Germantown, MD 20876 County: Montgomery		N/A - No CS	161157953	No	[redacted]	

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	
Dennis Albert Eyler	[redacted] Urbana , MD 21704	Project Director	Yes	*all states*

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority
Fisher Clinical Services, Inc.	7554 Schantz Road Allentown , PA 18106		100%	

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority
William Edward Turner	[redacted]	President & Secretary	No
Deanna Marie Connors		Assistant Secretary	
Stephen Eric Benson		Treasurer	
James E. Bruni		Assistant Secretary	No
Michael K. Michaud		Assistant Secretary	No

REGISTERED AGENT IN ALL APPLICABLE STATES

Name
Capitol Corporate Services, Inc.

Certificate of Good Standing

Commonwealth of Virginia

State Corporation Commission

CERTIFICATE OF GOOD STANDING

I Certify the Following from the Records of the Commission:

That FISHER BIOSERVICES INC. is duly incorporated under the law of the Commonwealth of Virginia;

That the corporation was incorporated on December 19, 1985;

That the corporation's period of duration is perpetual; and

That the corporation is in existence and in good standing in the Commonwealth of Virginia as of the date set forth below.

Nothing more is hereby certified.

Signed and Sealed at Richmond on this Date:

June 4, 2024

Bernard J. Logan, Clerk of the Commission

CERTIFICATE NUMBER : 2024060420349735

VOL

MARYLAND
Department of Health

Wes Moore, Governor • Aruna Miller, Lt. Governor • Laura Herrera M.D, MPH, Secretary

MARYLAND BOARD OF PHARMACY
4201, Patterson Avenue, Baltimore, Maryland 21215-2299
Kristopher Rusinko, Board President • Deena Speights-Napata, Executive Director

Maryland Board of Pharmacy
VERIFICATION OF GOOD STANDING

NAME OF REGISTRANT: **Fisher BioServices, Inc.**

TYPE OF REGISTRATION ISSUED: **Distributor**

MARYLAND REGISTRATION NUMBER: **D03009**

ORIGINAL ISSUANCE DATE: 03/31/2010

EXPIRATION DATE: 05/31/2025

CURRENT STATUS: Active X Non-Renewed ____ Null and Void _

GOOD STANDING: Yes X No _____

HAS LICENSEE BEEN FOUND GUILTY OF ANY VIOLATIONS FOR WHICH DISCIPLINARY ACTION WAS TAKEN? Yes ___ No **X**

SIGNATURE: _____

Deena Speights-Napata, M.A.
Executive Director
July 9, 2024

410-764-4755 • Fax 410-358-6207 • Toll Free 800-542-4964
DHMH 1-877-463-3464 • Maryland Relay Service 1-800-735-2258
Web Site: www.health.maryland.gov/pharmacy

DISTRIBUTOR REGISTRATION

STATE OF MARYLAND
DEPARTMENT OF HEALTH

152495 152495

Maryland Board of Pharmacy

4201 Patterson Avenue
Baltimore, Maryland 21215

Fisher Bioservices Inc
20439 Seneca Meadow Pkwy
GERMANTOWN MD 20876

THE MARYLAND STATE BOARD OF PHARMACY CERTIFIES THAT
Fisher Bioservices Inc
IS A REGISTERED Active
Distributor (exp.: 05/31/2025)

In accordance with the Health Occupations Article of the Annotated Code of Maryland

LIC. REG. PERM. NO.	EXPIRATION DATE
D03009	05/31/2025

SIGNATURE OF BEARER

152495 152495

State of Maryland

DEPARTMENT OF HEALTH

SIGNATURE OF BEARER

THE MARYLAND STATE BOARD OF PHARMACY
CERTIFIES THAT Fisher Bioservices Inc
IS A REGISTERED Active
Distributor (exp.: 05/31/2025)

IN ACCORDANCE WITH THE HEALTH OCCUPATIONS ARTICLE OF THE ANNOTATED CODE OF MARYLAND

LIC. REG. PERM. NO.	EXPIRATION DATE
D03009	05/31/2025

SECRETARY MDH

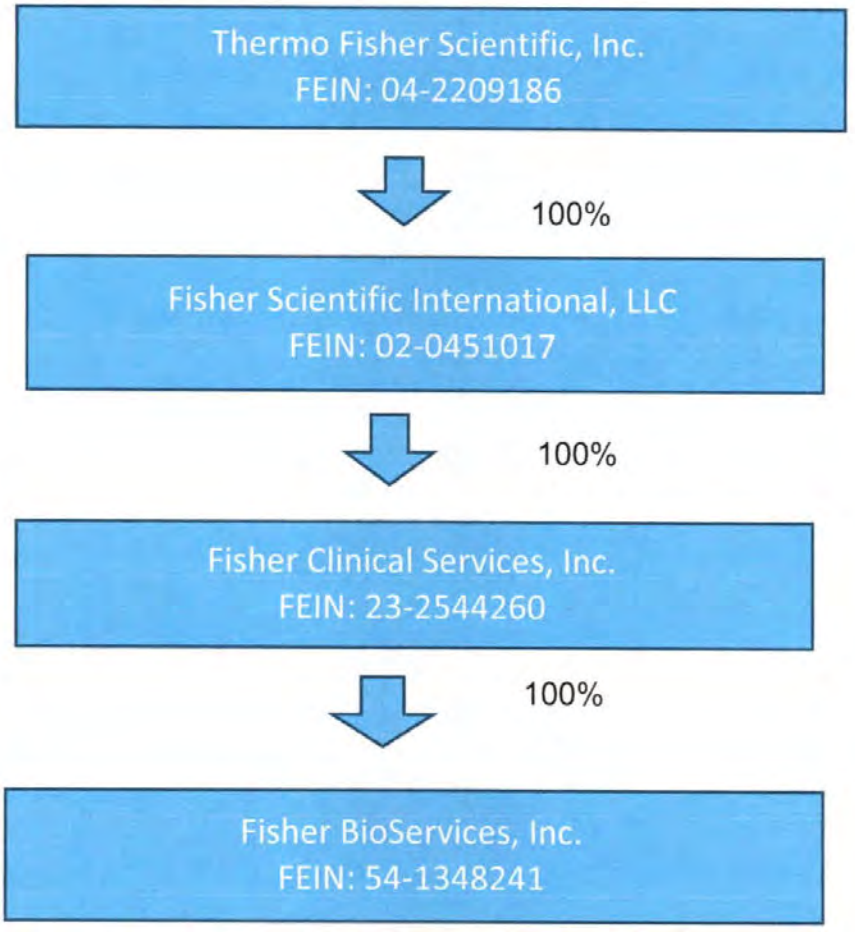
WHERE REQUIRED BY LAW THIS MUST BE CONSPICUOUSLY DISPLAYED IN OFFICE TO WHICH IT APPLIES

HS License

List of ownership

Fisher BioServices
A Thermo Fisher Scientific Brand

Ownership Organizational Chart



Certificate of Liability Insurance

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY): 07/13/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Aon Risk Services Northeast, Inc.
Boston MA Office
53 State Street
Suite 2201
Boston MA 02109 USA

CONTACT NAME:
PHONE (A/C. No. Ext): (866) 283-7122 FAX (A/C. No.): (800) 363-0105
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Travelers Property Cas Co of America	25674
INSURER B:	ACE American Insurance Company	22667
INSURER C:	ProAssurance Specialty Insurance Company	17400
INSURER D:	ACE Property & Casualty Insurance Co.	20699
INSURER E:		
INSURER F:		

INSURED
Fisher BioServices Inc.
Thermo Fisher Scientific Inc.
14665 Rothgeb Dr.
Rockville MD 20850 USA

Holder Identifier :

COVERAGES **CERTIFICATE NUMBER:** 570100819037 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE / X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY / PRO-JECT / LOC OTHER:			G71815067004 SIR applies per policy terms & conditions	07/01/2023	07/01/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$2,000,000 $1,000,000 $10,000 $2,000,000 $4,000,000 Excluded
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY / SCHEDULED AUTOS HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY			TC2JCAP-7439L260-TIL-23	07/01/2023	07/01/2024	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$2,000,000
D	X UMBRELLA LIAB / X OCCUR EXCESS LIAB / CLAIMS-MADE DED / RETENTION			XEUG71815080004	07/01/2023	07/01/2024	EACH OCCURRENCE AGGREGATE	$10,000,000 $10,000,000
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		UB5P0275212351K	07/01/2023	07/01/2024	X PER STATUTE / OTH-ER E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	$1,000,000 $1,000,000 $1,000,000
B	Products Liability			G72530494003 Claims Made SIR applies per policy terms & conditions	07/01/2023	07/01/2024	Aggregate Limit Each Claim	$5,000,000 $5,000,000

Certificate No : 570100819037

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
RE: Job/Location/Project: Rothgeb II.

CERTIFICATE HOLDER

Fisher BioServices, Inc.
14685 Rothgeb Drive
Rockville MD 20850 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast, Inc.

©1988-2015 ACORD CORPORATION. All rights reserved.

ACORD 25 (2016/03)

The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: 570000057847

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Fisher BioServices Inc.
POLICY NUMBER: See Certificate Number: 570100819037	
CARRIER: See Certificate Number: 570100819037 / NAIC CODE:	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER	
INSURER	
INSURER	
INSURER	

ADDITIONAL POLICIES If a policy below does not include limit information, refer to the corresponding policy on the ACORD certificate form for policy limits.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	EXCESS LIABILITY							
C				EX23MA380004 Excess Prods-Claims Made	07/01/2023	07/01/2024	Aggregate Limit	$10,000,000
							Each Claim	$10,000,000

ACORD 101 (2008/01)

© 2008 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

Nevada Bond

VERIFICATION OF BOND IN FORCE
Form SB-3

Type of Bond: License/Permit Bond

Name of Principal: FISHER BIOSERVICES, INC.

Obligee: STATE OF NEVADA AND NEVADA STATE BOARD OF PHARMACY

Carrier: WESTCHESTER FIRE INSURANCE COMPANY

Bond Number: K15334502

Effective Date: October 11, 2023

Limit: $ 100,000.00

Premium: $ 650.00

This Bond is continuous with no definite expiration date. Sufficient Premium has been paid to satisfy the requirements of the Carrier for this bond to October 11, 2024.

WESTCHESTER FIRE INSURANCE COMPANY

By: _____
Frances Rodriguez Attorney in Fact

Date: 06/17/2024

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company
Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **FEDERAL INSURANCE COMPANY**, an Indiana corporation, **VIGILANT INSURANCE COMPANY**, a New York corporation, **PACIFIC INDEMNITY COMPANY**, a Wisconsin corporation, **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint Valorie Spates and Beverly Woolford of Garden City, New York; Debra A. Deming, Sandra Diaz, Vilma Gonzalez, Peter Healy, Pablo Garcia Horcajo, Francesca Kazmierczak, Aklima Noorhassan, Anne Potter and Frances Rodriguez of New York, New York ----------

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said **FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** have each executed and attested these presents and affixed their corporate seals on this **23rd** day of **October, 2023.**

Dawn M. Chloros

Dawn M Chloros, Assistant Secretary

Stephen M Haney, Vice President

STATE OF NEW JERSEY
County of Hunterdon ss

On this **23rd** day of **October 2023** before me, a Notary Public of New Jersey, personally came Dawn M. Chloros and Stephen M. Haney, to me known to be Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Dawn M. Chloros and Stephen M. Haney, being by me duly sworn, severally and each for herself and himself did depose and say that they are Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and know the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that their signatures as such officers were duly affixed and subscribed by like authority.

Notarial Seal

Albert Centursi
NOTARY PUBLIC OF NEW JERSEY
No 50202369
Commission Expires August 22, 2027

Albert Centursi
Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016; WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006; and ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Dawn M. Chloros, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect,
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this **June 17, 2024**

Dawn M. Chloros

Dawn M Chloros, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903-3493 Fax (908) 903-3656 e-mail surety@chubb.com

Combined: FED-VIG-PI-WFIC-AAIC (rev 11-19)

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company
Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **FEDERAL INSURANCE COMPANY**, an Indiana corporation, **VIGILANT INSURANCE COMPANY**, a New York corporation, **PACIFIC INDEMNITY COMPANY**, a Wisconsin corporation, **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint Valorie Spates and Beverly Woolford of Garden City, New York; Debra A. Deming, Sandra Diaz, Vilma Gonzalez, Peter Healy, Pablo Garcia Horcajo, Francesca Kazmierczak, Aklima Noorhassan, Anne Potter and Frances Rodriguez of New York, New York ----------

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said **FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** have each executed and attested these presents and affixed their corporate seals on this **23rd** day of **October, 2023**.

Dawn M. Chloros

Dawn M. Chloros, Assistant Secretary

Stephen M. Haney, Vice President

STATE OF NEW JERSEY
County of Hunterdon ss

On this **23rd** day of **October 2023** before me, a Notary Public of New Jersey, personally came Dawn M. Chloros and Stephen M. Haney, to me known to be Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Dawn M. Chloros and Stephen M. Haney, being by me duly sworn, severally and each for herself and himself did depose and say that they are Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and know the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that their signatures as such officers were duly affixed and subscribed by like authority.

Notarial Seal

Albert Contursi
NOTARY PUBLIC OF NEW JERSEY
No 50202369
Commission Expires August 22,2027

Albert Contursi
Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016; WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006; and ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Dawn M. Chloros, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect.
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this June 17, 2024

Dawn M. Chloros

Dawn M. Chloros, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT
Telephone (908) 903-3493 Fax (908) 903-3656 e-mail: surety@chubb.com

Combined FED-VIG-PI-WFIC-AAIC (rev 11-19)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Fisher BioServices Inc. MDEG License # (if applicable) N/A

Physical Address 20439 Seneca Meadows Parkway

City Germantown State MD Zip 20876

Mailing Address (if different from physical address) 3500 Flatwoods Dr c/o State License Servicing, 1751 State Route 17A, Suite 3

City Urbana State MD Zip 21704

Telephone (845) 544-2482 Website www.thermofisher.com

Licensing Company Email FBS@slsny.com

Section 2: Personal Information

First Dennis Middle Albert Last Eyler

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Urbana State MD Zip 21704

Telephone [redacted] Email dennis.eyler@thermofisher.com

Are you a citizen of the United States? × Yes No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Maryland University College		01/2018 - 06/2019	
Address	City	State	Zip
1616 McCormick Dr	Largo	MD	20774
Diploma/Degree obtained, if any			
Master of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Shenandoah University School of Pharmacy		07/1996 - 05/2000	
Address	City	State	Zip
1775 N Sector Ct	Winchester	VA	22601
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Shepherd University		08/1993 - 08/1996	
Address	City	State	Zip
301 N King St	Shepherdstown	WV	25443
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Hagerstown Community College		08/1991 - 06/1993	
Address	City	State	Zip
11400 Robinwood Dr	Hagerstown	MD	21742
Diploma/Degree obtained, if any			
Associates Degree in Administration of Justice			

School Name		From - To (MM/YY – MM/YY	
Jefferson High School		09/1985 - 06/1989	
Address	City	State	Zip
4141 Flowing Springs Rd	Shenandoah Junction	WV	
Diploma/Degree obtained, if any			
High School Diploma			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/2020 - Present	[redacted]	Urbana	MD	21704
05/2013 - 03/2020		Mount Airy	MD	21771
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Fisher BioServices Inc.			01/2018 - Present	
Business Address		**City**	**State**	**Zip**
20439 Seneca Meadows Parkway		Germantown	MD	20876
Phone	**Title**		**Number of Employed Hours**	
(240) 477-1350	Project Director		~ 13,500 hours	

Description of Duties

Responsible for daily operations, staff, and facility management; Participated in FDA audits and facilitated FDA mock audits; Experience in cGMP environment; ensure that all employees adhere to Corporate and Bio Services policies and procedures. Meets all customer needs pertaining to made-to order products including over encapsulation, manufacturing PBS and other client request to meet the customer's needs in a demanding environment. Responsible for primary interface with DMID personnel, clinical site principal investigators, prime vendors & manufacturers

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

N/A

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Dennis Albert Eyler, **certify that as the MDEG Administrator for**

Fisher BioServices Inc.,

that I (initial that you have read and meet the following requirements):

1. DE Have a high school diploma or its equivalent;
2. DE Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. DE Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. DE Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dennis Albert Eyler
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

28 Aug 2024
Date

Board Use Only	Date Received: 9/10/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Fisher BioServices Inc.

Pharmacy/Wholesaler License # (if applicable) Pending

Physical Address 20439 Seneca Meadows Parkway

City Germantown State MD Zip 20876

Mailing Address (if different from physical address) c/o State License Servicing 1751 State Route 17A, Suite 3

City Florida State NY Zip 10921

Telephone (845) 544-2482 Website www.thermofisher.com

Licensing Company Email FBS@slsny.com

Section 2: Personal Information

First Dennis Middle Albert Last Eyler

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted]

City Urbana State MD Zip 21704

Telephone [redacted] Email dennis.eyler@thermofisher.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Maryland University College		01/2018 - 06/2019	
Address	City	State	Zip
1616 McCormick Dr	Largo	MD	20774
Diploma/Degree obtained, if any			
Master of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Shenandoah University School of Pharmacy		07/1996 - 05/2000	
Address	City	State	Zip
1775 N Sector Ct	Winchester	VA	22601
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Shepherd University		08/1993 - 08/1996	
Address	City	State	Zip
301 N King St	Shepherdstown	WV	25443
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Hagerstown Community College		08/1991 - 06/1993	
Address	City	State	Zip
11400 Robinwood Dr	Hagerstown	MD	21742
Diploma/Degree obtained, if any			
Associates Degree in Administration of Justice			

School Name		From - To (MM/YY – MM/YY	
Jefferson High School		09/1985 - 06/1989	
Address	City	State	Zip
4141 Flowing Springs Rd	Shenandoah Junction	WV	25442
Diploma/Degree obtained, if any			
High School Diploma			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/2020 - Present	[redacted]	Urbana	MD	21704
05/2013 - 03/2020		Mount Airy	MD	21771
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Fisher BioServices Inc.			01/2018 - Present	
Business Address		City	State	Zip
20439 Seneca Meadows Parkway		Germantown	MD	20876
Phone	Title		Number of Employed Hours	
(240) 477-1350	Project Director		~13,500 hours	

Description of Duties

Responsible for daily operations, staff, and facility management; Participated in FDA audits and facilitated FDA mock audits; Experience in cGMP environment; ensure that all employees adhere to Corporate and Bio Services policies and procedures. Meets all customer needs pertaining to made-to order products including over encapsulation, manufacturing PBS and other client request to meet the customer's needs in a demanding environment. Responsible for primary interface with DMID personnel, clinical site principal investigators, prime vendors & manufacturers

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
08/30/1990		CA	Los Angeles	Los Angeles

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
LAP90S04841-02	Police Department Los Angeles, CA

Reason/Charge
Throwing a substance at a vehicle

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Dennis Albert Eyler	

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

28 Aug 2024
Date

July 24, 2024

Dr. Dennis A. Eyler
[redacted]
Urbana, MD 21704

Subject: Letter of Explanation for Misdemeanor Charge

Dear Sir or Madam,

I hope this letter finds you well. I am writing to provide an explanation for my Misdemeanor charge that was filed in August 1990. Please find the detailed account of the circumstances surrounding this incident.

Thirty-Four (34) years ago, in 1990, while I was driving a vehicle, my passenger threw an object from the vehicle and struck another car. A police officer observed this incident and charged us with "Throwing a Substance at Vehicle Prohibited". As the driver of the vehicle, I was given probation and completed community service. The object thrown was considered a weapon since it was "thrown". However, the charge was dropped.

On July 15, 2024, I had an attorney file an expungement to remove the 34-year-old misdemeanor from my record. I have attached the expungement for your references.

Warm Regards,

Dr. Dennis A. Eyler, Pharm.D., MBA

Case Information for LAP90S04841-02

Print | New Search

Case Number
LAP90S04841-02

Defendant ID
02

Filing Date
8/31/1990

Arrest Date
8/30/1990

Filing Courthouse
Governor George Deukmejian Courthouse

Case Type
Misdemeanor

Case Title
The People of the State of California vs. EYLER, DENNIS ALBERT

Charges

Proceedings

Bail

Sentencing

2 record(s). Type a keyword to filter.

Count	Charge Statute	Plea	Last Disposition	Notes
001	VC23110(a)-M Throwing Substance at Vehicle Prohibited	9/27/1990: Pleads Nolo Contendere	9/27/1990 - Conviction After Plea	**Offense Date**: 8/30/1990

CR-180

ATTORNEY OR PARTY WITHOUT ATTORNEY: STATE BAR NO.: 238622 NAME: Bob M. Farahan, Esq. FIRM NAME: Law Offices of Bob M. Farahan STREET ADDRESS: 6320 Canoga Avenue, Suite 1500 CITY: Woodland Hills STATE: CA ZIP CODE: 91367 TELEPHONE NO.: (818) 687-1084 FAX NO.: (818) 615-2099 E-MAIL ADDRESS: bfarahan81@gmail.com ATTORNEY FOR (name): Dennis Albert Eyler	CONFORMED COPY ORIGINAL FILED Superior Court of California County of Los Angeles JUL 15 2024 David W. Slayton, Executive Officer/Clerk of Court S. Ortiz
PEOPLE OF THE STATE OF CALIFORNIA v. DEFENDANT: Dennis Albert Eyler DATE OF BIRTH: 08/24/1971	CASE NUMBER: 90S04841-02
PETITION FOR DISMISSAL **(Pen. Code, §§ 17(b), 17(d)(2), 1203.4, 1203.4a, 1203.41, 1203.42, 1203.43, 1203.49)**	FOR COURT USE ONLY DATE: TIME: DEPARTMENT:

1. On *(date)*: 09/27/1990 , the petitioner *(the defendant in the above-entitled criminal action)* was convicted of a violation of the following offenses or was granted deferred entry of judgment for the following offenses:

Code	Section	Type of offense *(felony, misdemeanor, or infraction)*:	Eligible for reduction to misdemeanor under Penal Code, § 17(b) *(yes or no)*	Eligible for reduction to infraction under Penal Code, § 17(d)(2) *(yes or no)*
Vehicle	23110(a)	Misdemeanor	-	-

If additional space is needed for listing offenses, use *Attachment to Judicial Council Form* (form MC-025).

2. ☒ **Felony or misdemeanor with probation granted *(Pen. Code, § 1203.4)***

Probation was granted on the terms and conditions stated in the docket of the above-entitled court; the petitioner is not serving a sentence for any offense, on probation for any offense, or under charge of commission of any crime, and the petitioner *(check all that apply)*

a. ☐ has fulfilled the conditions of probation for the entire period thereof.

b. ☐ has been discharged from probation prior to the termination of the period thereof.

c. ☒ should be granted relief in the interests of justice. *(Please note: You may explain why granting a dismissal would be in the interests of justice. You can provide that information by writing in the space below, or by attaching a letter or other relevant documents. If you need more space for your writing, you can use the Attached Declaration (form MC-031) and attach it to this petition.)*

Petitioner has had no new cases nor any convictions since this conviction back in 1990. Petitioner has since relocated to Maryland and obtaind a college degree and also obtianed his Pharmacist License, which he has been gainfully employed as a licensed Pharmacist in Maryland.

On July 12, 2024, Counsel for Petitioner appeared in court before the Honorable Judge, Jennifer H. Cops. Judge Cops recalled and quashed Petitioner's bench warrant and terminated Petitioner's Probation, without any finding of a violation of Probation. Petitioner submits the attached documentation for mitigaation purposes and requests that the Court grant his Petition for Dismissal pursuant to Penal Code Section 1203.4 in the interests of justice to clear his criminal history.

RECEIVED BY
CITY ATTORNEY'S OFFICE

Form Approved for Optional Use
Judicial Council of California
CR-180 [Rev. January 1, 2016]

Penal Code, §§ 17(b), 17(d)(2), 1203.4, 1203.4a, 1203.41, 1203.42, 1203.43, and 1203.49
www.courts.ca.gov

JUL 15 2024

PACIFIC BRANCH -LONG BEACH

RECEIVED BY
CITY ATTORNEY'S OFFICE

JUL 15 2024

PACIFIC BRANCH -LONG BEACH

PEOPLE OF THE STATE OF CALIFORNIA v. DEFENDANT: Dennis Albert Eyler	CASE NUMBER: 90S04841-02

3. ☐ **Misdemeanor or infraction with sentence other than probation** ***(Pen. Code, § 1203.4a)***
Probation was not granted; more than one year has elapsed since the date of pronouncement of judgment. Petitioner has complied with the sentence of the court and is not serving a sentence for any offense or under charge of commission of any crime; and the petitioner ***(check one)*****:**

a. ☐ **has lived an honest and upright life since pronouncement of judgment and conformed to and obeyed the laws of the land;** ***or***

b. ☐ **should be granted relief in the interests of justice.** ***(Please note: You may explain why granting a dismissal would be in the interests of justice. You can provide that information by writing in the space below or by attaching a letter or other relevant documents. If you need more space for your writing, you can use the Attached Declaration (form MC-031) and attach it to this petition.)***

4. ☐ **Misdemeanor conviction under Penal Code section 647(b)** ***(Pen. Code, § 1203.49)***
Petitioner has completed a term of probation for a conviction under Penal Code section 647(b) and should be granted relief because the petitioner can establish by clear and convincing evidence that the conviction was the result of his or her status as a victim of human trafficking.

(Please note: You may provide evidence that the conviction was the result of your status as a victim of human trafficking. You can provide that information by writing in the space below or by attaching a letter or other relevant documents. If you need more space for your writing, you can use the Attached Declaration (form MC-031) and attach it to this petition.)

5. ☐ **Felony county jail sentence under Penal Code section 1170(h)(5)** ***(Pen. Code, § 1203.41)***
Petitioner is not under supervision under Penal Code section 1170(h)(5)(B); is not serving a sentence for, on probation for, or charged with the commission of any offense; and should be granted relief in the interests of justice, and ***(check one)***

a. ☐ **more than one year has elapsed since petitioner completed the felony county jail sentence with a period of mandatory supervision imposed under Penal Code section 1170(h)(5)(B);** ***or***

b. ☐ **more than two years have elapsed since petitioner completed the felony county jail sentence without a period of mandatory supervision imposed under Penal Code section 1170(h)(5)(A).**

(Please note: You may explain why granting a dismissal would be in the interests of justice. You can provide that information by writing in the space below or by attaching a letter or other relevant documents. If you need more space for your writing, you can use the Attached Declaration (form MC-031) and attach it to this petition.)

PEOPLE OF THE STATE OF CALIFORNIA v. DEFENDANT: Dennis Albert Eyler	CASE NUMBER: 90S04841-02

6. ☐ **Felony prison sentence that would have been eligible for a felony county jail sentence after 2011 under Penal Code section 1170(h)(5)** ***(Pen. Code, § 1203.42)***

Petitioner is not under supervision and is not serving a sentence for, on probation for, or charged with the commission of any offense; more than two years have elapsed since petitioner completed the felony prison sentence; and petitioner should be granted relief in the interests of justice.

(Please note: You may explain why granting a dismissal would be in the interests of justice. You can provide that information by writing in the space below or by attaching a letter or other relevant documents. If you need more space for your writing, you can use the Attached Declaration (form MC-031) and attach it to this petition.)

7. ☐ **Deferred entry of judgment** ***(Pen. Code, § 1203.43)***

Petitioner performed satisfactorily during the period in which deferred entry of judgment was granted. The criminal charge(s) were dismissed under former Penal Code section 1000.3 on *(date):* 07/13/2024 . Furthermore *(check one)*,

a. ☐ court records are available showing the case resolution; *or*

b. ☐ petitioner declares under penalty of perjury that the charges were dismissed after he or she completed the requirements for deferred entry of judgment. Petitioner (*check one*)

(1) ☐ has

(2) ☐ has not

attached a copy of his or her state summary criminal history information.

8. Petitioner requests that the eligible felony offenses listed above be reduced to misdemeanors under Penal Code section 17(b) and eligible misdemeanor offenses be reduced to infractions under Penal Code section 17(d)(2).

9. Petitioner requests that he or she be permitted to withdraw the plea of guilty, or that the verdict or finding of guilt be set aside and a plea of not guilty be entered and the court dismiss this action under the Penal Code section(s) noted above.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Date: 07/15/2024

/s/ Bob M. Farahan, Esq. for Petitioner
(SIGNATURE OF PETITIONER OR ATTORNEY)

6320 Canoga Avenue, Suite 1500 (ADDRESS OF PETITIONER) | Woodland Hills (CITY) | CA (STATE) | 91367 (ZIP CODE)

For your protection and privacy, please press the Clear This Form button after you have printed the form.

Print this form | Save this form | Clear this form

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Dennis Albert Eyler, **certify that as the designated representative for**

Fisher BioServices Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Dennis Albert Eyler

Print Name (First, Last)

_____

Original Signature (electronic, copies or stamps not accepted)

28 Aug 2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dennis Albert Eyler

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04 Sept 2024

Date

Please have this section completed in the presence of a Notary Public.

State of Maryland, ss. County of Montgomery

I, Dennis Eyler, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Dennis Albert Eyler

04 Sept 2024

Date

Subscribed and Sworn to before me this 4th day of September 2024

Notary Public Signature

WYATT TRUMBOUR
NOTARY PUBLIC
MONTGOMERY COUNTY
MARYLAND
MY COMMISSION EXPIRES AUG. 24, 2026

(Seal)

Employee List

Employee List	
20439 Seneca Meadows Parkway Germantown, MD 20876	
Name	**Title**
Ma, Melissa	Lead Repository Technician
Howard, Michelle	Operations Technician
Vidal Rico, Monica	Operations Technician
Villareal, Marie Juliet	Lab Technician III
Katelin Mryglot	Project Manager II
Alvin Manbodh	Operations Manager
Fathima Deen	Operation-Team Leader
Adiba Hossen	Admin- Services coordinator
Weiner, Emily	Asst. Project Director
Dennis Eyler	Project Director

4JJ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: ONE BEAT CPR LEARNING CENTER, LLC

Physical Address: 3151 EXECUTIVE WAY

City: MIRAMAR State: FL Zip: 33025

Mailing Address (if different from physical address): 5000 TUTTLE CROSSING BLVD

City: DUBLIN State: OH Zip: 43016

Telephone: 614-760-5000 Website: WWW.ONEBEATMEDICAL.COM

Name of Designated Representative (DR): LAWRENCE FRANCHETTI

Licensing Company Email: REGULATORY@SARNOVA.COM DR Email: REGULATORY@SARNOVA.COM

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

DARRELL HUGHES, SECRETARY

5/15/24

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: ONE BEAT CPR LEARNING CENTER, LLC DOES NOT SELL OR DISTRIBUTE PHARMCEUTICALS

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: MI

Parent Company (if any): CARDIO PARTNERS, INC.

Corporation/Organization Name: ONE BEAT CPR LEARNING CENTER, LLC

Mailing Address: 5000 TUTTLE CROSSING BLVD

City: DUBLIN State: OH Zip: 43016

Telephone: 614-760-5000 Email: REGULATORY@SARNOVA.COM

Contact Person Name: JILL VENNEKOTTER

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

ONE BEATCPR Learning Center, LLC
Facility Name

DARRELL HUGHES, SECRETARY
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

5/15/24
Date

Board Use Only	Date Received: _____	Amount: _____

Sarnova HC, LLC
(100% Owner of Cardio Partners, Inc.)

PO Box 8023, Dublin, Ohio 43016

State of Organization: DE Date of Organization: 05/01/2008 EIN: 26-2549813
File No. 4540843

Officers	
NAME	**TITLE**
Brian LaDuke	President
Shawn Saylor	CFO
Darrell Hughes	Secretary

Cardio Partners, Inc.
(Owned 100% by Sarnova HC, LLC)

State of Incorporation: OH Date of Incorporation: 12/03/2012 EIN: 80-0874694
Charter No. 2155064

Officers	
NAME	**TITLE**
Brian LaDuke	CEO
Lawrence Franchetti	President
Shawn Saylor	CFO
Darrell Hughes	Secretary

State of Florida
Department of State

I certify from the records of this office that ONE BEAT CPR LEARNING CENTER LLC is a Michigan limited liability company authorized to transact business in the State of Florida, qualified on January 16, 2019.

The document number of this limited liability company is M19000001388.

I further certify that said limited liability company has paid all fees due this office through December 31, 2024, that its most recent annual report was filed on March 15, 2024, and that its status is active.

I further certify that said limited liability company has not filed a Certificate of Withdrawal.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Eleventh day of June, 2024

Secretary of State

Tracking Number: 6331088438CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

ONE BEAT
MEDICAL & TRAINING

Statement of Explanation for Wholesale Distributor License Documentation Requests

Applicant: One Beat CPR Learning Center, LLC
3151 Executive Way
Miramar, FL 33025

Explanation for not having Home State License:

One Beat CPR Learning Center, LLC is a national leader in providing emergency preparedness solutions for public access. One Beat CPR Learning Center, LLC offers a proven and complete suite of products and services including employee CPR training, AED deployments, and AED program management to help organizations of all sizes be heart safe.

One Beat CPR Learning Center, LLC is not required to be licensed to operate as wholesale device distributor in Florida. Florida does not regulate the distribution of legend devices. One Beat CPR Learning Center, LLC does not sell prescription drugs and therefore is not required by Florida to obtain a wholesale drug distributor license. In fact, Florida does not define Wholesale Distribution to include device distribution at all. (See **499.003 Wholesale Distribution**)

Florida Code Citation:

Chapter 499.003 "Wholesale distribution"

Section 48 "Wholesale distribution" means the distribution of a prescription drug to a person other than a consumer or patient, or the receipt of a prescription drug by a person other than the consumer or patient.

Explanation for not having a recent Inspection Report:

Wholesale device distributors are not regulated by the state of Florida unless the distribution is to residential customers. One Beat CPR Learning Center, LLC does not sell to residential customers as explained in the statements above. Therefore, One Beat CPR Learning Center, LLC is not subject to the Florida Department of Business and Professional Regulations inspections and does not have a recent home state inspection report.

Sincerely,

Jill Vennekotter

Regulatory Specialist

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 01/31/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER STERLING INSURANCE GROUP 13900 Lakeside Circle Sterling Heights MI 48313-1318	CONTACT NAME: Becky Zannetti PHONE (A/C, No, Ext): (586) 323-5700 FAX (A/C, No): (586) 323-5703 E-MAIL ADDRESS: rzannetti@sterlingagency.com
INSURED One Beat CPR Learning Center LLC American AED LLC 3151 Executive Way Miramar FL 33025	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A: Federal Insurance Company — 20281 INSURER B: Great Northern Insurance Company — 20303 INSURER C: Chubb Custom Insurance Co — 38989 INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** CL2413035031 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [ ] POLICY [ ] PRO-JECT [ ] LOC OTHER:	Y		99497199	02/01/2024	02/01/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG Employee Benefits	$ 1,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ Excluded $ 1,000,000
B	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [X] HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY			73607621	02/01/2024	02/01/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) 	$ 1,000,000 $ $ $ $
A	[X] UMBRELLA LIAB [ ] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED [ ] RETENTION $			78181782	02/01/2024	02/01/2025	EACH OCCURRENCE AGGREGATE 	$ 5,000,000 $ 5,000,000 $
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y / N [ ] (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		71756400	02/01/2024	02/01/2025	[X] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
C	Products Liability			99497198	02/01/2024	02/01/2025	Claims Made	$5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

1250 Broadway Associates LLC c/o Global Holdings Management Group US Inc, Global Holdings Management Group US Inc, HSBC Bank USA National Association ISAOA ATIMA and Varonis Systems Inc are named as additional insured with respect to general liability as required by written contract.

CERTIFICATE HOLDER

1250 Broadway Associates LLC c/o Global Holdings Management Group US Inc
1250 Broadway, 38th FL
New York NY 10001

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

© 1988-2015 ACORD CORPORATION. All rights reserved.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 107894358

Application/License No. _____

ONE BEAT CPR LEARNING CENTER, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 3151 Executive Way Miramar, FL 33025 (Address of Applicant/Principal), as PRINCIPAL, and TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA (Surety Company), a corporation organized under the laws of the state of CT (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Tower Square Hartford, CT 06183 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on May 13, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 13th day of May, 2024.

APPLICANT/PRINCIPAL
ONE BEAT CPR LEARNING CENTER, LLC

COMPANY

Authorized Representative

SURETY
TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA

Surety Company's Representative

Richard Casas, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Ann Formhals

Witness Bartlomiej Siepierski

Countersigned by:

Nevada Resident Agent

Christopher P. Troha,
Non-Resident Agent

Posted February 20, 2020

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **Richard Casas** of **CHICAGO**, **Illinois**, their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **21st** day of **April**, **2021**.

State of Connecticut

City of Hartford ss.

By: _____
Robert L. Raney, Senior Vice President

On this the **21st** day of **April**, **2021**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June**, **2026**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this **13th** day of **May**, **2024**

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: ONE BEAT CPR LEARNING CENTER, LLC MDEG License # (if applicable): _____

Physical Address: 3151 EXECUTIVE WAY

City: MIRAMAR State: FL Zip: 33025

Mailing Address (if different from physical address): 5000 TUTTLE CROSSING BLVD

City: DUBLIN State: OH Zip: 43016

Telephone: 614-760-5000 Website: WWW.ONEBEATMEDICAL.COM

Licensing Company Email: REGULATORY@SARNOVA.COM

Section 2: Personal Information

First: LAWRENCE Middle: _____ Last: FRANCHETTI

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: MIAMI State: FL Zip: 33138

Telephone: 614-760-5000 Email: REGULATORY@SARNOVA.COM

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF DELAWARE		1999 - 2001	
Address	City	State	Zip
210 South College Ave.	Newark	DE	19716
Diploma/Degree obtained, if any			
Bachelors.			

School Name		From - To (MM/YY – MM/YY)	
SALESIANUM SCHOOL		1993 - 1997	
Address	City	State	Zip
1801 N BROOM ST	WILMINGTON	DE	19802
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Tulane University		1997 - 1999	
Address	City	State	Zip
6823 St. Charles Ave.	New Orleans	LA	70118
Diploma/Degree obtained, if any			
—			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2019-PRESENT	[redacted]	MIAMI	FL	33138
01/2019-05/2019		MIAMI	FL	33131
04/2011-01/2019		NEW YORK	NY	10001
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
ONE BEAT CPR LEARNING CENTER, LLC			01/2019-PRESENT	
Business Address		**City**	**State**	**Zip**
3151 EXECUTIVE WAY		MIRAMAR	FL	33025
Phone	**Title**		**Number of Employed Hours**	
614-760-5000	CEO		10,000	
Description of Duties				
SEE ATTACHED				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5-15-2024
Date

I, LAWRENCE FRANCHETTI, **certify that as the MDEG Administrator for**

ONE BEAT CPR LEARNING CENTER, LLC,

that I (initial that you have read and meet the following requirements):

1. LF Have a high school diploma or its equivalent;
2. LF Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. LF Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. LF Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

LAWRENCE FRANCHETTI

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5-15-2024

Date

Board Use Only	Date Received:

Contact

[redacted]

www.linkedin.com/in/lawrence-franchetti-4619a55 (LinkedIn)

Top Skills

Capital Equipment
Market Development
Medical Devices

Languages

Spanish

Honors-Awards

FY'13 Rep of the Year
FY'13 President's Club Winner
FY'11, FY'12, FY'13, FY'15 - Highest Producing Team Rep
FY'15 Presidents Club Winner
FY'15 Rep of the Year

Lawrence Franchetti

Helping Save Lives, One Beat At A Time
Miami, Florida, United States

Summary

No one should die suddenly from an acute, treatable, medical event. I've dedicated my career to making sure as many people and places have life-saving medical equipment within reach, and the skills to use it at a moment's notice.

As the CEO of One Beat Medical, American AED, Altra Medical, and LifeSure, I'm fighting to unseat sudden cardiac arrest as a leading cause of death in the United States. Through the distribution of medical equipment like AEDs, medical training for everyone from emergency response teams and the general public, and connecting individuals in need with AEDs, I work to ensure there's a life-saving tool and someone to use it — everywhere.

I started my career in medical equipment and training over twenty years ago. Over the course of a dozen years at Physio-Control, beginning with an office management and reception position, I held positions in sales, distribution, and national enterprise management. Since 2016, I have also been CEO/President of the Cignet Medical Division.

I have a B.A. in Political Science and Government from the University of Delaware and also studied history at Tulane.

My life's work is to facilitate a seamless connection between the latest tools in healthcare innovation when it comes to resuscitation and first aid — and anyone (that's everyone) who needs them. That includes schools, airports, sports teams, businesses, pets (like my dogs Bree and Beau) and you. It takes just one beat to save a life. Let's do this.

Experience

One Beat Medical & Training

Chief Executive Officer
January 2019 - Present (5 years 5 months)
Miami/Fort Lauderdale Area

Cignet, LLC
President - Healthcare
April 2016 - Present (8 years 2 months)

Executive with exceptional experience in strategic and tactical marketing, sales, business development, P&L management, multi-channel product distribution, strategic relationship development. Operational improvement driving significant business results in both startup and established companies. Managed multi-million-dollar business and budgets that exceeded market share and revenue growth.

Physio-Control, Inc.
12 years 6 months

Enterprise Sales Manager
April 2015 - April 2016 (1 year 1 month)

Lead national team of enterprise sales reps to drive revenue across Fortune 1000 accounts and strategic partnerships with an ultimate goal of creating a society in which no person dies suddenly as a result of an acute, treatable medical event.

Regional Distribution Manager
April 2009 - April 2015 (6 years 1 month)
Greater New York City Area

Regional Account Manager for Physio-Control, the leading manufacturer in external defibrillation products. Previously, I have held roles in direct enterprise sales and customer service focusing on the successful deployment of public access automated external defibrillators. My current responsibilities which include distribution and indirect sales channel management add to my previous experiences of selling to and supporting a wide-scale of various enterprise customers. I am fortunate enough to work for a company that has as much passion for saving lives as I do and my efforts have contributed to saving lives of untold numbers of people.

Enterprise Account Manager
March 2007 - April 2009 (2 years 2 months)

Solutions Account Specialist
November 2005 - March 2007 (1 year 5 months)
Greater New York City Area



Office Manager - Reception
November 2003 - November 2005 (2 years 1 month)
Washington D.C. Metro Area

New Leaders for New Schools
Special Assistant
March 2003 - October 2003 (8 months)

Jack Markell for Delaware Treasurer
Campaign Manager
February 2002 - January 2003 (1 year)
Wilmington, DE

Education

University of Delaware
Bachelor of Arts (B.A.), Political Science and Government · (1999 - 2001)

Tulane University
Political Science and Government, History · (1997 - 1999)

ONE BEAT
MEDICAL & TRAINING

CEO JOB DESCRIPTION

- Act as the figurative head of the organization when communicating with stockholders, government entities and the general public.
- Lead the development of the organization's long- and short-term strategies.
- Manage overall operations and make major decisions affecting the organization.
- Manage the organization's resources.
- Negotiate or approve agreements and contracts for the organization.
- Manage company organizational structure.
- Communicate with the board of directors.
- Assess and minimize risks to the company.
- Set strategic goals.
- Provide company-wide leadership.
- Serve as the company's primary spokesperson.
- Identify and address companywide problems.
- Develop and uphold the company's culture and mission/vision.
- Implement strategic plans by working with senior stakeholders.
- Evaluate and track the success of the company in reaching its goals.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler ONE BEAT CPR LEARNING CENTER, LLC

Pharmacy/Wholesaler License # (if applicable) PENDING

Physical Address 3151 EXECUTIVE WAY

City MIRAMAR State FL Zip 33025

Mailing Address (if different from physical address) 5000 TUTTLE CROSSING BLVD

City DUBLIN State OH Zip 43016

Telephone 614-760-5000 Website WWW.ONEBEATMEDICAL.COM

Licensing Company Email REGULATORY@SARNOVA.COM

Section 2: Personal Information

First LAWRENCE Middle _____ Last FRANCHETTI

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITI [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City MIAMI State FL Zip 33138

Telephone 614-760-5000 Email REGULATORY@SARNOVA.COM

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF DELAWARE		1999 - 2001	
Address: 210 South College Ave	City: Newark	State: DE	Zip: 19716
Diploma/Degree obtained, if any: BACHELORS			

School Name		From - To (MM/YY – MM/YY)	
SALESIANUM SCHOOL		1993 - 1997	
Address: 1801 N BROOM ST	City: WILMINGTON	State: DE	Zip: 19802
Diploma/Degree obtained, if any: HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Tulane University		1997 - 1999	
Address: 6823 ST CHARLES AVE	City: NEW ORLEANS	State: LA	Zip: 70118
Diploma/Degree obtained, if any: —			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2019-PRESENT	[redacted]	MIAMI	FL	33138
01/2019-05/2019		MIAMI	FL	33131
04/2011-01/2019		NEW YORK	NY	10001
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
ONE BEAT CPR LEARNING CENTER, LLC			01/2019-PRESENT	
Business Address		**City**	**State**	**Zip**
3151 EXECUTIVE WAY		MIRAMAR	FL	33025
Phone	**Title**		**Number of Employed Hours**	
614-760-5000	CEO		10,000	
Description of Duties				
SEE ATTACHED				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5-15-2024
Date

I, LAWRENCE FRANCHETTI, **certify that as the designated representative for**

ONE BEAT CPR LEARNING CENTER, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. LF I am at least 21 years of age;
3. LF I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. LF I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. LF I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. LF I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. LF I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

LAWRENCE FRANCHETTI

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5-15-2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

LAWRENCE FRANCHETTI

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5-15-2024

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Broward

I, LAWRENCE FRANCHETTI, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5/15/2024

Date

Subscribed and Sworn to before me this 15th day of May

Notary Public Signature

RUTH E. BONILLA
Notary Public - State of Florida
Commission # HH 339734
My Comm. Expires Dec 22, 2026
Bonded through National Notary Assn.

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: CARDIO PARTNERS, INC.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PENDING

Physical Address: 1033 COLLINS RD. SUITE B

City: GREENWOOD State: IN Zip: 46143

Mailing Address (if different from physical address): 5000 TUTTLE CROSSING BLVD

City: DUBLIN State: OH Zip: 43016

Telephone: 614-760-5000 Website: WWW.CARDIOPARTNERS.COM

Licensing Company Email: REGULATORY@SARNOVA.COM

Section 2: Personal Information

First: BRIAN Middle: Last: LADUKE

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: PLAIN CITY State: OH Zip: 43064

Telephone: 614-760-5000 Email: REGULATORY@SARNOVA.COM

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
XAVIER UNIVERSITY		2009-2011	
Address	**City**	**State**	**Zip**
3000 VICTORY PKWY	CINCINNATI	OH	45207
Diploma/Degree obtained, if any			
MBA, BUSINESS			

School Name		From - To (MM/YY – MM/YY)	
POINT LOMA NAZARENE UNIVERSITY		1994-2000	
Address	**City**	**State**	**Zip**
3900 LOALAND	SAN DIEGO	CA	92106
Diploma/Degree obtained, if any			
B.A., BUSINESS COMMUNICATIONS			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2018-PRESENT	[redacted]	PLAIN CITY	OH	43064
06/2013-07/2018		STRONGSVILLE	OH	44136
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
CARDIO PARTNERS, INC.			10/2017-PRESENT
Business Address	**City**	**State**	**Zip**
5000 TUTTLE CROSSING BLVD	DUBLIN	OH	43016
Phone	**Title**		
614-760-5000	CEO		
Description of Duties			
SEE ATTACHED			

Business Name			From - To (MM/YY – MM/YY)
INVACARE CORPORATION			01/2013-10/2017
Business Address	**City**	**State**	**Zip**
ONE INVACARE WAY	ELYRIA	OH	44035
Phone	**Title**		
–	VP, NORTH AMERICA REHAB CHANNEL & PRODUCT MARKETING		
Description of Duties			
SEE ATTACHED			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

BRIAN LADUKE

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/27/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio., ss. County of Franklin.

I, Brian LaDuke., being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/27/2024

Date

Subscribed and Sworn to before me this 27th day of September 2024

Notary Public Signature

NOTARIAL SEAL STATE OF OHIO

JILL VENNEKOTTER
NOTARY PUBLIC • STATE OF OHIO
Comm. No. 2023-RE-869823
My Commission Expires Oct. 23, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site CARDIO PARTNERS, INC.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PENDING

Physical Address 1033 COLLINS RD, SUITE B

City GREENWOOD State IN Zip 46143

Mailing Address (if different from physical address) 5000 TUTTLE CROSSING BLVD

City DUBLIN State OH Zip 43016

Telephone 614-760-5000 Website WWW.CARDIOPARTNERS.COM

Licensing Company Email REGULATORY@SARNOVA.COM

Section 2: Personal Information

First DARRELL Middle _____ Last HUGHES

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City UPPER ARLINGTON State OH Zip 43220

Telephone 614-760-5000 Email REGULATORY@SARNOVA.COM

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
CAPITAL UNIVERSITY LAW SCHOOL		1996-1999	
Address: 303 EAST BROAD ST	City: COLUMBUS	State: OH	Zip: 43215
Diploma/Degree obtained, if any: J.D.			

School Name		From - To (MM/YY – MM/YY)	
INDIANA UNIVERSITY, BLOOMINGTON		1991-1995	
Address: 107 S INDIANA AVE	City: BLOOMINGTON	State: IN	Zip: 47405
Diploma/Degree obtained, if any: B.A. PSYCHOLOGY			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2003-PRESENT	[redacted]	UPPER ARLINGTON	OH	43220
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
CARDIO PARTNERS, INC.			2012-PRESENT	
Business Address		**City**	**State**	**Zip**
5000 TUTTLE CROSSING BLVD		DUBLIN	OH	43016
Phone	**Title**			
614-760-5000	SECRETARY			
Description of Duties				
SEE ATTACHED				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

DARRELL HUGHES

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/24/24

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Franklin

I, Darrell Hughes, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/24/24

Date

Subscribed and Sworn to before me this 24 day of September 2024

Notary Public Signature

NOTARIAL SEAL STATE OF OHIO

JILL VENNEKOTTER
NOTARY PUBLIC • STATE OF OHIO
Comm. No. 2023-RE-869823
My Commission Expires Oct. 23, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site CARDIO PARTNERS, INC.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PENDING

Physical Address 1033 COLLINS RD. SUITE B

City GREENWOOD State IN Zip 46143

Mailing Address (if different from physical address) 5000 TUTTLE CROSSING BLVD

City DUBLIN State OH Zip 43016

Telephone 614-760-5000 Website WWW.CARDIOPARTNERS.COM

Licensing Company Email REGULATORY@SARNOVA.COM

Section 2: Personal Information

First LAWRENCE Middle _____ Last FRANCHETTI

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITI[redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City MIAMI State FL Zip 33138

Telephone 614-760-5000 Email REGULATORY@SARNOVA.COM

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF DELAWARE		1999-2001	
Address	**City**	**State**	**Zip**
210 SOUTH COLLEGE AVE	NEWARK	DE	19716
Diploma/Degree obtained, if any			
BACHELORS			

School Name		From - To (MM/YY – MM/YY)	
TULANE UNIVERSITY		1997-1999	
Address	**City**	**State**	**Zip**
6823 ST CHARLES AVE	NEW ORLEANS	LA	70118
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
SALESIANUM SCHOOL		1993-1997	
Address	**City**	**State**	**Zip**
1801 N BROOM ST	WILMINGTON	DE	19802
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2019-PRESENT	[redacted]	MIAMI	FL	33138
01/2019-05/2019		MIAMI	FL	33131
04/2011-01/2019		NEW YORK	NY	10001

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
ONE BEAT CPR LEARNING CENTER, LLC			01/2019- PRESENT
Business Address	**City**	**State**	**Zip**
3151 EXECUTIVE WAY	MIRAMAR	FL	33025
Phone	**Title**		
614-760-5000	CEO		
Description of Duties			
SEE ATTACHED			

Business Name			From - To (MM/YY – MM/YY)
CARDIO PARTNERS, INC.			08/2024-PRESENT
Business Address	**City**	**State**	**Zip**
5000 TUTTLE CROSSING BLVD	DUBLIN	OH	43016
Phone	**Title**		
614-760-5000	PRESIDENT		
Description of Duties			
SEE ATTACHED			

Business Name			From - To (MM/YY – MM/YY)
CIGNET, LLC			04/2014-01/2019
Business Address	**City**	**State**	**Zip**
24601 CAPITAL BLVD	CLINTON TOWNSHIP	MI	48036
Phone	**Title**		
586-307-3790	PRESIDENT		
Description of Duties			
CIGNET IS NO LONGER A COMPANY			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

LAWRENCE FRANCHETTI

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9-25-24

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Franklin

I, Lawrence Franchetti, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9-25-24

Date

Subscribed and Sworn to before me this 25 day of September 2024

Notary Public Signature

JILL VENNEKOTTER
NOTARY PUBLIC • STATE OF OHIO
Comm. No. 2023-RE-869823
My Commission Expires Oct. 23, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site CARDIO PARTNERS, INC.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PENDING

Physical Address 1033 COLLINS RD, SUITE B

City GREENWOOD State IN Zip 46143

Mailing Address (if different from physical address) 5000 TUTTLE CROSSING BLVD

City DUBLIN State OH Zip 43016

Telephone 614-760-5000 Website WWW.CARDIOPARTNERS.COM

Licensing Company Email REGULATORY@SARNOVA.COM

Section 2: Personal Information

First SHAWN Middle _____ Last SAYLOR

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITI [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City POWELL State OH Zip 43065

Telephone 614-760-5000 Email REGULATORY@SARNOVA.COM

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
THE OHIO STATE UNIVERSITY		2002-2004	
Address	City	State	Zip
281 W LANE AVE	COLUMBUS	OH	43210
Diploma/Degree obtained, if any			
MASTERS OF ACCOUNTING/CPA			

School Name		From - To (MM/YY – MM/YY)	
OHIO UNIVERSITY		2003	
Address	City	State	Zip
1 OHIO UNIVERSITY	ATHENS	OH	45701
Diploma/Degree obtained, if any			
BACHELOR OF BUSINESS ADMINISTRATION			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2008-PRESENT	[redacted]	POWELL	OH	43065
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
CARDIO PARTNERS, INC.		2009-PRESENT	
Business Address	**City**	**State**	**Zip**
5000 TUTTLE CROSSING BLVD	DUBLIN	OH	43016
Phone	**Title**		
614-760-5000	CFO		
Description of Duties			
SEE ATTACHED			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SHAWN SAYLOR

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/25/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Franklin.

I, Shawn Saylor, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/25/2024

Date

Subscribed and Sworn to before me this 25 day of September 2024

Notary Public Signature

NOTARIAL SEAL STATE OF OHIO

JILL VENNEKOTTER
NOTARY PUBLIC • STATE OF OHIO
Comm. No. 2023-RE-869823
My Commission Expires Oct. 23, 2028

(Seal)

One Beat CPR Learning Center, LLC	TITLE
EMPLOYEE NAME BIO-MED DEPT.	BIO-MED DEPT.
Bruce Batista	Bio-med Technichian
Garrett Mooney	Bio-med Technichian
WAREHOUSE DEPT.	
Michael Alfaro	Purchasing & Supply Chain
Steven Bansie	Warehouse Associate
Dorothy Beauvais	Warehouse Associate
Monica Castañeda	Warehouse Associate
Yvonne Castillo	Warehouse Associate
James Evans	Wareshouse Operations
Eddy del Rosario	Warehouse Associate
Carlos Felipe	Warehouse Associate
Justin Hessler	Warehouse Associate
Nilsa Leon	Warehouse Associate
Jonathan Lopez	Warehouse Associate
Carlos Meneses	Warehouse Associate
Edgar Rivera	Warehouse Associate
Martha Rodriguez	Warehouse Associate
Raushaid Tyson	Warehouse Associate
Walter Williams	Warehouse Manager
ADMINISTRATIVE SERVICES DEPT.	
Melanie Bustillo	Dept. Co-Manager
Rebecca Capel	Dept. Co-Manager

Mabelle Cruz	Customer Service
Teresa Dunn	Front Desk
Denise Fowler	Device Tracking Specialist
Alexandra Hassell	Returns Specialist
Travis Henry	Live Chat Representative
Raysa Lizardo	Customer Service
Brittnie Roberts	Customer Service
Rocio "Rosey" Rodriguez	Customer Service Lead
Frances Rosales	Customer Service Lead
RESELLER DEPT.	
Ruth Bonilla	Reseller Dept. Manager
Desiree Olivera	Customer Service
Cynthia Thompson	Customer Service
Jon Warnock	Dir. of Business Development
ACCOUNTING DEPT.	
Cortney Charlery	Accounts Payable
Mary Doyle	Accounts Receivables
Jackie Esteves	Collections Specialist (Lifesure)
Urmella Larsson	Accounting Manager
Bonnie Merkel	Controller
Ana Roncallo	Accounts Receivables
MARKETING DEPT.	
Michael Drag	Marketing
Derek Martinez	E-Commerce & Digital Mark.
Christy McNutt	Dir. of Strategic Initiatives
TRAINING DEPT.	

Isachi Cruz	Training Coordinator
Jaylin DeArmas	P/T Astt. Training Coordinator
Vanessa Demoya	Training Dept. Manager
SALES	
Dan Andrade	Sales
Basil Arena	Sales
Joshua Merkel	Sales
Meredith Lockard	Sales Manager
AMERICAN AED	
Nicolas Acosta	American AED Sales
Gray Barnes	American AED Sales
Alexandra Davis	American AED Sales
Karen Kleinman	American AED Cust. Service
Carlos Parrales	Dir. of Digital Strategy
Jeff Petak	VP of Sales
Jennifer Vega	American AED Sales
LIFESURE	
Haydee Avila	Authorization & Appeals
Augusto Bocanegra	Authorization & Appeals
Paris Nedd	Claims Specialist
Paula Stone	Authorization & Appeals
Crystal Valdes	Dir. of Operations
Meg Weber	Dir. of Patient Advocacy
ALTRA MEDICAL	
Loretta "Lori" Valantiejus	Customer Service
I.T. DEPT.	

Oscar Sigas	IT Support Specialist
WEST REGION SUPPORT	
Lamonte Lamoureux	Director of Strategy & Operations
MANAGEMENT	
Bellice Ayala	Director of HR & Benefits
Emily Drag	COO
Lawrence Franchetti	CEO

4KK

WH0238 5
Closed 2020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Pharmaceutical Trade Services, Inc.

Physical Address: 5820 Gulf Tech Drive

City: Ocean Springs State: MS Zip: 39564

Mailing Address (if different from physical address): Same

City: _____ State: _____ Zip: _____

Telephone: 228-244-1530 Website: www.durbinglobal.com

Name of Designated Representative (DR): Melissa McLaughlin

Licensing Company Email: mmclaughlin@durbin-usa.com DR Email: mmclaughlin@durbin-usa.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: RX and OTC	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1-5. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A	N/A	N/A	N/A	N/A

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
N/A	N/A

Reason/Charge
N/A

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
N/A	N/A

Name of Business/Industry/Entity
N/A

Provide explanation below:
N/A

Original Signature (electronic, copies or stamps not accepted)

3/11/24
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Amerisource Bergen
Address: 1 West First Ave City: Conshohocken State: PA Zip: 19428

Name: Capital Drug Co.
Address: 873 Williams Ave City: Columbus State: OH Zip: 43212

Name: Mckesson
Address: 6555 State Hwy 161 City: Irving State: TX Zip: 75039

Name: Callion Pharma
Address: 232 Presenential #7 City: Jonesborough State: TN Zip: 37659

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Mississippi
Parent Company (if any): Uniphar PLC
Corporation/Organization Name: Uniphar PLC/ Durbin USA
Mailing Address: 5820 Gulftech
City: Ocean Springs State: MS Zip: 39564
Telephone: 228-234-0388 Email: mmclaughlin@durbin-usa.com
Contact Person Name: Melissa McLaughlin

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Pharmaceutical Trade Services, Inc

Facility Name

Melissa McLaughlin

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

3/11/2024

Date

Board Use Only	Date Received: 3/19/24	Amount: $1000 - Check 80821

2 - List of corporate officers (full name/title)

Name: Ms Melissa McLaughlin

Title: Officer, Senior Vice President

Maria Herrera

From: Melissa McLaughlin <mmclaughlin@durbin-usa.com>
Sent: Friday, June 21, 2024 3:07 PM
To: Maria Herrera
Subject: RE: Nevada Out-of-State Wholesaler Application-Pharmaceutical Trade Service, Inc.

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Yes, confirmed.

Melissa McLaughlin
Senior Vice President, Durbin USA
mmclaughlin@durbin-usa.com
5820 Gulf Tech Dr., Ocean Springs, Mississippi 39564 USA
T. +1-228-244-1530 x103
F. +1-228-244-1535
C. [redacted]
www.durbinglobal.com

Durbin USA will be closed Thursday, July 4th returning Friday, July 5th. If you have a urgent inquiry please call me cell phone.

durbin
part of the uniphar group

From: Maria Herrera <m.herrera@pharmacy.nv.gov>
Sent: Friday, June 21, 2024 5:06 PM
To: Melissa McLaughlin <mmclaughlin@durbin-usa.com>
Subject: RE: Nevada Out-of-State Wholesaler Application-Pharmaceutical Trade Service, Inc.
Importance: High

Hi Melissa,

Please confirm there are no individual owners, shareholders or stockholders.

Michael Watson
SECRETARY OF STATE

Office of the Secretary of State
Jackson, Mississippi

Certificate of Good Standing

I, MICHAEL WATSON, Secretary of State of the State of Mississippi, and as such, the legal custodian of the records as required by the laws of Mississippi, to be filed in my office, do hereby certify:

That on the 8th day of July, 1998, the State of Mississippi issued a Charter/ Certificate of Authority to:

PHARMACEUTICAL TRADE SERVICES INC.

That the state of incorporation is Mississippi.

That the period of duration is perpetual.

That according to the records of this office, Articles of Dissolution or a Certificate of Withdrawal have not been filed.

That according to the records of this office, a current Annual Report has been delivered to the Office of the Secretary of State.

I further certify that all fees, taxes and penalties owed to this state, as reflected in the records of the Secretary of State, have been paid and that the corporation is in existence or has authority to transact business in Mississippi.

That insofar as the records of this office are concerned, the said PHARMACEUTICAL TRADE SERVICES INC. is in good standing at this time.

Given under my hand and seal of office
the 24th day of January, 2024

Michael Watson

Certificate Number: CN24180860
Verify this certificate online at http://corp.sos.ms.gov/corpconv/verifycertificate.aspx

MISSISSIPPI
Board of Pharmacy

Permit #
15652 / 16.5

Drug Facility
Wholesale Distributor (In-State)

Pharmaceutical Trade Services, Inc.
DBA Durbin USA

5820 Gulf Tech Drive
Ocean Springs, MS 39564
Jackson

Permit Holder:
Melissa A McLaughlin

This permit is not transferable or assignable.

Issued: 05/01/2017
Renewed: 09/19/2023
Expires: 12/31/2024

Susa McCoy
Executive Director

Mississippi Board of Pharmacy | 6360 I-55 North | Suite 400 | Jackson, MS 39211
Phone: 601-899-8880 | Fax: 601-899-8851

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RP0495019	03-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	02-14-2024

PHARMACEUTICAL TRADE SERVICES INC
DBA DURBIN USA
5820 GULF TECH DR
OCEAN SPRINGS, MS 395648212

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RP0495019	03-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	02-14-2024

PHARMACEUTICAL TRADE SERVICES INC
DBA DURBIN USA
5820 GULF TECH DR
OCEAN SPRINGS, MS 395648212

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RP0495019	03-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	02-14-2024

PHARMACEUTICAL TRADE SERVICES INC
DBA DURBIN USA
5820 GULF TECH DR
OCEAN SPRINGS, MS 395648212

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

A	B	C	D	E	F
Current List of Licenses (as of 2/11/2019)					
/Federal Agency	Name on License	License Number	Type of License	Date License Acquired	Expiration Date
ISSIPPI	Pharmaceutical Trade Services, Inc. dba Durbin USA	15652/16.5	Wholesaler/Manufacturer	7/14/1998	12/31/2024
ISSIPPI	Pharmaceutical Trade Services, Inc. dba Durbin USA	CS-15652/16.5	Controlled Substance	7/14/1998	12/31/2024
ISSIPPI	Pharmaceutical Trade Services, Inc. dba Durbin USA	16358/16.3	3PL	9/15/2017	12/31/2024
	Pharmaceutical Trade Services, Inc. dba Durbin USA	RP0495019	US DEA - Distributor	2/9/2018	3/31/2024
	Pharmaceutical Trade Services, Inc. dba Durbin USA	RG0249183	US DEA - Exporter	3/8/2018	3/31/2024
	Pharmaceutical Trade Services, Inc. dba Durbin USA	RP0453085	US DEA - Importer	2/9/2018	3/31/2024
	Pharmaceutical Trade Services, Inc. dba Durbin USA	007337PCZ	US DEA - List 1 Chemical Exporter	2/9/2018	3/31/2024
)NA	Pharmaceutical Trade Services, Inc	WD002957	Wholesaler/Manufacturer	6/1/2017	10/31/2024
ANSAS	Pharmaceutical Trade Services, Inc. dba Durbin USA	WD04796	Wholesaler/Manufacturer	1/3/2017	12/31/2024
NECTICUT	Pharmaceutical Trade Services, Inc	CSW.0003881	Wholesaler/Manufacturer AND Controlled Substance	7/1/2017	6/30/2014
RGIA	Durbin USA	PHWH004191	Wholesaler/Manufacturer	7/17/2017	6/30/2025
AII	Pharmaceutical Trade Services, Inc	E12941	Controlled Substance	12/6/2016	**3/31/2024**
SAS	Pharmaceutical Trade Services, Inc. dba Durbin USA	5-103758	Wholesaler/Manufacturer AND Controlled Substance	8/16/2017	6/30/2024
TUCKY	Pharmaceutical Trade Services, Inc. dba Durbin USA	W03862	Wholesaler/Manufacturer and Controlled Subastance	2/3/2017	9/30/2024
SIANA	Pharmaceutical Trade Services, Inc. dba Durbin USA	1113	Wholesaler/Manufacturer		12/31/2024
SACHUSETTS	Pharmaceutical Trade Services, Inc. dba Durbin USA	NOT REQUIRED	Wholesaler/Manufacturer	NOT REQUIRED	NOT REQUIRED
HAMPSHIRE	Durbin USA (Pharmaceutical Trade Services Inc.)	2636	Wholesaler/Manufacturer	1/5/2017	11/31/2025
JERSEY	Pharmaceutical Trade Services, Inc. dba Durbin USA	5005274	Wholesaler/Manufacturer	1/14/2018	1/1/2025
YORK	Pharmaceutical Trade Services, Inc	35354	Wholesaler/Manufacturer	2/16/2017	7/31/2024
H CAROLINA	Pharmaceutical Trade Services, Inc	1421	Wholesaler	2/4/2016	12/31/2024
	Pharmaceutical Trade Services, Inc. dba Durbin USA	WCSW-2919	Wholesaler/Manufacturer AND Controlled Substance	9/1/2017	6/30/2024
HOMA	Pharmaceutical Trade Services, Inc. dba Durbin USA	88-W-4957	Wholesaler/Manufacturer	1/17/2019	7/31/2024
SYLVANIA	Pharmaceutical Trade Services, Inc	3000009602	Wholesaler/Manufacturer AND Controlled Substance	12/7/2016	10/31/2024
DE ISLAND	Pharmaceutical Trade Services, Inc	DIS02986	Wholesaler/Manufacturer		
KA	Pharmaceutical Trade Services, Inc. dba Durbin USA	NOT REQUIRED	Wholesaler/Manufacturer	NOT REQUIRED	NOT REQUIRED

Pharmaceutical Trade Services Inc. Organization Chart

Uniphar plc
Publicly traded Uniphar Group PLC (UPR) Ireland and London Exchange
4045 Kingswood Road, Citywest Business Park, CO Dublin D24 V06K
Parent company contact - John Preston, Global Head of Quality, jpreston@uniphar.com

100% Ownership

Durbin Inc.
United States Holding Company,
Incorporated Mississippi 10/29/2014
FEIN 47-2396647
5820 Gulf Tech Drive, Ocean Springs, MS 39564
President - Dan Piggott
Vice President - Melissa McLaughlin

100% Ownership

Pharmaceutical Trade Services Inc.
dba Uniphar dba Uniphar Clinical dba Durbin USA
Mississippi Corporation formed 7/8/1998, FEIN 64-0897326
with locations at
5820 Gulf Tech Drive, Ocean Springs, MS 39564
and 5100 Jones Sausage Drive, Suite 140, Garner, NC 27529
Sr. Vice President - Melissa McLaughlin
Head of Quality, US - Erin Driggers

MELISSA A MCLAUGHLIN
5820 GULF TECH DRIVE 39564-8212
OCEAN SPRINGS, MS 39564

1-787 (Rev. 08-10-2016)

U.S. Department of Justice
Federal Bureau of Investigation
Criminal Justice Information Services Division
Clarksburg, WV 26306

MELISSA A MCLAUGHLIN
5820 GULF TECH DRIVE 39564-8212
OCEAN SPRINGS, MS 39564

Date: 10-12-2023

The Criminal Justice Information Services (CJIS) Division of the Federal Bureau of Investigation (FBI) has completed the following fingerprint submission:

Subject Name

MELISSA A MCLAUGHLIN

Search Completed Result 10-12-2023 E2023285000000149350

A SEARCH OF THE FINGERPRINTS PROVIDED BY THIS INDIVIDUAL HAS REVEALED NO PRIOR ARREST DATA AT THE FBI. THIS DOES NOT PRECLUDE FURTHER CRIMINAL HISTORY AT THE STATE OR LOCAL LEVEL.

Date of Birth: 03/18/1983

Social Security number: XXX-XX-9925

The result of the above response is only effective for the date the submission was originally completed. For more updated information, please submit new fingerprints of the Subject.

In order to protect Personally Identifiable Information, as of August 17, 2009, FBI policy has changed to no longer return the fingerprint cards. This form will serve as the FBI's official response.

This Identity History Summary (IdHS) is provided pursuant to 28 CFR 16.30-16.34 solely for you to conduct a personal review and/or obtain a change, correction, or updating of your record. **This IdHS is not provided for the purpose of licensing or employment or any other purpose enumerated in 28 CFR 20.33.**

Any questions may be addressed to the Customer Service Group at 304-625-5590. You may also visit the website at www.fbi.gov/checks for further instructions.

Chris Ormerod
Section Chief
Biometric Services Section
Criminal Justice Information
Services Division

COPY

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 107881566

Application/License No. _____

Pharmaceutical Trade Services, Inc. dba Durbin USA (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5100 Jones Sausage Road ~ Garner, NC 27529 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty and Surety Company of America (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Tower Square – Hartford, CT 06183 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on December 6, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 6th day of December, 20 23.

APPLICANT/PRINCIPAL

COMPANY
Pharmaceutical Trade Services, Inc.
dba Durbin USA

Authorized Representative

SURETY

Travelers Casualty and Surety Company of America

Surety Company's Representative

Susan Skrmetta, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness
Kathleen Scarborough

Witness
Darlene Landry

Countersigned by:

Nevada Resident Agent
Kaley Campbell
10000 W. Charleston Blvd Ste 200
Las Vegas, NV 89135

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **Susan Skrmetta** of **GULFPORT**, **Mississippi**, their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **21st** day of **April, 2021**.

State of Connecticut

By: _____
Robert L. Raney, Senior Vice President

City of Hartford ss.

On this the **21st** day of **April, 2021**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June, 2026**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this **6th** day of **December**, **2023**.

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Pharmaceutical Trade Services, inc.
Pharmacy/Wholesaler License # (if applicable):
Physical Address: 5820 Gulf Tech Drive
City: Ocean Springs State: MS Zip: 39564
Mailing Address (if different from physical address): Same
City: State: Zip:
Telephone: Website:
Licensing Company Email: mmclaughlin@durbin-usa.com

Section 2: Personal Information

First: Melissa Middle: Ann Last: McLaughlin
Alias(es, nicknames, name changes, etc.):
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X
Mailing Address: 5820 Gulf Tech Drive
City: Ocean Springs State: MS Zip: 39564
Telephone: [redacted] Email: mmclaughlin@durbin-usa.com
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Muncie Central		1998-2001	
Address: 801 N. Walnut	City: Muncie	State: IN	Zip: 47305
Diploma/Degree obtained, if any: Diploma			
School Name: Ball State University		From - To (MM/YY – MM/YY): 2001-2006	
Address: 2000 W. University	City: Muncie	State: IN	Zip: 47306
Diploma/Degree obtained, if any: Accounting			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2020-Curr	[redacted]	Queensprings	MS	39505
2015-2020	[redacted]	Queensprings	MS	39505
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Pharmaceutical Trade Services			2015 - Current	
Business Address		City	State	Zip
5820 GulfTech		Ocean Springs	MS	39564
Phone	Title		Number of Employed Hours	
228-244-1580	SVP		18,720	
Description of Duties				
Oversee Quality, ops, commercial				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below: N/A

Original Signature (electronic, copies or stamps not accepted)

3/11/24
Date

I, Melissa McLaughlin, **certify that as the designated representative for** Pharmaceutical Trade Services, Inc. dba Durbin USA,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. mm I am at least 21 years of age;
3. mm I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. mm I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. mm I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. mm I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. mm I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Melissa McLaughlin
Print Name (First, Last)

Melissa McLaughlin
Original Signature (electronic, copies or stamps not accepted)

3/11/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

McLaughlin, Melissa

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/11/24

Date

Please have this section completed in the presence of a Notary Public.

State of Mississippi, ss. County of Jackson

I, Melissa McLaughlin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/15/24

Date

Subscribed and Sworn to before me this 15th day of March 2024

Notary Public Signature

STATE OF MISSISSIPPI NOTARY PUBLIC ID # 76605 ANGELA A. MACON (Seal) Commission Expires July 23, 2026 JACKSON COUNTY

OUR ORGANIZATION'S TELEPHONE LIST

LAST NAME	FIRST NAME	JOB ROLE	DEPARTMENT	BUSINESS UNIT	LINE MGR.
Belton	Chris	Business Development Manger	Business Development		Melissa McLaughlin
Berryhill	Toy	Key Account Manager	Procurment		Melissa McLaughlin
Bersonnet	Allen	Logistics Clerk	Warehouse/Operations		Tim McCabe
Favre	Cheyenne	HR Assistant	HR		Melissa McLaughlin
Holbert	Kayla	Quality Officer	Regulatory		Joelle Knight
Howton	Julie	IT Coordinator	IT		Melissa McLaughlin
Jackson	Coraletta	Accounts Payable	Accounting		Angela Macon
Jones	Jonathan	Regulatory Associate	Regulatory		Tim McCabe
Jones	Josh	Shipping and Receiving Clerk	Warehouse/Operations		Tim McCabe
Knight	Joelle	Regulatory/Quality Assurance manager	Regulatory		Melissa McLaughlin
Macon	Angela	Accounting Manager	Accounting		Melissa McLaughlin
McCabe	Tim	Operations Manager	Warehouse/Operations		Melissa McLaughlin
McCallum	Cordell	Senior Buyer	Procurment		Melissa McLaughlin
McLaughlin	Melissa	SVP			Padraig Flynn
Moerer	Mercedes	Logistics Manager	Warehouse/Operations		Melissa McLaughlin
Phillips	Bradley	Warehouse Manager	Warehouse/Operations		Melissa McLaughlin

LAST NAME	FIRST NAME	JOB ROLE	DEPARTMENT	BUSINESS UNIT	LINE MGR.
Schier	Jessica	MAPs Administrative Coordinator	MAPS		Mark Haxton
Spicer	Miranda	MAPs Administrative Coordinator	MAPS		Mark Haxton
Stockstill	Madison	Key Account Manager	Procurment		Melissa McLaughlin
Stokley	Payton	Clinical Trials Coordinator	Procurment		Melissa McLaughlin
Talbot	David	Shipping and Receiving Clerk	Warehouse/Operations		Tim McCabe
Waller	Azure	Key Account Manager	Procurment		Melissa McLaughlin

4LL

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☑ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: SMC RETURNS Corp.

Physical Address: 1183A Broadway

City: Hewlett State: NY Zip: 11557

Mailing Address (if different from physical address): 1183A Broadway

City: _____ State: _____ Zip: _____

Telephone: _____ Website: www.SMCRETURNS.com

Name of Designated Representative (DR): Avraham Sacks

Licensing Company Email: Abe@SMCRETURNS.com DR Email: Abe@SMCRETURNS.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☑ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☑ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☑ Reverse Distributor
☐ Wholesalers	☑ Others: OTC + expired NON controlled medication	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, Licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6/26/2024
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: NA

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: NA

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: NA

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: NA

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: AVRAHAM SACKS

Business Name: SMC RETURNS CORP.

Business Address: 1183A Broadway

City: Hewlett State: NY Zip: 11557

Telephone: 646-772-1964 Email: abe@smcreturns.com

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		✓
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	NA	
1. Copy of FDA registration NA 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** (NA)	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** (NA)	✓			
• **List of all corporation shareholders and their percent ownership.** (NA)		✓		
• **List of all partners and their percent ownership.** (NA)			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) (NA)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[1]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ (NA)	✓	✓	✓	✓
• **If providing [1]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

SMC RETURNS Corp.

Facility Name

AVRAHAM SACKS

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

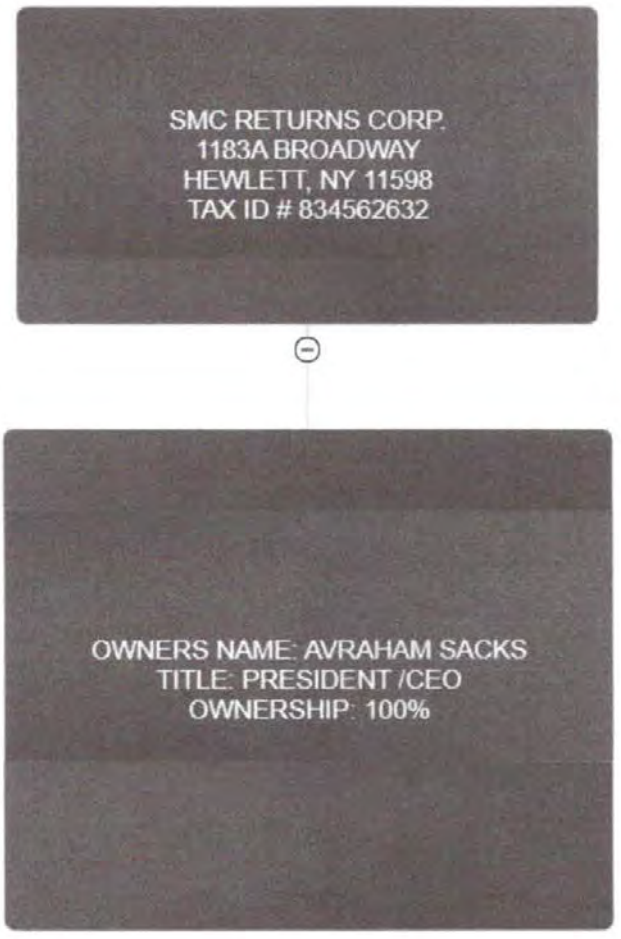
6/26/2024

Date

Board Use Only	Date Received: 7/8/24	Amount: $1,000-CK 1055

SMC Returns

ORGANIZATIONAL CHART



- CONFIDENTIAL-

The information contained in this communication is the property of SMC RETURNS and remains confidential, private, proprietary, or otherwise privileged and is intended only for the use of the addressee. Unauthorized use, disclosure, distribution or copying is strictly prohibited and may be unlawful.

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, WALTER T. MOSLEY, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	SMC RETURNS CORP.
DOS ID Number:	5536624
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	04/18/2019
Statement Status:	CURRENT
Statement Due Date:	04/30/2025

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on July 18, 2024 at 02:00 P.M.

WALTER T. MOSLEY
Secretary of State

Brendan C. Hughes

BRENDAN C. HUGHES
Executive Deputy Secretary of State

Authentication Number: 100006103300 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, WALTER T. MOSLEY, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	SMC RETURNS CORP.
DOS ID Number:	5536624
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	04/18/2019
Statement Status:	CURRENT
Statement Due Date:	04/30/2025

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on July 18, 2024 at 02:00 P.M.

WALTER T. MOSLEY
Secretary of State

Brendan C. Hughes

BRENDAN C. HUGHES
Executive Deputy Secretary of State

Authentication Number: 100006103300 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2022-25

NAME OF SUPERVISOR
AVRAHAM SACKS

THIS IS TO CERTIFY

SMC RETURNS CORP.
1183A BROADWAY
HEWLETT, NY 11557

is duly recorded as a

REGISTERED WHOLESALER OF DRUGS AND/OR DEVICES

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE FIRST DAY OF JULY, 2022.
THIS CERTIFICATE EXPIRES ON THE THIRTIETH DAY OF JUNE, 2025.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER

037586

Dana Lyn

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RS0571302	02-28-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	REVERSE DISTRIB	01-18-2024

SMC RETURNS CORP
1183A BROADWAY
HEWLETT, NY 11557

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RS0571302	02-28-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	REVERSE DISTRIB	01-18-2024

SMC RETURNS CORP
1183A BROADWAY
HEWLETT, NY 11557

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEW YORK STATE DEPARTMENT OF HEALTH
CONTROLLED SUBSTANCE LICENSE

Class: 020
DISTRIBUTOR

SMC RETURNS CORP
1183-A BROADWAY
HEWLETT, NY 11557

Licensed Location:
SMC RETURNS CORP
1183-A BROADWAY
HEWLETT, NY 11557

Schedule:
II III IV V

HAS GIVEN SATISFACTORY EVIDENCE THAT ALL QUALIFICATIONS AS REQUIRED BY ARTICLE 33 OF THE PUBLIC HEALTH LAW AND PART 80 OF THE ADMINISTRATIVE RULES AND REGULATIONS HAVE BEEN MET AND IS HEREBY GRANTED A LICENSE TO ENGAGE IN CONTROLLED SUBSTANCE ACTIVITY IN THE STATE OF NEW YORK IN THE CLASSIFICATION STATED ABOVE.

LICENSE #: 0200411
EFFECTIVE: Nov 05 2023
EXPIRES: Nov 04 2025

JAMES V. McDONALD, M.D., M.P.H.
COMMISSIONER OF HEALTH

TO BE PERMANENTLY DISPLAYED AT THE LICENSED SITE

NEVADA STATE BOARD OF PHARMACY
431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. TCS26496

Application/License No. _____

SMC Returns Corp, doing or intending to do
Applicant/Principal
business as a pharmaceutical wholesaler, whose address for purposes of service is

1183A Broadway, Hewlett, NY 11557-2335, as
Address of Applicant/Principal
PRINCIPAL, and Hudson Insurance Company, a
Surety Company
corporation organized under the laws of the state of Delaware
State of Incorporation
and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is

8777 N Gainey Center Dr Ste 240, Scottsdale, AZ 85258-2154 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 06/26/2024.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 27th day of June, 20 24.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

Mark E. Sherwood, Attorney-in-fact

print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A

Nevada Resident Agent

HUDSON INSURANCE GROUP

TCS26496

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That HUDSON INSURANCE COMPANY, a corporation of the State of Delaware, with offices at 100 William Street, New York, New York, 10038, has made, constituted and appointed, and by these presents, does make, constitute and appoint

Mark E. Sherwood

of the State of California

its true and lawful Attorney(s)-in-Fact, at New York, New York, each of them alone to have full power to act without the other or others, to make, execute and deliver on its behalf, as Surety, bonds and undertakings given for any and all purposes, also to execute and deliver on its behalf as aforesaid renewals, extensions, agreements, waivers, consents or stipulations relating to such bonds or undertakings provided, however, that no single bond or undertaking shall obligate said Company for any portion of the penal sum thereof in excess of the sum of

One Hundred Thousand Dollars and Zero Cents

Such bonds and undertakings when duly executed by said Attorney(s)-in-Fact, shall be binding upon said Company as fully and to the same extent as if signed by the President of said Company under its corporate seal attested by its Secretary.

In Witness Whereof, HUDSON INSURANCE COMPANY has caused these presents to be of its Senior Vice President thereunto duly d, on this 2nd day of June, 20 22 at New York, New York.

: seal)

HUDSON INSURANCE COMPANY

Attest.....
Dina Daskalakis No. 01MU6067553
Corporate Secretary

By.....
Michael P. Cifone
Senior Vice President

STATE OF NEW YORK
COUNTY OF NEW YORK SS.

On the 2nd day of June, 20 22 before me personally came Michael P. Cifone to me known, who being by me duly sworn did depose and say that he is a Senior Vice President of **HUDSON INSURANCE COMPANY**, the corporation described herein and which executed the above instrument, that he knows the seal of said Corporation, that the seal affixed to said instrument is such corporate seal, that it was so affixed by order of the Board of Directors of said Corporation, and that he signed his name thereto by like order.

(Notarial Seal)

ANN M. MURPHY NOTARY PUBLIC STATE OF NEW YORK

.....
ANN M. MURPHY
Notary Public, State of New York
No. 01MU6067553
Qualified in Nassau County
Commission Expires December 10, 2025

CERTIFICATION

STATE OF NEW YORK
COUNTY OF NEW YORK SS.

The undersigned **Dina Daskalakis** hereby certifies:

That the original resolution, of which the following is a true and correct copy, was duly adopted by unanimous written consent of the Board of Directors of Hudson Insurance Company dated July 27th, 2007, and has not since been revoked, amended or modified:

"RESOLVED, that the President, the Executive Vice Presidents, the Senior Vice Presidents and the Vice Presidents shall have the authority and discretion, to appoint such agent or agents, or attorney or attorneys-in-fact, for the purpose of carrying on this Company's surety business, and to empower such agent or agents, or attorney or attorneys-in-fact, to execute and deliver, under this Company's seal or otherwise, bonds obligations, and recognizances, whether made by this Company as surety thereon or otherwise, indemnity contracts, contracts and certificates, and any and all other contracts and undertakings made in the course of this Company's surety business, and renewals, extensions, agreements, waivers, consents or stipulations regarding undertakings so made; and

FURTHER RESOVLED, that the signature of any such Officer of the Company and the Company's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seal when so used whether heretofore or hereafter, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed."

THAT the above and foregoing is a full, true and correct copy of Power of Attorney issued by said Company, and of the whole of the original and that the said Power of Attorney is still in full force and effect and has not been revoked, and furthermore that the Resolution of the Board of Directors, set forth in the said Power of Attorney is now in force.

Witness the hand of the undersigned and the seal of said Corporation this 27th day of June, 20 24

seal)

By.....
Dina Daskalakis, Corporate Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

WE are NOT a wholesaler

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler SMC RETURNS CORP. (RETURNS PROCESSOR only)

Pharmacy/Wholesaler License # (if applicable) 037586 - HOME STATE LICENSE

Physical Address 1183A Broadway

City Hewlett [redacted] State NY Zip 11598

Mailing Address (if different from physical address)

City State Zip

Telephone 516-612-0882 Website WWW.SMCRETURNS.COM

Licensing Company Email [redacted] @ SMCRETURNS.COM ABE

Section 2: Personal Information

First AVRAHAM Middle Last SACKS

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Far Rockaway State NY Zip 11691

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Azrieli Graduate Institute		JUNE 1990 - JUNE 1995	
Address: 500 W. 185th Street	City: NY	State: NY	Zip: 10033
Diploma/Degree obtained, if any: MASTERS DEGREE IN Education & Administration			
School Name: Yeshiva University		From - To (MM/YY – MM/YY): 1988 - 1996	
Address: 500 W. 185th Street	City: NY	State: NY	Zip: 10033
Diploma/Degree obtained, if any: BACHELORS			
School Name: Duquesne University		From - To (MM/YY – MM/YY): 1987	
Address: 600 Forbes Avenue	City: Pittsburgh	State: PA	Zip: 15282
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2019 - 2024	[redacted]	far rockaway	NY	11691
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)	
SMC RETURNS CORP.		2019 - 2024	
Business Address	**City**	**State**	**Zip**
1183A Broadway	Hewlett	NY	11557
Phone	**Title**	**Number of Employed Hours**	
516 - 612 - 0882	President / CEO	10,000 +	

Description of Duties
CEO & Director of operations at SMC returns corp. Serves as person in charge for licences required from state & federal licensures. oversees day to day operations.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6/26/2024
Date

I, Avraham Sacks, **certify that as the designated representative for** SMC RETURNS CORP. located at 1183a Broadway, Hewlett, NY 11557

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AS I am at least 21 years of age;
3. AS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Avraham, Sacks

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/20/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Arraham, Sacks

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/26/2024

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Nassau

I, Arraham Sacks, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/27/2024

Date

Subscribed and Sworn to before me this 27 day of June 2024

Cindy Henggeler

Notary Public Signature

CINDY HENGGELER
Notary Public - State of New York
NO. 01HE6143717
Qualified in Nassau County
My Commission Expires 4-17-26

(Seal)

Avraham Sacks

[redacted]

WORK EXPERIENCE

2019-2024

CEO and Director of operations at SMC Returns Corp (Pharmaceutical Returns Company)

- **Serves as the Person in Charge and Responsible person for licenses required from State and Federal Licensure/s.**
- **Responsibilities include**
  - **Overseeing day to day operations of SMC Returns Corp**
  - **Overseeing operations and compliance with respect to all matters related to receiving and processing Legend Drugs and Controlled substances.**
  - **Compliance matters as it relates to all aspects of a Returns Processor / Reverse Distributor.**
  - **Overseeing training of all staff in matters of process and compliance.**

2013-2019

Chief Academic Officer for the AJE project and Education Consultant for Private Day Schools

2009-2012 **Hillel Academy of Pittsburgh** **Pittsburgh, PA**

Principal and Education Director (Early Childhood through 12th grade)

- Responsible for all aspects of running a Day School from Early Childhood through 12th grade.
- Produce itemized budget for personnel, programs, supplies, training, professional development etc....
- Responsible for staffing and supervision of 70 members of our educational team, which included administrators, faculty, general staff, and office staff.
- Created a warm, respectful, collaborative, and professional school culture.
- Supervised curriculum and instruction for Early Childhood, and K-12th Grade.
- Implementation of curriculum and assessments from Pre Nursery through 12th Grade.
- Co-Directed the Early Childhood

2005-2009 **Ramaz Lower School** **NY, NY**

Assistant Headmaster

- Responsible for the supervision of teachers. Worked collaboratively with them to create a positive behavior program for 1st - 4th Grade.
- Responsible for discipline for 1st - 4th Grade. Worked with teachers, parents, and a school psychologist to run a comprehensive system of tracking and following up on issues, in order to support the teachers and students. Included systems of data recording, collection, and analysis.

- Responsible for scheduling, including classes, meetings, specials, duties, special programs, rehearsals, and more.
- Organized, ran and attended meetings including team meetings, Oneg committee meetings, parent meetings, heads of recess and lunch meetings, and more.
- Director of Music program in the Early Childhood and Lower School.

2000-2005 **Ramaz Middle School / Lower School / ECC** **NY, NY**

Educational Program Coordinator

1996-2000 **Ramaz Lower School** **NY, NY**

Director of Educational Programs

1993-1996 **Manhattan Day School** **NY, NY**

Teacher

PROFESSIONAL DEVELOPMENT

- Attended BRAVE Bullying program workshops/seminars.
- Completed the RBT (Research for Better Teaching) Administrator's course for Supervision of classroom teachers.
- Attended The Harvard Principal's Program: *Improving Schools, The Art of Leadership.*
- Received Pennsylvania SAP certification.
- Received certification as a School Director in the state of Pennsylvania.

EDUCATION

August 2011
Received Principal/Director certification from the state of Pennsylvania

June 2011
Received certification as a "Student Assistance Professional"

June 1996
Received Rabbinical Ordination From RIETS (YU)

June 1995
Master's Degree in Education and Administration, (BA/MA)

1988-1996:
Yeshiva University, New York, NY
Azrieli Graduate Institute, New York, NY

1987:
Duquesne University, Pittsburgh, PA

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application
Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site SMC RETURNS Corp.
Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) D37586 – HOME State License
Physical Address 11834 Broadway
City Hewlett State NY Zip 11598
Mailing Address (if different from physical address) _____
City _____ State _____ Zip _____
Telephone 516.612.0882 Website www.SMCRETURNS.com
Licensing Company Email [redacted] SMCRETURNS.COM
ABE ©

Section 2: Personal Information

First Avraham Middle _____ Last Sacks
Alias(es, nicknames, name changes, etc.) _____
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X
Mailing Address [redacted]
City Far Rockaway State NY Zip 11691
Telephone [redacted] Email [redacted]
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Azrielli Graduate Institute		June 1990 - June 1995	
Address: 500 W. 185th Street	City: NY	State: NY	Zip: 10033
Diploma/Degree obtained, if any: MASTERS DEGREE in Education + Administration			

School Name		From - To (MM/YY – MM/YY)	
Yeshiva University		1988 - 1996	
Address: 500 W. 185th Street	City: NY	State: NY	Zip: 10033
Diploma/Degree obtained, if any: Bachelors			

School Name		From - To (MM/YY – MM/YY)	
Duquesne University		1987	
Address: 600 Forbes Avenue	City: Pittsburgh	State: PA	Zip: 15282
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2014 - 2024	[redacted]	Far Rockaway	NY	11691
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
SMC RETURNS Corp.			2019 - 2024	
Business Address	City		State	Zip
1183A Broadway	HEWLETT		NY	11557
Phone	Title			
516-612-0882	PRESIDENT/CEO			
Description of Duties				
CEO + director of operations at SMC returns corp. Serves as person in charge for licenses required from state + federal licensures. Oversees day to day operations.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

6/26/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Avraham Sacks

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/26/2024

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Nassau

I, Avraham Sacks, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/27/2024

Date

Subscribed and Sworn to before me this 27 day of June 2024

Cindy Henggeler

Notary Public Signature

CINDY HENGGELER
Notary Public – State of New York
NO. 01HE6143717
Qualified in Nassau County
My Commission Expires 4-17-26

(Seal)



SMC Returns Corp Employee List

1. Avraham Sacks – President
2. Isaac Bloch – Operations Coordinator
3. Mellisa Brandt – Narcotics & Operations Technician
4. Carla Martinez – Narcotics & Operations Technician
5. Irvin Saravia – Lead Technician

1183A BROADWAY HEWLETTE, NY 11557-2336
T (516) 612-0882

4MM

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada ☐ Out-of-Nevada	☑ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☐ Retail/Community ☑ Hospital (# beds 9) ☐ Internet ☐ Nuclear ☐ Other:	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☑ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☑ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☑ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☑ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: ER at South Summerlin an Extension of Summerlin Hospital

Physical Address: 10290 West Flamingo Road Suite 100

City: Las Vegas State: NV Zip: 89135

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: N/A Toll Free # (NAC 639.708, NRS 639.23286): N/A

Fax: N/A Contact Email: N/A

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Mona Mazloumi

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 20584

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Cheyenne Santee	NV Pharmacist Registration #: 20003
Name: Carissa Smith	NV Pharmacist Registration #: 20094
Name: Serena Evans	NV Pharmacist Registration #: 16958
Name: Gabrielle Szczeblowski	NV Pharmacist Registration #: 23064
Name: Mouna Mazloumi	NV Pharmacist Registration #: 20584
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: DELAWARE

Parent Company (if any): UNIVERSAL HEALTH SERVICES, INC. (ultimate parent company)

Corporation Name: SUMMERLIN HOSPITAL MEDICAL CENTER LLC

Mailing Address: 367 SOUTH GULPH ROAD

City: KING OF PRUSSIA State: PA Zip: 19406-0958

Telephone: 610-768-3300 Email: uhscorpfilings@uhsinc.com

Contact Person Name: STEVE FILTON

Date of SEC Registration: 1981 | SEC Registration Number: 1-10765 | Stock Exchange Symbol: UHS

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☒ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

ER at South Summerlin, an Extension of Summerlin Hospital

1. I am the AUTHORIZED OFFICIAL (title) for _____ (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

STEVE FILTON

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

10/1/2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Mouna Mazloumi hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Managing Pharmacist (title) for ER at South Summerlin, an exterion of Summerlin Hospital (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 25 day of September, 2024

Notary Public

RITA SEPIAN SACCOYAN
NOTARY PUBLIC
STATE OF NEVADA
APPT. NO. 12-7577-1
MY APPT. EXPIRES FEBRUARY 24, 2025

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Mouna Mazloumi Pharmacist Registration #: 20584

Pharmacy Name: ER at South Summerlin, an extension of Summerlin Hospital

Initial each statement below to indicate you have read and agree with the following:

MM MM I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

MM MM I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

MM MM I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

MM MM I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

MM MM I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✓

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

9/24/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Steve Filton

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

10/1/2024

Date

Board Use Only	Date Received: 10/7/24	Amount: $500-CK 113138638

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "RBNY 830 LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SEVENTH DAY OF SEPTEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "RBNY 830 LLC" WAS FORMED ON THE TWENTY-EIGHTH DAY OF DECEMBER, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.





2847887 8300

SR# 20243807630

Authentication: 204502881

Date: 09-27-24

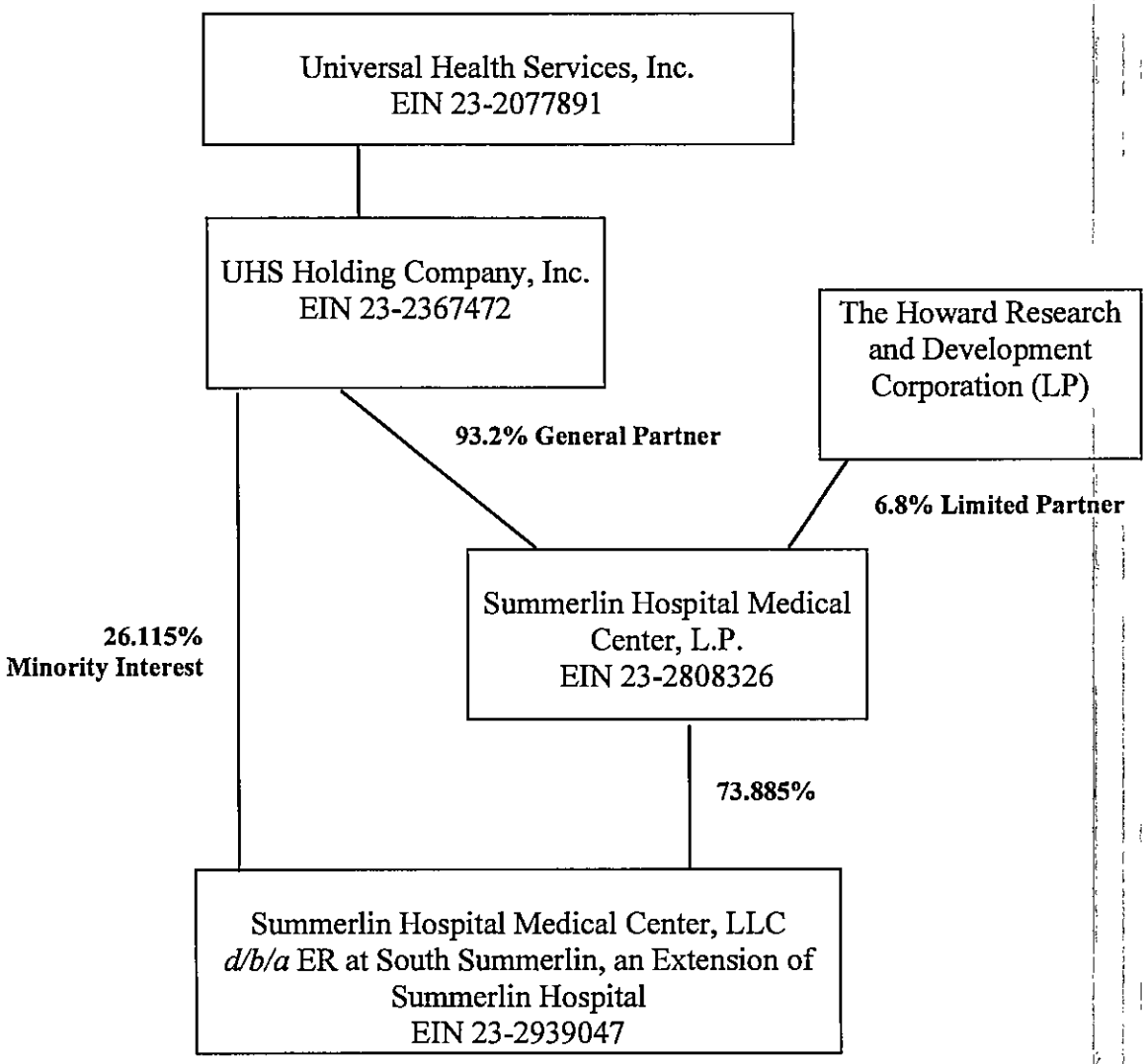
You may verify this certificate online at corp.delaware.gov/authver.shtml

- **List all Officers and Directors: NRS 639.231(2)(b), NAC 639.214(5)(a)**
  - Edward Sim – President (Director)
  - Steve Filton – Vice President (Director)
  - Matthew Klein – Vice President, Secretary (Director)
  - George H. Brunner, Jr. – Assistant Secretary
  - Cheryl K. Ramagano – Treasurer
  - Katharine Lyver – Assistant Treasurer

- **List the top four stockholders and their percent ownership. NRS 639.231(3)**

  For UHS, Inc.: Alan B. Miller – 12.5%; The Vanguard Group – 11.7%; First Eagle Investment Management, LLC – 7.7%; BlackRock, Inc. – 7.3%

SUMMERLIN HOSPITAL MEDICAL CENTER LLC
CORPORATE STRUCTURE



SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

SUMMERLIN HOSPITAL MEDICAL CENTER LLC

Nevada Business Identification # NV19981003735
Expiration Date: 01/31/2025

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 01/15/2024.

Certificate Number: B202401154265726
You may verify this certificate online at http://www.nvsos.gov

FRANCISCO V. AGUILAR
Secretary of State

4NN

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
■ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
☐ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FL1004059
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 04389		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	■ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	■ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: LV Pharmacy and Medical Supplies

Physical Address: 4503 W Sahara Ave #170

City: Las Vegas State: NV Zip: 89102

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-866-7777 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 702-778-4798 Contact Email: lvpharmacyandsupplies@gmail.com

Website: LV Pharmacy & Medical Supplies

Nevada Business License # (if applicable) NV20212096144

Supervising/Managing Pharmacist Name (NRS 639.220): Angela Balian, PharmD

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): Angela Balian, PharmD 17025

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Angela Balian	NV Pharmacist Registration #: 01725
Name: Bijal Patel	NV Pharmacist Registration #: 19645
Name: Phuong Mai	NV Pharmacist Registration #: 23799
Name: Nirmala Mallela	NV Pharmacist Registration #: 13501
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: Angela Balian	Credentials: Owner/PIC	%: 100
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Angela Balian

Business Name: LV Pharmacy and Medical Supplies

Business Address: 4503 W Sahara Ave #170

City: Las Vegas State: NV Zip: 89102

Telephone: 702-866-7777 Email: LVPharmacyandsupplies@gmail.com

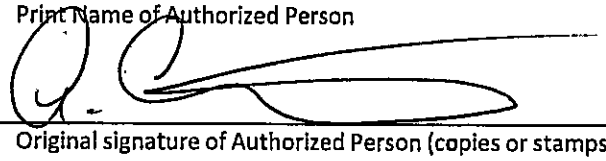
Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner/PIC (title) for LV Pharmacy and Medical Supplies (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Angela Balian, PharmD

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

10/15/2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Angela Balian hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Owner and PIC (title) for LV Pharmacy and Medical Supplies (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 15th day of October, 2024

Notary Public

ETHAN BRIAN KLINGLER
Notary Public-State of Nevada
Appointment No. 23-3014-01
My Appointment Expires Sept. 29, 2027

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Angela Balian Pharmacist Registration #: 17025

Pharmacy Name: LV Pharmacy and Medical Supplies

Initial each statement below to indicate you have read and agree with the following:

AB I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

AB I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

AB I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

AB I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

AB I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

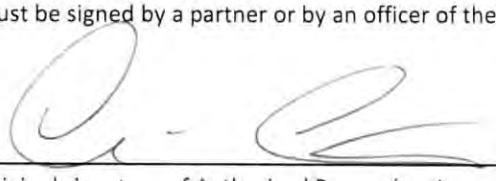
Original signature of Managing Pharmacist (copies or stamps not accepted)

10/15/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Angela Balian, PharmD

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

10/15/2024

Date

Board Use Only	Date Received: 10/21/24	Amount: $800 CC

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FL1004059	03-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	12-01-2021

LV UNIQUE CARE LLC
DBA LV PHARMACY AND MEDICAL SUPPLIES
4503 W SAHARA AVE # 170
LAS VEGAS, NV 89102-3760

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

1819

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site LV Pharmacy and Medical Supplies

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH04389

Physical Address 4503 W Sahara Ave #170

City Las Vegas State NV Zip 89102

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-866-7777 Website LV Pharmacy & Medical Supplies

Licensing Company Email LVpharmacyandsupplies@gmail.com

Section 2: Personal Information

First Angela Middle _____ Last Balian

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Addre[redacted]Dark Hollow PL

City Las Vegas State NV Zip 89117

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Massachusetts College of Pharmacy and Health Siences Boson		2001-2006	
Address	**City**	**State**	**Zip**
179 Longwood Ave	Boston	MA	02115
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Watertown High School		1996-2001	
Address	**City**	**State**	**Zip**
50 Columbia St	Watertown	MA	02472
Diploma/Degree obtained, if any			
High School			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2012-present	[redacted]Dark Hollow Pl	Las Vegas	NV	89117
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: LV Pharmacy and Medical Supplies			From - To (MM/YY – MM/YY): 02/21- pesent
Business Address: 4503 W Sahara Ave #170	City: Las Vegas	State: NV	Zip: 89102
Phone: 702-866-7777	Title: Owner/PIC		
Description of Duties: Owner and Pharmacist in Charge.			

Business Name: Savon Pharmacy			From - To (MM/YY – MM/YY): 07/2006-02/2021
Business Address: 11720 W Charleston BLVD	City: Las Vegas	State: NV	Zip: 89135
Phone: 702-363-3306	Title: Pharmacist		
Description of Duties: Performed all pharmacist duties.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.		Yes	No
1.	Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2.	If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3.	Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4.	Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5.	Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6.	Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7.	Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8.	Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9.	Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10.	Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Angela Balian

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/15/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, ANGELA BALIAN, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date 10/15/2024

Subscribed and Sworn to before me this 15th day of October.

Notary Public Signature

ETHAN BRIAN KLINGLER
Notary Public-State of Nevada
Appointment No. 23-3014-01
My Appointment Expires Sept. 29, 2027

(Seal)

400

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
■ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Southwest Medical Associates, Inc. dba Southwest Medical Specialties Pharmacy

Physical Address: 2300 West Charleston Blvd. Suite 201A and 201B

City: Las Vegas State: NV Zip: 89102

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: TBD Toll Free # (NAC 639.708, NRS 639.23286): 800-588-5766

Fax: _____ Contact Email: susie.monahan@optum.com

Website: www.smalv.com

Nevada Business License # (if applicable) NV19841012123

Supervising/Managing Pharmacist Name (NRS 639.220): Susan M. Monahan

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 16735

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Susan M. Monahan	NV Pharmacist Registration #: 16735
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): Sierra Health Services Inc.

Corporation/Organization Name: Southwest Medical Associates, Inc. dba Southwest Medical Specialties Pharmacy

Mailing Address: 2300 West Charleston Blvd. Suite 201A and 201B

City: Las Vegas State: NV Zip: 89102

Telephone: _____ Email: susie.monahan@optum.com

Contact Person Name: Susan Monahan

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Director (title) for Southwest Medical Associates, Inc. dba Southwest Medical Specialties Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Dr. Carl Edward Allen

Print Name of Authorized Person

Carl Edward Allen — 8/28/24

Original signature of Authorized Person (copies or stamps not accepted) — Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Susan M. Monahan hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist in Charge (title) for Southwest Medical Specialties Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Susan Monahan
Signature

CHRISTOPHER S. CATABONA
NOTARY PUBLIC
STATE OF NEVADA
APPT. No. 23-6737-01
MY APPT. EXPIRES AUGUST 24, 2027

SUBSCRIBED AND SWORN TO
Before me, a notary public this 28TH day of AUGUST, 2024

Notary Public

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Susan M. Monahan Pharmacist Registration #: 16735

Pharmacy Name: Southwest Medical Associates, Inc. dba Southwest Medical Specialties Pharmacy

Initial each statement below to indicate you have read and agree with the following:

SM I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

SM I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

SM I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

SM I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

SM I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Susan Monahan 9/21/24

Original signature of Managing Pharmacist (copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Susan M. Monahan

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Susan Monahan

Original signature of Authorized Person (copies or stamps not accepted)

9/27/24

Date

Board Use Only	Date Received: 10/3/24	Amount: $500-cc

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **SOUTHWEST MEDICAL ASSOCIATES, INC.** as a DOMESTIC CORPORATION (78) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 08/31/1984, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 08/28/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202408284910924
You may verify this certificate online at https://www.nvsilverflume.gov/home

Management Structure Report

Southwest Medical Associates, Inc.

Directors

Name	Title	Last Elected
Allen, Carl Edward	Director	05/01/2024
Corbin, Toni M	Director	05/01/2024
Gokal, M.D., Nilesh Neil	Director	05/01/2024
Kaur, M.D., Girisha	Director	05/01/2024
Rhodes, John C.	Director	05/01/2024

Officers

Name	Title	Last Elected
Rhodes, John C.	President	05/01/2024
Flynn, Conor Patrick	Secretary	05/01/2024
Gill, Peter Marshall	Treasurer	05/01/2024
Lang, Heather Anastasia	Assistant Secretary	05/01/2024
Zuba, Jessica Leigh	Assistant Secretary	05/01/2024
Rappleye, Ryan Chad	Vice President, Finance	05/01/2024

Data: 8/28/2024 5:02:28 AM **Run: 8/28/2024 10:23:01 AM**

Top four stockholders/Stockholders who own more than 10%.

Owner.Name	Security Interest	Number of Shares	% Owned	Owner Type	Total % Owned
Sierra Health Services, Inc.	Common	100.000000	100.000000	Entity	100.000000

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Southwest Medical Associates, Inc. dba Southwest Medical Specialties Pharmacy

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 2300 West Charleston Blvd. Suite 201A and 201B

City: Las Vegas State: NV Zip: 89102

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: TBD Website: www.smalv.com

Licensing Company Email:

Section 2: Personal Information

First: Susan Middle: Marie Last: Monahan

Alias(es, nicknames, name changes, etc.): Susie

Date of Birt[redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Addr[redacted] Courtney Ann Drive

City: Henderson State: NV Zip: 89074

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Roseman University of Health Sciences		08/2002-06/2005	
Address	**City**	**State**	**Zip**
11 Sunset Way	Henderson	NV	89014
Diploma/Degree obtained, if any			
Doctorate of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
University of Nevada, Las Vegas		01/1998 - 06/2002	
Address	**City**	**State**	**Zip**
4505 S Maryland Way	Las Vegas	NV	89154
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Community College of Southern Nevada		1/1998 - 6/2002	
Address	**City**	**State**	**Zip**
4505 S Maryland Pkwy	Las Vegas	NV	89154
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
University of Nevada, Reno		08/1996 -12/1997	
Address	**City**	**State**	**Zip**
1664 N Virginia Street MS 0249	Reno	NV	89557
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Eldorado High School		8/1992 - 6/1996	
Address	**City**	**State**	**Zip**
1139 N Linn Ln	Las Vegas	NV	89110
Diploma/Degree obtained, if any			
High School Diploma			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2022-Current	[redacted]Courtney Ann Drive	Henderson	NV	89074
09/2012-11/2022	[redacted]listening Cloud Drive	Henderson	NV	89012
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Southwest Medical Pharmacy & Home Medical Equipment			08/2015- Current	
Business Address		City	State	Zip
6720 Placid Street		Las Vegas	NV	89119
Phone	Title		Number of Employed Hours	
702-796-1016	Lead Specialty Pharmacist		18,720	
Description of Duties				
Consulting services for skilled nursing facilities. Pharmacist in charge at Ambulatory Surgery Centers. Perform monthly pharmacy inspections at Cancer Center. Assist pharmacy with obtaining ACHC and URAC accreditation.				

Business Name			From - To (MM/YY – MM/YY)	
Smiths Pharmacy			01/2015-08/2015	
Business Address		City	State	Zip
4001 S Decatur		Las Vegas	NV	89103
Phone	Title		Number of Employed Hours	
702-248-6510	Staff Pharmacist		1,280	
Description of Duties				
Fill and Dispense prescriptions, record keeping of prescription drugs, medication therapy management, administration of vaccinations				

Business Name			From - To (MM/YY – MM/YY)	
Albertsons Pharmacy			6/2005-1/2015	
Business Address		City	State	Zip
5881 E Charleston Blvd		Las Vegas	NV	89142
Phone	Title		Number of Employed Hours	
702-457-1503	Staff Pharmacist		19,760	
Description of Duties				
Fill and dispense prescriptions, record keeping of prescription drugs, medication therapy management, adminstration of vaccinations				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Susan Monahan, **certify that as the designated representative for**

Southwest Medical Associates, Inc. dba Southwest Medical Specialties Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SM I am at least 21 years of age;
3. SM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

SUSAN MONAHAN
Print Name (First, Last)

Susan Monahan
Original Signature (electronic, copies or stamps not accepted)

9/24/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

MONAHAN, SUSAN
Print Name (First, Last)

Susan Monahan
Original Signature (electronic, copies or stamps not accepted)

9/24/24
Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, SUSAN MONAHAN, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Susan Monahan
Original Signature

9/24/2024
Date

Subscribed and Sworn to before me this 24 day of Sept 2024.

Notary Public Signature

COURTNEY L-C WEBER
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 12-06-25
Certificate No: 14-12483-1

(Seal)

4PP

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada ☐ Out-of-Nevada	☑ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (If only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☑ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☑ Retail/Community ☑ Dangerous drugs ☑ Controlled substances DEA #: _____ ☑ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: St. mary pharmacy

Physical Address: 3511 volunteer Boulevard suite 110

City: Henderson State: N.V. Zip: 89044

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: _____ Contact Email: St Mary pharmacy Henderson@gmail.com

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Mathew Eissa

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23068

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Mathew Eissa	NV Pharmacist Registration #: 23068
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): ~~Aliante LLC~~

Corporation/Organization Name: Aliante LLC

Mailing Address: [redacted] valadon ave

City: Henderson State: N.V. Zip: 89044

Telephone: [redacted] Email: [redacted]

Contact Person Name: Mathew

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner (title) for St. mary pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Mathew Eissa

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

6/10/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Mathew Eissa. hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the owner (title) for St. mary pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 19 day of July, 2024

Notary Public

WILLIAM R. HAGGARD
NOTARY PUBLIC
STATE OF NEVADA
APPT. No. 23-1414-01
MY APPT. EXPIRES MAY 28, 2027

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Matthew Eisig Pharmacist Registration #: 23068

Pharmacy Name: _____

Initial each statement below to indicate you have read and agree with the following:

ME — I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

ME — I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

ME — I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

ME — I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

ME — I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

6/10/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Matthew Eissa

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

6/10/2024

Date

Board Use Only	Date Received: 7/29/24	Amount: $500-cc

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Aliante LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 10/17/2023, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 08/03/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202408034854773
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler St. mary pharmacy

Pharmacy/MDEG/Wholesaler License # (if applicable) _____

Physical Address 3581 Volunteer Blvd Suite 110

City Henderson State N.V. Zip 89044

Mailing Address (if different from physical address) [redacted] valadon Ave

City Henderson State N.V. Zip 89044

Telephone [redacted] Website N/A

Licensing Company Email N/A

Section 2: Personal Information

First Mathew Middle _____ Last Eissa

Alias(es, nick[redacted]anges, etc.) _____

Date of Birth [redacted] SSN or ITI[redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] Valadon ave

City HENDERSON State nv Zip 89044

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Roseman University of Health Sciences		07/2019-05/2022	
Address	**City**	**State**	**Zip**
11 sunset way	henderson	NV	89014
Diploma/Degree obtained, if any			
PharmD. MBA.			

School Name		From - To (MM/YY – MM/YY)	
Nevada State University		09/2015-07/2019	
Address	**City**	**State**	**Zip**
1300 Nevada state Dr	Henderson	NV	89002
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/2010 - present	[redacted]valadon	Henderson	NV	89044
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Saint Mary Pharmacy			10/2023-present
Business Address	**City**	**State**	**Zip**
4180 S rainbow blvd #808	Las Vegas	NV	89044
Phone	**Title**		
702-722-3707	staff pharmacist		

Description of Duties

supervise the activities of the pharmacy and distribute medications in accordance with doctor's orders.

Business Name			From - To (MM/YY – MM/YY)
Desert Hope Treatment center			06/2023-present
Business Address	**City**	**State**	**Zip**
2465 E twain ave	Las Vegas	NV	89121
Phone	**Title**		
702-201-6937	Staff Pharmacist		

Description of Duties

distributing prescription drugs, performing health examinations, administering vaccinations, and offering guidance on the responsible use of medications.

Business Name			From - To (MM/YY – MM/YY)
Omnia Pharmacy			10/2022-11/2023
Business Address	**City**	**State**	**Zip**
1807 W charleston Blvd ste #110	Las Vegas	NV	89044
Phone	**Title**		
702-405-8585	Pharmacist In Charge		

Description of Duties

Among my responsibilities were overseeing pharmacy employees, filling and distributing prescriptions, keeping in touch with medical professionals, and making sure the pharmacy ran smoothly every day.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Eissa, Mathew
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

~~08/01/2024~~ 8/29/24
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Mathew Eissa, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/29/24
Date

Subscribed and Sworn to before me this 29 day of August, 2024

Notary Public Signature

WILLIAM R. HAGGARD
NOTARY PUBLIC
STATE OF NEVADA
APPT. No. 23-1414-01
MY APPT. EXPIRES MAY 28, 2027

(Seal)

4QQ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
■ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	■ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: NA
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.)	☐ Other:	■ Non-sterile Compounding
			■ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			■ Long Term Care
	* Current license #:		■ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: The Medicine Shoppe LTC Pharmacy

Physical Address: 5801 W Craig Dr. Ste 130

City: Las Vegas State: NV Zip: 89130

Mailing Address (if different from physical address): NA

City: _____ State: _____ Zip: _____

Telephone: 702 268 8808 Toll Free # (NAC 639.708, NRS 639.23286): NA

Fax: 702 268 8848 Contact Email: 2169@medicineshoppe.com

Website: www.medicineshoppe.com

Nevada Business License # (if applicable) NV20191561333

Supervising/Managing Pharmacist Name (NRS 639.220): Angela Marie Caracci

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 20417

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Angela Marie Caracci	NV Pharmacist Registration #: 20417
Name: NA	NV Pharmacist Registration #: NA
Name: NA	NV Pharmacist Registration #: NA
Name: NA	NV Pharmacist Registration #: NA
Name: NA	NV Pharmacist Registration #: NA
Name: NA	NV Pharmacist Registration #: NA
Name: NA	NV Pharmacist Registration #: NA
Name: NA	NV Pharmacist Registration #: NA
Name: NA	NV Pharmacist Registration #: NA
Name: NA	NV Pharmacist Registration #: NA

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: Mariana Tadros	Credentials: NA	%: 40
Name: Wael Anwar	Credentials: NA	%: 40
Name: Chad Valencia	Credentials: NA	%: 20
Name: NA	Credentials: NA	%: NA
Name: NA	Credentials: NA	%: NA

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: NA

Parent Company (if any):

Corporation Name: NA

Mailing Address: NA

City: NA State: NA Zip: NA

Telephone: NA Email: NA

Contact Person Name: NA

Date of SEC Registration: NA	SEC Registration Number: NA	Stock Exchange Symbol: NA

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): NA

Corporation/Organization Name: The Medicine Shoppe

Mailing Address: 11027 Sardina Sands Dr.

City: Las Vegas State: NV Zip: 89141

Telephone: 702 268 8808 Email: 2169@medicineshoppe.com

Contact Person Name: Mariana Tadros

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: NA

Mailing Address: NA

City: NA State: NA Zip: NA

Telephone: NA Email: NA

Contact Person Name: NA

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: NA

Business Name: NA

Business Address: NA

City: NA State: NA Zip: NA

Telephone: NA Email: NA

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Mariana Tadros (title) for The Medicine Shoppe LTC Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Mariana Tadros

Print Name of Authorized Person

Mariana A. [illegible]

Original signature of Authorized Person (copies or stamps not accepted)

8/28/2024

Date

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Angela Caracci Pharmacist Registration #: 20417

Pharmacy Name: The Medicine Shoppe LTC Pharmacy

Initial each statement below to indicate you have read and agree with the following:

AC I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

AC I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

AC I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

AC I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

AC I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✔

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:
N/A	N/A	N/A	N/A

Criminal Action:	State:	Date:	Case #:	County:	Court:
N/A		N/A	N/A	N/A	N/A

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

Date 9/3/24

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mariana Tadros

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Mariana T

Original signature of Authorized ~~Person~~ (copies or stamps not accepted)

8/28/2024

Date

Board Use Only	Date Received: 9/26/24	Amount: $500-cc

SECRETARY OF STATE

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **ALLIED HEALTH CARE SOLUTIONS, INC.** as a DOMESTIC CORPORATION (78) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 08/26/2019, and in good standing in this State.

I further certify that the above DOMESTIC CORPORATION (78) has its formation or qualification document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 09/09/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202409094948231
You may verify this certificate online at https://www.nvsilverflume.gov/home

List of officers and directors

President	Mariana Tadros
Secretary	Mariana Tadros
Treasurer	Mariana Tadros
Director	Mariana Tadros

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: The Medicine Shoppe LTC Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): ~~NA~~

Physical Address: 5801 W Craig Road Suite 130

City: Las Vegas State: NV Zip: 89130

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: N/A Toll Free # (NAC 639.708, NRS 639.23286): N/A

Fax: N/A Contact Email: [redacted]

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Angela Caracci

Supervising/Managing Pharmacist NV Pharmacist Registration #: 20417

Name of Person with direct knowledge of compounding procedures: Angela Caracci

Email of Person with direct knowledge of compounding procedures: [redacted]

Telephone of Person with direct knowledge of compounding procedures: [redacted]

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☒ Low ☒ Medium ☐ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ☒ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Antibiotics; Ceftriaxone, Cefepime, Zosyn, Vancomycin, Tobramycin, Gentamycin, Amikacin

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☒ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
N/A

6. What laboratory performs this additional testing?

Name: N/A

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

7. What is your procedure for visual inspection of compounded sterile products?
-Checking vial/bags before compounding
-Checking calculations and dosing before compounding
-Checking final product for any particulate and/or for turbidity
-Checking final product for any leaking
-Checking expiration dates pursuant to recommended guidelines

8. How often do you perform glove fingertip and medial fill testing?
Once every 6 months

9. What is your policy if an employee fails a glove fingertip or media-fill test?
Repeat the test - Incubate the test as per guidelines- Check results

10. Describe your initial and annual training program for all personnel performing sterile compounding:
Initial orientation of workspace and process of sterile compounding
Initial testing of sterile compounding personnel (mediafill- fingertip- calculations- gowning and didactic training)
Testing of IV personnel every 6 months thereafter

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
Daily cleaning in the beginning and at the end of the day using sterile alcohol in the AM - weekly cleaning in the PM
Weekly cleaning using Oxivir or equivalent
Pharma' d cleaner/ TexQ
Monthly cleaning using Sporoicidal

12. Who performs the sterile compounding process at your facility?
The trained IV (sterile compounding) personnel only

13. Who is responsible and accountable for the sterile compounding process at your facility?
Pharmacist on duty

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
Following USP 797 conditions

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)

1. What type of primary engineering controls will you be using in your facility?
N/A

2. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No

7. If yes, list the name of the device:

8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?
N/A

9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?
N/A

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:
N/A

2. What sterilization methods are utilized at your facility?
N/A

3. Does your facility utilize biological indicators? ☐ Yes ■ No

4. If yes, describe how they are utilized:

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Angela Caracci
Name of Person who Completed the Form

Pharmacist in Charge
Title

Signature (copies or stamps not accepted)

9/10/24
Date

Board Use Only	Date Received: 9/24/24 Date Approved: _____ Approved By: _____

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **ALLIED HEALTH CARE SOLUTIONS, INC.** as a DOMESTIC CORPORATION (78) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 08/26/2019, and in good standing in this State.

I further certify that the above DOMESTIC CORPORATION (78) has its formation or qualification document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 09/09/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202409094948231
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site The Medicine Shoppe LTC Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 5801 W Craig Rd., Suite 130

City Las Vegas State NV Zip 89130

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Chad Middle Alexander Last Valencia

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]ardinia Sands Dr

City Las Vegas State NV Zip 89141

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of California, Los Angeles		09/00-06/03	
Address	**City**	**State**	**Zip**
405 Hilgard Ave.	Los Angeles	CA	90095
Diploma/Degree obtained, if any: Bachelor of Science, Mathematics-Economics			

School Name		From - To (MM/YY – MM/YY)	
Walnut High School		09/97-06/00	
Address	**City**	**State**	**Zip**
400 N Pierre Rd	Walnut	CA	91789
Diploma/Degree obtained, if any: High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
NA			
Address	**City**	**State**	**Zip**
NA	NA	NA	
Diploma/Degree obtained, if any: NA			

School Name		From - To (MM/YY – MM/YY)	
NA		NA	
Address	**City**	**State**	**Zip**
NA	NA	NA	NA
Diploma/Degree obtained, if any: NA			

School Name		From - To (MM/YY – MM/YY)	
NA		NA	
Address	**City**	**State**	**Zip**
NA	NA	NA	NA
Diploma/Degree obtained, if any: NA			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/19-08/24	[redacted]ardinia Sands Dr	Las Vegas	NV	89141
09/18-10/19	[redacted]52nd St., Apt 3F	Woodside	NY	11377
03/2013-09/2018	[redacted]aurel Ridge Dr	Riverside	CA	92509
NA	NA	NA	NA	NA
NA	NA	NA	NA	NA
NA	NA	NA	NA	NA
NA	NA	NA	NA	NA
NA	NA	NA	NA	NA
NA	NA	NA	NA	NA
NA	NA	NA	NA	NA

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
The Medicine Shoppe			09/22-08/24	
Business Address	**City**		**State**	**Zip**
5801 W. Craig Rd, Suite 110	Las Vegas		NV	89141
Phone	**Title**			
725-251-2253	Partner/Owner, Business Development			
Description of Duties				
Managed new and existing accounts Consulted in pharmacy operations				

Business Name			From - To (MM/YY – MM/YY)	
ThriveDX			11/20-03/	
Business Address	**City**		**State**	**Zip**
2021 Ponce De Leon St, Suite 800	Miami		FL	33134
Phone	**Title**			
786-628-3783	Associate Curriculum Engineer			
Description of Duties				
Designed Data Analysis & Data Science Courses				

Business Name			From - To (MM/YY – MM/YY)	
Lumious			03/20-10/20	
Business Address	**City**		**State**	**Zip**
12110 Sunset Hills Rd., Suite 600	Reston		VA	20190
Phone	**Title**			
703-467-8600	Instructor, Course Development			
Description of Duties				
Developed and Instructed Tableau Courses (Contract)				

Business Name			From - To (MM/YY – MM/YY)	
Noble Desktop			05/19-12/19	
Business Address	**City**		**State**	**Zip**
185 Madison Ave	New York		NY	10016
Phone	**Title**			
212-226-4149	Instructor			
Description of Duties				
Taught Data Analysis & Web Development Courses				

Business Name			From - To (MM/YY – MM/YY)	
Codecademy			05/18-05/19	
Business Address	**City**		**State**	**Zip**
575 Broadway	New York		NY	10012
Phone	**Title**			
N/A	Instructor			
Description of Duties				
Taught Data Science courses				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Owl Homecare Pharmacy			10/04-09/17	
Business Address		**City**	**State**	**Zip**
13851 Garvey Ave., Suite A		Baldwin Park	CA	91706
Phone	**Title**			
N/A (Defunct)	Billing Analyst, Consultant, Business Devlopment			
Description of Duties				
Managed existing pharmacy accounts Managed billing of non-covered pharmacy items				

Business Name			From - To (MM/YY – MM/YY)	
NA				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
NA				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
NA				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
NA				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

CHAD VALENCIA

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08-24-24

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, CHAD VALENCIA, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

08-24-24

Date

Subscribed and Sworn to before me this 24th day of August 2024

Notary Public Signature

La Kiesha Lampkin
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 24-1240-01
My Appt. Expires Oct. 5, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: The Medicine Shoppe

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 5801 W Carig Dr. Ste 130

City: Las Vegas State: NV Zip: 89130

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 702-268-8808 Website: www.medicineshoppe.com

Licensing Company Email: 2169@medicineshoppe.com

Section 2: Personal Information

First: Mariana Middle: Awni ALFakhouri Last: Tadros

Alias(es, nicknames, name changes, etc.): Maiden Name: Mariana Alfakhouri

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] Spyglass Dr.

City: Corona State: CA Zip: 92883

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
La Sierra University		2007-2010	
Address	**City**	**State**	**Zip**
4500 Riverwalk Pkwy	Riverside	CA	92505
Diploma/Degree obtained, if any			
Bachelor's of Science - Biology			
School Name		**From - To (MM/YY – MM/YY)**	
Granite Hills		2002-2004	
Address	**City**	**State**	**Zip**
22900 Esaws Ave	Apple Valley	CA	92307
Diploma/Degree obtained, if any			
High School Graduate			
School Name		**From - To (MM/YY – MM/YY)**	
NA			
Address	**City**	**State**	**Zip**
NA	NA	NA	NA
Diploma/Degree obtained, if any			
NA			
School Name		**From - To (MM/YY – MM/YY)**	
NA			
Address	**City**	**State**	**Zip**
NA	NA	NA	NA
Diploma/Degree obtained, if any			
NA			
School Name		**From - To (MM/YY – MM/YY**	
NA		NA	
Address	**City**	**State**	**Zip**
NA	NA	NA	NA
Diploma/Degree obtained, if any			
NA			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/15-Present	[redacted]Spyglass Dr.	Corona	CA	92883
09/13-03/15	[redacted]Dakin Dr.	Corona	CA	92882
04/08-09/13	[redacted]Miami St	Riverside	CA	92506
05/02-04/08	[redacted]pple Valley Rd. #4	Apple Valley	CA	92307
07/95-05/02	[redacted]	Jordan	NA	NA
NA	NA	NA	NA	NA
NA	NA	NA	NA	NA
NA	NA	NA	NA	NA
NA	NA	NA	NA	NA
NA	NA	NA	NA	NA

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
The Medicine Shoppe			06/15-04/18	
Business Address		**City**	**State**	**Zip**
10237 Magnolia Ave		Riverside	CA	92503
Phone	**Title**			
951 710 3151	CEO			
Description of Duties				
Administration and Management				

Business Name			From - To (MM/YY – MM/YY)	
Allergan			12/13-05/15	
Business Address		**City**	**State**	**Zip**
2525 Dupont Dr.		Irvine	CA	92612
Phone	**Title**			
NA	Human Resources Associate			
Description of Duties				
Assist with employee training, relations, benefits, compensation				

Business Name			From - To (MM/YY – MM/YY)	
Adecco Medical Sciences			07/13-12/13	
Business Address		**City**	**State**	**Zip**
2525 Dupont Dr.		Irvine	CA	92612
Phone	**Title**			
NA	Compounting Management Associate			
Description of Duties				
Compound inventory, preparation and data entry				

Business Name			From - To (MM/YY – MM/YY)	
LLVare			09/10-08/12	
Business Address		**City**	**State**	**Zip**
710 Brookside Ave		Redlands	CA	92373
Phone	**Title**			
NA	Research Technician			
Description of Duties				
Isolation of RNA & DNA measurements of mRNA & Pre-mRNA				

Business Name			From - To (MM/YY – MM/YY)	
La Sierra University			01/09-06/10	
Business Address		**City**	**State**	**Zip**
4500 Riverwalk Pkwy		Riverside	CA	92505
Phone	**Title**			
NA	Teacher Assistant			
Description of Duties				
Assistance in office & Lab classes for Physics & Biology				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mariana Tadros

Print Name (First, Last)

Mariana A. T — 8/28/2024

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Riverside

I, Mariana Tadros, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Mariana A. T — 8/28/2024

Original Signature — **Date**

Subscribed and Sworn to before me this 28 day of August, 2024.

Notary Public Signature

Please see attached California Notary Jurat

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Riverside

Subscribed and sworn to (or affirmed) before me on this 28 day of August, 2024, by Mariana Tadros

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

SARA GHOMESHI
COMM. #2449115
NOTARY PUBLIC - CALIFORNIA
RIVERSIDE COUNTY
My Comm. Expires July 2, 2027

(Seal)

Signature

Personal History Application
Nevada State Board of
Pharmacy

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: The Medicine Shoppe LTC Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 5801 Craig Dr. Ste 130

City: Las Vegas State: NV Zip: 89130

Mailing Address (if different from physical address): NA

City: NA State: NA Zip: NA

Telephone: NA Website: www.medicineshoppe.com

Licensing Company Email: 2169@medicine Shoppe.com

Section 2: Personal Information

First: Wael Middle: Nabil Last: Anwar

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Addres[redacted]Lion St.

City: Rancho Cucamonga State: CA Zip: 91730

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Helwan University		09/94-05/98	
Address	**City**	**State**	**Zip**
Cairo , Egypt	NA	NA	NA
Diploma/Degree obtained, if any			
Bachelor In Commerce and Business Administration			
School Name		**From - To (MM/YY – MM/YY)**	
College De La Salle		09/90-05/93	
Address	**City**	**State**	**Zip**
Cairo , Egypt	NA	NA	NA
Diploma/Degree obtained, if any			
High School Graduate			
School Name		**From - To (MM/YY – MM/YY)**	
College Patriarcal		09/81-05/90	
Address	**City**	**State**	**Zip**
Cairo , Egypt	NA	NA	NA
Diploma/Degree obtained, if any			
Middle School Graduate			
School Name		**From - To (MM/YY – MM/YY)**	
NA			
Address	**City**	**State**	**Zip**
NA	NA	NA	NA
Diploma/Degree obtained, if any			
NA			
School Name		**From - To (MM/YY – MM/YY**	
NA		NA	
Address	**City**	**State**	**Zip**
NA	NA	NA	NA
Diploma/Degree obtained, if any			
NA			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/12-Present	[redacted]on st	Rancho Cucamonga	CA	91730
01/07-08/12	[redacted]Grove Ave #1403	Rancho Cucamonga	CA	91730
02/05-12/06	[redacted]omita Dr. #B	Alta Loma	CA	91701
02/03-01/05	[redacted]Placer St. #D	Rancho Cucamonga	CA	91730
06/02-01/03	[redacted]Brevoort St	Kew Gardens	NY	11415
01/02-05/02	[redacted]118th St	Kew Gardens	NY	11415
04/02-12/01	[redacted]Talbot St. #PH-6E	Kew Gardens	NY	11415
01/01-03/01	[redacted]Cameron Ave	Rancho Cucamonga	CA	91729
01/2000-12/2000	[redacted]Pacific Ave	Riverside	CA	92509
10/1999-12/1999	[redacted]W. Badillo St.	West Covina	CA	91790

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Miracle Medical Industries			12/2010-Present
Business Address	**City**	**State**	**Zip**
1701 S. Vineyard Ave #E	Ontario	CA	91761
Phone	**Title**		
	CEO		

Description of Duties

Importing and Distributing of Medical Supplies

Business Name			From - To (MM/YY – MM/YY)
Delicare Medical Supplies			09/2013-11/2014
Business Address	**City**	**State**	**Zip**
2132 S. Grove Ave #6	Ontario	CA	91761
Phone	**Title**		
NA	President		

Description of Duties

Distribution of Medical Supplies

Business Name			From - To (MM/YY – MM/YY)
Valero			03/2005-12/2010
Business Address	**City**	**State**	**Zip**
401 W. 6th St	Corona	CA	92882
Phone	**Title**		
NA	Owner		

Description of Duties

Mange, own and operate Gas Station

Business Name			From - To (MM/YY – MM/YY)
Valero			01/2003-02/2005
Business Address	**City**	**State**	**Zip**
5700 Atlantic Blvd.	Maywood	CA	90270
Phone	**Title**		
NA	Owner		

Description of Duties

Manage, Own and operate Gas Station

Business Name			From - To (MM/YY – MM/YY)
Mobil			01/2000-05/2001
Business Address	**City**	**State**	**Zip**
6824 Valley Way	Riverside	CA	92509
Phone	**Title**		
NA	Manager		

Description of Duties

Manage Employees and Daily operations

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Delta Bank			06/1999-09/1999
Business Address	**City**	**State**	**Zip**
1191 Kornish El Nile - EGYPT	Downtown	NA	NA
Phone	**Title**		
NA	Accountant		
Description of Duties			
Process Letter of Credits to receive and send internationally			

Business Name			From - To (MM/YY – MM/YY)
NA			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
NA			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
NA			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
NA			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Wael Anwar

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/31/24

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

See Attached Notarial Certificate

(Seal)

CALIFORNIA JURAT **GOVERNMENT CODE § 8202**

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of San Bernardino

Subscribed and sworn to (or affirmed) before me on

this 31 *Date* day of August *Month*, 20 24 *Year*, by

(1) Wael Anwar

(and (2) _____ *Name(s) of Signer(s)*),

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

STEPHANIE FREE
Notary Public - California
San Bernardino County
Commission # 2431122
My Comm. Expires Dec 16, 2026

Place Notary Seal and/or Stamp Above

Signature _____ *Signature of Notary Public*

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: _____

Document Date: _____ Number of Pages: _____

Signer(s) Other Than Named Above: _____

©2019 National Notary Association

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: The Medicine Shoppe LTC Pharmacy

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 5801 W Craig Road Suite 130

City: Las Vegas State: NV Zip: 89130

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: N/A Website: N/A

Licensing Company Email: N/A

Section 2: Personal Information

First: Angela Middle: Marie Last: Caracci

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] Verismo Street

City: Las Vegas State: NV Zip: 89141

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Roseman University of Health Sciences		08/14-06/18	
Address	**City**	**State**	**Zip**
11 Sunset Way	Henderson	NV	89014
Diploma/Degree obtained, if any			
Master of Business Administration, Doctor of Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
SUNY Potsdam		06/10-06/14	
Address	**City**	**State**	**Zip**
44 Pierrepont Ave.	Potsdam	NY	13676
Diploma/Degree obtained, if any			
Bachelor of Science-Biology			
School Name		**From - To (MM/YY – MM/YY)**	
College of Southern Nevada		01/09-05/10	
Address	**City**	**State**	**Zip**
6375 W Charleston Blvd.	Las Vegas	NV	89146
Diploma/Degree obtained, if any			
N/A			
School Name		**From - To (MM/YY – MM/YY)**	
Great Basin College		08/08-12/08	
Address	**City**	**State**	**Zip**
551 E Calvada Blvd.	Pahrump	NV	89048
Diploma/Degree obtained, if any			
N/A			
School Name		**From - To (MM/YY – MM/YY)**	
Sierra Vista High School		08/04-06/08	
Address	**City**	**State**	**Zip**
8100 W Robindale Rd.	Las Vegas	NV	89113
Diploma/Degree obtained, if any			
High School Diploma			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/03-Present	(Lived off and on) [redacted]Verismo St.	Las Vegas	NV	89141
08/18-07/19	[redacted]E Murray Canyon Dr. #825	Palm Springs	CA	92264
05/13-05/14	[redacted]Washington St.	Potsdam	NY	13676
06/10-04/13	[redacted]Birchwood Dr.	Gouverneur	NY	13642
01/00-01/03	[redacted] S Eastern Ave.	Henderson	NV	89052
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Centennial Hills Hospital-CentRx			03/20-Present	
Business Address		**City**	**State**	**Zip**
6850 N Durango Dr.		Las Vegas	NV	89149
Phone	**Title**		**Number of Employed Hours**	
702-835-9700	Pharmacist		5000	

Description of Duties

Dispensed bedside delivery prescription medications to patients within the hospital, worked in the inpatient setting verifying medication orders and overseeing IV compounding, and provided immunizations.

Business Name			From - To (MM/YY – MM/YY)	
Walmart Pharmacy			02/21-03/23	
Business Address		**City**	**State**	**Zip**
1807 W Craig Rd.		Las Vegas	NV	89032
Phone	**Title**		**Number of Employed Hours**	
702-633-6521	Pharmacist		1800	

Description of Duties

Participated and lead COVID-19 vaccine clinics, dispensed medications, counseled patients.

Business Name			From - To (MM/YY – MM/YY)	
Eisenhower Medical Center			07/18-02/19	
Business Address		**City**	**State**	**Zip**
39000 Bob Hope Dr.		Rancho Mirage	CA	92270
Phone	**Title**		**Number of Employed Hours**	
760-340-3911	Graduate Intern Pharmacist		1200	

Description of Duties

Sterile preparation of medications, updated existing clinical guidelines with current data and evidence based practice.

Business Name			From - To (MM/YY – MM/YY)	
Walgreens Pharmacy			01/16-08/17	
Business Address		**City**	**State**	**Zip**
10510 Southern Highlands Pkwy		Las Vegas	NV	89141
Phone	**Title**		**Number of Employed Hours**	
702-260-1992	Pharmacy Intern		620	

Description of Duties

Received new prescriptions by phone, transferred prescriptions, counseled patients, provided immunizations.

Business Name			From - To (MM/YY – MM/YY)	
N/A			N/A	
Business Address		**City**	**State**	**Zip**
N/A		N/A	N/A	N/A
Phone	**Title**		**Number of Employed Hours**	
N/A	N/A		N/A	

Description of Duties

N/A

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Angela Caracci, **certify that as the designated representative for**

The Medicine Shoppe LTC Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AC I am at least 21 years of age;
3. AC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Angela Caracci

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/3/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Angela Caracci

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/3/24

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Angela Caracci, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/3/24

Date

Subscribed and Sworn ~~to before~~ me this 3rd day of September. 2024

Notary Public Signature

JONATHAN SOSA
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 18-2069-1
My Appt. Expires January 31, 2026

(Seal)

4RR

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New OUTSOURCING FACILITY
☑ Ownership Change (Provide current license number if making changes:) OUT 00020
☐ 503a OR ☐ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4
☑ Non Publicly Traded Corporation – Pages 1-3 & 5
☐ Partnership - Pages 1-3 & 6
☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: Wedgewood Connect LLC

Physical Address: 17 Great Oaks Blvd

City: San Jose State: CA Zip Code: 95119

Telephone: 800-216-5005 Fax: 800-589-4250

Toll Free Number: 800-216-5005 (Required per NAC 639.708)

E-mail: licensing@wedgewoodpharmacy.com Website: www.wedgewoodpharmacy.com

Supervising Pharmacist: Paul Yamamoto Nevada License #: 19734

SERVICES PROVIDED

Yes/No

☑ ☐ Parenteral
☑ ☐ Sterile Compounding
☑ ☐ Non Sterile Compounding
☐ ☑ Mail Service Sterile Compounding
☐ ☑ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: _____ Amount: $500-check 55859

FEI Number (From FDA application): 46-1904395

Please provide the name of the facility as registered with the FDA and the registration number:
Wedgewood Connect LLC - The FDA does not provde registration numbers.

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
Wedgewood Connect LLC

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Paul Yamamoto Nevada License Number: 19734

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: N/A

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☑ No ☐

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☑

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Joseph Costa

Print Name of Authorized Person

4/15/2024

Date

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Wedgewood Holdings Inc

Address: 405 Heron Drive Suite 200

City: Swedesboro State: NJ Zip: 08085

Telephone: 800-331-8272 Fax: 856-491-4409

Contact Person: Joseph Costa, President & COO

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) There are no individual shareholders in Wedgewood Connect/Village Pharmacy as it is a member managed limited liability company.
Name Address

b) All shares in Wedgewood Holdings Inc. are held by Specialty Pharma III Inc.
Name Address

c) N/A
Name Address

d) N/A
Name Address

2) Provide the number of shares issued by the corporation. N/A

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information

Include with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	11/1/2023-11/17/2023* FEI NUMBER 3003434972

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Craig Mastenbaum, General Manager

FIRM NAME	STREET ADDRESS
Wedgewood Connect, LLC	17 Great Oaks Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Jose, CA 95119-1359	Outsourcing Facility

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Written records are not always made of investigations into unexplained discrepancies.

Specifically,

A) Investigations are not always performed for environmental/personnel monitoring excursions within the ISO-5 and ISO-7 (action limits of 1cfu and 10cfu, respectively) areas as required by SOP 3.030, Environmental Monitoring, Version: 10, Date Effective: 09/22/2023. The following are examples where investigations were not performed to determine a root cause, product impact, and the need to implement a CAPA to prevent recurrence:

Date of Sampling	Location	ISO	Result	Organism (if identified)	Associated Product and Lot Number
09/26/2022	SPO-RG-JN (right glove)	5	1cfu	Fungal (Unable to ID)	Cyclosporine 0.2% in Corn Oil, 15mL Lot #222-04359668
03/10/2022	PRO-RSL-JSF (right sleeve)	5	1cfu	*Kocuria rhizophila*	Demecarium Bromide 0.125% Ophthalmic Solution, Lot #222-03828066
03/10/2023	PRO-LG-RSS (left glove)	5	1cfu	*Micrococcus luteus*	Tacrolimus 0.02% in Corn Oil, 15mL Lot #222-04773588

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jeffrey P Raimondi, Consumer Safety Officer Anney Lin, Investigator Andrew Le, Investigator	X	11/17/2023

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	11/1/2023-11/17/2023* FEI NUMBER 3003434972

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Craig Mastenbaum, General Manager

FIRM NAME	STREET ADDRESS
Wedgewood Connect, LLC	17 Great Oaks Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Jose, CA 95119-1359	Outsourcing Facility

04/14/2023	SPO-LG-JCS (left glove)	5	1cfu	*Bacillus altitudinis*	Cyclosporine 2% Ophthalmic Suspension, 15mL Lot #222-04867883
05/01/2023	PRO-RSL-RL2 (right sleeve)	5	1cfu	*Kocuria palustris*	Buprenorphine 0.6 mg/mL Injection Solution, Lot #222-0492660
11/03/2022	FH-RSS 2 (operator forehead)	7	13cfu	*Staphylococcus aureus* and *Staphylococcus epidermidis*	Tacrolimus 0.03% in Corn Oil, 15mL Lot #222-04449139, Tacrolimus 0.03% in Corn Oil, 5mL Lot #222-04449798, and Tacrolimus 0.02% in MCT Oil 10mL Lot #222-04449137
07/06/2023	Cart Wheel #2	7	TNTC	Unable to ID	No production in this room
08/04/2023	RSS (operator forehead)	7	13	*Rhizobium* species	Tacrolimus 0.03% Ophthalmic Suspension, 15mL Lot #222-05158064 and Tacrolimus 0.02% in MCT Oil, 5mL Lot #222-05173240

B) Investigation into the turbid media fill 15ml bottle under OOS00041, for lot# 222-05200073 did not include identification of the microorganism recovered. Additionally, the operator who performed this media fill was not requalified through performance of an additional media fill, and to date, this operator has filled approximately 21 batches of sterile human and animal drug products.

C) Complaint investigations do not include evaluation of retain samples as required by procedure 5.031, Customer Complaints, Version: 5.0, Date Effective: 06/01/2022. The following are examples were retain samples were not evaluated:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jeffrey P Raimondi, Consumer Safety Officer Anney Lin, Investigator Andrew Le, Investigator	X	11/17/2023

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	11/1/2023-11/17/2023* FEI NUMBER 3003434972

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Craig Mastenbaum, General Manager	
FIRM NAME Wedgewood Connect, LLC	STREET ADDRESS 17 Great Oaks Blvd
CITY, STATE, ZIP CODE, COUNTRY San Jose, CA 95119-1359	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

Complaint Number	Due Date	Product	Lot Number	Description
C-350-2022	10/20/2022	Cyclosporine 2% in Corn Oil-15mL	222-03548354	Fuzzy layer on the bottle that looks like crystals
C-650-2022	02/14/2023	Cyclosporine Corn 2% Ophth 15ml	222-03859621	Medication looks cloudy and has particulates
C-147-2023	06/28/2023	Cyclosporine Corn 2% Ophth 15ml	222-04175692	Medication has chunks in it
C-266-2023	08/17/2023	Cyclosporine Corn 1% Ophth 15ml	222-04470208	Black spec inside bottle

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, disinfectant efficacy studies have not been performed for the Decon-Quat 200, Decon SPORE 200 Plus, Sterile 70% IPA, and the Hypo-Chlor 0.52% cleaning solutions used within your ISO-5 and ISO-7 aseptic processing areas, to confirm these solutions are appropriate for use within these areas and against all surface types they are used on. The ISO-5 and ISO-7 aseptic processing areas are used for human and animal drug production.

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jeffrey P Raimondi, Consumer Safety Officer Anney Lin, Investigator Andrew Le, Investigator	X	11/17/2023

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	11/1/2023-11/17/2023* FEI NUMBER 3003434972

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Craig Mastenbaum, General Manager	
FIRM NAME Wedgewood Connect, LLC	STREET ADDRESS 17 Great Oaks Blvd
CITY, STATE, ZIP CODE, COUNTRY San Jose, CA 95119-1359	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

Specifically,

A) Surface sampling locations within the ISO-5 areas for processing human and animal drugs are not supported with appropriate studies.

B) The non-viable particle monitoring probes within the ISO-5 Biological Safety Cabinets (BSC) (such as E-0077-W, E-0078-W, and E-0079-W) and Laminar Airflow Hoods (LAF) (such as E-0082-W) are not pointed into the direction of the airflow. Within the BSCs, probes were observed pointing towards the operator and perpendicular to the direction of airflow. The probes within the LAF were observed pointing the same direction as the airflow.

C) The non-viable particle monitoring probes within the ISO-7 cleanrooms such as rooms 120 and 121 are not pointed into the direction of the airflow. Rather these probes are hanging from the ceiling and pointed towards the floor.

D) The ISO-7 rooms containing the ISO-5 filling BSCs and LAFs are only required to be tested for viable (surface and active air) microorganisms once per week as required by SOP 30.030, Environmental Monitoring, Version 10, Effective Date: 09/22/2023, Table 2: Frequency of Sampling in ISO-7 Classifications. The ISO-7 rooms are not required to be tested each day the ISO-5 BSC and LAFs are in use.

OBSERVATION 4

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

Specifically,

A) Requalification of the Steam Sterilization Process for Liquid Loads (1L Bottle Formats) in the

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jeffrey P Raimondi, Consumer Safety Officer Anney Lin, Investigator Andrew Le, Investigator	X	11/17/2023

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	11/1/2023-11/17/2023* FEI NUMBER 3003434972

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Craig Mastenbaum, General Manager	
FIRM NAME Wedgewood Connect, LLC	STREET ADDRESS 17 Great Oaks Blvd
CITY, STATE, ZIP CODE, COUNTRY San Jose, CA 95119-1359	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

Fedegari Autoclave, Model FOAF3/AG, Equipment ID# E-0832-W, performed 11/11/2022 failed to meet the minimum requirement of 121°C on thermocouple TC-09. Thermocouple TC-09 reported a value of 120.05 during the qualification. The acceptance criteria states the minimum temperatures from all thermocouples during sterilization phase must be ≥ 121°C.

Additionally, Thermocouple TC-19, failed its pre- and post- calibration check and was used during the requalification.

Although the requalification occurred 11/11/2022, to date, the final report has not been approved by the quality unit.

This autoclave is used to sterilize human and animal drug products inside 1L bottles, prior to these products being aseptically filled. Between 11/11/2022 and now, there have been approximately 112 batches of drug product sterilized with this equipment.

B) Operators were observed blocking first pass air on 11/01/2023 while filling the following drug products:
- Tacrolimus 0.02% in Corn Oil, Ophthalmic Solution, 15 mL lot #222-05403992
- Cyclosporine 2%/Tacrolimus 0.2% in Corn Oil, Ophthalmic Solution, 15 mL lot #222-05400373

C) Airflow visualization studies are inadequate for the following reason:

1. The generated smoke was not robust enough to show the flow of air.

2. Smoke was not always observed to be directly above the area where the activity was occurring during video "E-0077-W Dropper Bottles Process APR2023". Smoke appeared to be in the back corner of the BSC while operator activities were occurring in the center of the BSC.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jeffrey P Raimondi, Consumer Safety Officer Anney Lin, Investigator Andrew Le, Investigator	X	11/17/2023

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	11/1/2023-11/17/2023* FEI NUMBER 3003434972

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Craig Mastenbaum, General Manager	
FIRM NAME Wedgewood Connect, LLC	STREET ADDRESS 17 Great Oaks Blvd
CITY, STATE, ZIP CODE, COUNTRY San Jose, CA 95119-1359	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

3. Unidirectional airflow was interrupted with eddy currents detected at timepoint 0:31 during video "E-0078-W Dynamic Basic APR2023".

4. While smoke studies were performed for opening and closing droppers among the ISO-5 hoods, the entire filling process including setup and filling operations have not been evaluated within each hood under dynamic conditions as part of qualification.

OBSERVATION 5

Employees are not given training in the particular operations they perform as part of their function.

Specifically, the visual inspection qualification program is inadequate. There is no assurance that personnel qualified for 100% visual inspection can identify all known critical defects found in your sterile drug products. Operators must score at least a 75% on the qualification, however, the Visual Inspection Qualification Test document shows 10 out of 10 operators who perform visual inspection failed to identify critical defects such as particles during their qualification.

OBSERVATION 6

The quality control unit lacks the responsibility and authority to approve and reject all in process materials and drug products.

Specifically,

A)An Acceptable Quality Limit (AQL) for visual inspection is not performed for sterile drug products.

B)There is no test kit for the 2mL vial, rather operators are qualified using 5mL vial test kits. The 2mL vial is the size of Moxifloxacin 1mg/mL drug product and represents the smallest vial sized

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jeffrey P Raimondi, Consumer Safety Officer Anney Lin, Investigator Andrew Le, Investigator	X	11/17/2023

used for drug products. Additionally, there are no test kits for operator qualification for any product placed in droppers, such as the Cyclosporine and Tacrolimus drug products.

C)The visual inspection qualification Challenge Sets A and B contain vials pre-labeled with a "(P)" on the cap identifying them as containing particles. Personnel performing visual inspection of sterile drug products are required to correctly identify the defects during qualification. These vials pre-labeled with a "(P)" inform the operator that the vial contains a particulate.

D)A standard timer is not used to ensure operators visually inspect each vial and dropper for 5 seconds against white and black backgrounds. Procedure 9.170, Visual Inspection, Version: 2, Effective Date: 06/26/2020 requires operators to visually inspect each unit for a minimum of 5 seconds against each background.

OBSERVATION 7

The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically, your firm has designated hazardous (HD, room 121) and non-hazardous (NHD, room 120) production areas, however, it was noted both forms of drug products could be compounded at the same time within separate BSCs in the formulation room (room 118). For example, on 07/06/2023 Moxifloxacin 1 mg/mL in Sterile Balance Salt Solution (BSS) lot #222-05084791 (which is a NHD drug) was compounded at the same time as Tacrolimus 0.02% in Corn Oil lot #222-05082806 (which is a HD).

OBSERVATION 8

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER 1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	DATE(S) OF INSPECTION 11/1/2023-11/17/2023* FEI NUMBER 3003434972
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Craig Mastenbaum, General Manager	
FIRM NAME Wedgewood Connect, LLC	STREET ADDRESS 17 Great Oaks Blvd
CITY, STATE, ZIP CODE, COUNTRY San Jose, CA 95119-1359	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

Specifically, the following information is not found on your drug product labels:

A) The name of the outsourcing facility.

Example of your drug product labels that do not contain this information:

- Moxifloxacin 1 mg/mL in Sterile Balanced Salt Solution Injection, 1 mL in 2 mL vial (NDC 79926-068-05)

***DATES OF INSPECTION**
11/01/2023(Wed), 11/02/2023(Thu), 11/03/2023(Fri), 11/06/2023(Mon), 11/07/2023(Tue), 11/09/2023(Thu), 11/13/2023(Mon), 11/15/2023(Wed), 11/17/2023(Fri)

X Anney Lin
Investigator
Signed By: 2003914351
Date Signed: 11-17-2023 14:20:44

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jeffrey P Raimondi, Consumer Safety Officer Anney Lin, Investigator Andrew Le, Investigator	X	DATE ISSUED 11/17/2023

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

wedgewood
connect

Wedgewood Connect
17 Great Oaks Blvd
San Jose, CA 95119

December 07th, 2023

Mr. Steven Porter, Program Division Director
Office of Pharmaceutical Quality Operations (OPQO), Division 4
U.S. Food and Drug Administration
San Francisco District Office
1201 Harbor Bay Parkway
Alameda, CA 94502
510-337-6700

Reference: FDA 483 dated November 17th, 2023

Dear Mr. Porter,

This letter is in response to the form FDA 483 issued to Wedgewood Connect, a 503B outsourcer, on 11/17/2023. As an introductory comment, Wedgewood Connect takes all of the Investigators' remarks seriously and intends to be fully compliant with all aspects of current 503B guidance, as well as all appropriate sections of 21 CFR 211.

In regard to the inspection that occurred between 11/01/2023 and 11/17/2023, we appreciate the professionalism of Investigator Anney Lin, Investigator Jeffrey P. Raimondi and Investigator Andrew Le. We acknowledge the FDA's inspectional observations in the FDA 483 issued on 11/17/2023. We recognize that the FDA 483 only touched on specific aspects and that it is the responsibility of Wedgewood Connect to be in full compliance with the regulations and 503B guidance. We have or will enhance our systems and processes as stated in our responses below to address the Agency's observations.

Wedgewood Connect responds as follows to the specific observations from the FDA 483 in the same order found in the FDA 483. The observation is restated, and the response follows.

Observation 1:
Written records are not always made of investigations into unexplained discrepancies.

Specifically,

A) Investigations are not always performed for the environmental/personnel monitoring excursions within ISO-5 and ISO-7 (action limits of 1 cfu and 10cfu, respectively) areas as required by SOP 3.030 Environmental Monitoring, version: 10, Date effective: 9/22/2023. The following are examples where investigations were not performed to determine a root cause, product impact, and need to implement CAPA to prevent recurrence:

wedgewood connect

Date of Sampling	Location	ISO	result	Organism (if identified)	Associated Product and Lot Number
09/26/2022	SPO-RG JN, (right glove)	5	1 cfu	Fungal (Unable to ID)	Cyclosporine 0.2% in corn oil, 15mL Lot # 222-04359668
03/10/2022	PRO-RSL. JSF (right sleeve	5	1 cfu	Kocuria rhizophila	Demecarium Bromide 0.125% Ophthalmic solution, Lot #222-03828066
03/10/2022	PRO-LG RSS (left glove)	5	1 cfu	Micrococcus luteus	Tacrolimus 0.02% 1n Corn Oil, 15mL Lot #222-04773588
04/14/2023	SPO-LG-JCS (left glove)	5	1 cfu	Bacillus altitudinis	Cyclosporine 2% Ophthalmic Suspension 15mL, Lot #222-04867883
05/01/2023	PRO-RSL-RL2 (right sleeve)	5	1 cfu	Kocuria palustris	Buprenorphine 0.6mg/mL injection solution lot # 222-04926600
11/03/2023	FH-RSS 2 (operator forehead)	7	13 cfu	Staphylococcus aureus and Staphylococcus epidermis	Tacrolimus 0.03% in Corn Oil, 15mL Lot #222-04449 139, Tacrolimus 0.03% in Corn Oil, 5mL Lot #222-04449798 and Tacrolimus 0.02% in MCT oil, 10 mL Lot # 222-04449137
07/06/2023	Cartwheel #2	7	TNTC	Unable to ID	No Production in this room
08/04/2023	RSS (operator forehead)	7	13	Rhizobium species	Tacrolimus 0.03% Ophthalmic Suspension 15mL Lot #222-0515806 Tacrolimus 0.03% in MCT oil, 5 mL Lot # 222-05173240

Observation 1 A) Response: We acknowledge the observation. It was pointed out during the inspection that the five ISO 5 recoveries did not require an investigation. SOP 3.030 version 10 *Environmental Monitoring*, at the time of inspection stated that recoveries *beyond* the stated action level of 1 cfu required investigation. Since the results listed in this observation did not exceed the action limit of 1 cfu, no investigations were performed. Wedgewood Connect had based this acceptance criteria for ISO-5 samples as well as when to perform an investigation on USP 797. (See Attachment # 1)

Out of an abundance of caution, a retrospective investigation was performed during the inspection for the one ISO 5 recovery which impacted a single product that had not yet met its expiration date. This investigation (23DR0151) was provided to the inspectors during the audit and is attached to this response (See attachment # 2). The retrospective investigation concluded that there was no impact to the product being produced.

Since the close of the inspection, Wedgewood Connect has completed retrospective investigations for all remaining ISO5 recoveries listed above (See attachment # 3).

All of the ISO5 retrospective investigations concluded that there was no impact to any of the products produced.

Wedgewood Connect acknowledges the three ISO 7 excursions which were missed. Retrospective investigations were performed for all three ISO 7 recoveries. All of the ISO 7 retrospective investigations concluded that there was no impact to any of the products produced. Copies of all the ISO 7 retrospective investigations (23DR0149, 23DR0150, 23DR0152) were provided to the inspectors during the audit (See attachment # 4).

SOP 3.030, *Environmental Monitoring*, was revised to provide clarity and now requires an investigation be performed should any recoveries be found in ISO 5. Step 9.13.1.2 states if the action level is reached or exceeded, Wedgewood Connect must initiate an investigation.
A copy of the newly implemented SOP 3.030 version 11, *Environmental Monitoring* **Date effective: 11/08/2023**; was provided to the inspectors before the conclusion of the audit.
Training record for revised SOP 3.030 version 11 (See attachment # 5).

B) Investigation into the turbid media fill 15ml bottle under OOS00041, for lot# 222-05200073 did not include identification of the microorganism recovered. Additionally, the operator who performed this media fill was not requalified through performance of an additional media fill, and to date, this operator has filled approximately 21 batches of sterile human and animal drug products.

Observation 1 B) Response: We acknowledge the observation. However, Wedgewood Connect had pointed out during the inspection that the media filled unit in question was not integral and was open to the environment. The OOS investigation report OOS00041 stating this container defect was provided to the inspectors (See attachment # 6 for OOS report). During the investigation by the testing laboratory, a hairline fracture was discovered at the bottom of the turbid unit which exposed the contents to environment. Based on this finding, the biannual re-qualification media fill for the operator was not invalidated, and neither was there any requirement to identify or repeat the media fill. The OOS report provided to the inspectors also contained a picture of the hairline fracture. Also based on this finding, and as part of routine Quality process, a Nonconformance Report (NCR) report NCR0052 was initiated on 10/06/2023 for the bottle manufacturer to assess possible damage in transit. The NCR was closed on 11/28/2023. The NCR includes investigation report by the manufacturer and is concluded as inconclusive (See attachment # 7 for NCR report).

All past successive media fill qualification results for this operator were reviewed. There were 4 media fills that this operator had completed since beginning his

employment with Wedgewood Connect. All results met the acceptance criteria of 0 positive units.
As background, Wedgewood Connect has performed approximately 190 media fills since 2020, covering approximately 139892 media filled units. All media filled units during this time have had zero growth.

Although the media fill in question is acceptable based on the fact that the investigation showed the turbid unit was the result of a non-integral unit, out of an abundance of caution, the operator in question has repeated the media fill on 11/22/2023. OOS00041 will be re-opened to add the performance of re-qualification of operator along with the results.

C) Complaint investigations do not include evaluation of retain samples as required by procedure 5.031, Customer Complaints, Version: 5.0, Date Effective; 06/01/2022. The following are examples where retain samples were not evaluated:

Complaint Number	Due Date	Product	Lot number	Description
C- 350-2022	10/20/2022	Cyclosporine 2% in Corn Oil Ophthalmic Solution -15mL	222-03548354	Fuzzy layer on the bottle that look like crystals
C-650-0022	02/14/2023	Cyclosporine 2% in Corn Oil Ophthalmic Solution -15mL	222-03859621	Medication looks cloudy and has particulates
C-147-2023	06/28/2023	Cyclosporine 2% in Corn Oil Ophthalmic Solution -15mL	222-04175692	Medication has chunks in it
C-266-2023	08/17/2023	Cyclosporine 1% in Corn Oil Ophthalmic Solution-15mL	222-04470208	Black spec inside bottle

Observation 1 C) Response: We acknowledge the observation. As discussed, during the inspection, the Quality department investigates each quality related complaint received. As part of the investigation, the Quality department will assess all complaint facts reported, as per procedure. This includes an evaluation of retains. The evaluation of retains was in fact performed at the time the complaints were received and investigated, but inadvertently were not documented.

Retrospectively, Wedgewood Connect has re-evaluated the retains for the lots listed in the observation, as well as the retains for additional batches of the same products.

After evaluating the retains, we found no defects or particles, and there are no concerns with the safety, identity, strength, quality, or purity of our drug products (See attachment # 8)

As a corrective action, Quality department staff involved in complaint investigations were re-trained on the SOP 5.031, Version: 5.0 *Customer Complaints*, (attachment # 9 for re-training).

Observation 2:
Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, disinfectant efficacy studies have not been performed for the Decon-Quat 200, Decon SPORE 200 Plus, Sterile 70% IPA and the Hypo-Chlor 0.52% cleaning solution used within your ISO-5 and ISO-7 aseptic processing areas, to confirm these solutions are appropriate for use within these areas and against all surface types they are used on. The ISO-5 and ISO-7 aseptic processing areas are used for human and animal drug production.

Observation 2 Response: Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act Guidance for Industry states: *"Based on the results of environmental monitoring, the disinfection program must be revised if there are indications that the frequency of disinfection or the methods or type of disinfectant(s) used are inadequate to ensure appropriately clean surfaces. Conducting disinfectant effectiveness testing may be useful in guiding revision of the disinfection program in such cases."*
It also states, *"published literature and supplier certificates of analysis (COAs) can be relied on when initially determining the effectiveness of agents used to clean and disinfect, as necessary, the facility and equipment surfaces, provided that the supplier's cleaning procedures are followed."* (Attachment # 10 for guidance instruction)

Taking the above guidance into reference with results of environmental monitoring, Wedgewood Connect has relied on the manufacturer's CoA and their efficacy studies for determining the effectiveness of cleaning and disinfecting agents and did not see the need to revise the disinfection program. The history of recoveries at Wedgewood Connect indicates 0.04% of the samples recovered growth in the past two years (Over 82,000 environmental samples taken in the sterile ISO 5 and ISO 7 areas).

Wedgewood Connect is fully compliant with known guidance. However, in response to this observation and in contradiction to the Agency's own guidance document, Wedgewood Connect will perform disinfectant efficacy studies on the surface types found in our sterile ISO 7 and ISO 5 areas. This study will commence in December with expected results reported in January 2024.

Observation 3:
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

A) **Surface sampling locations within the ISO 5 areas for processing human and animal drugs are not supported with appropriate studies.**

Observation 3 A) Response: We acknowledge the observation. It was discussed with the inspectors that Wedgewood Connect Surface Sampling locations for ISO 5 areas are based on USP 797. (Same as Attachment # 1 for USP reference).
Based on the history of EM results for ISO-5 locations, Wedgewood Connect is fully complaint with known guidance. However, out of an abundance of caution and in an effort to continuously improve, Wedgewood Connect plans to perform EMPQ for the ISO 5 area. Target time of completion is the end of December 2023.

B) **The non-viable particle monitoring probes within the ISO-5 Biological safety Cabinets (BSC) (such as E-OC77-W, E-0078-W, and E-0079-W) and Laminar Airflow Hoods (LAF) (such as E-0082-W) are not pointed into the direction of the airflow. Within the BSCs, probes were observed pointing towards the operator and perpendicular to the direction of the airflow. The probes within the LAF were observed pointing the same direction as the airflow.**

Observation 3 B) Response: We acknowledge the observation. It was discussed with the inspectors that the non-viable particle monitoring probes in BSCs and LAFs point towards the compounding area to cover the worst case based on *Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practices* that details the recommendation for the sampling head position (Attachment # 11 for reference). Based on this, it was believed that pointing the probes towards the compounding area would be the worst and most appropriate case. Additionally, having the probes facing toward the filter would not be the worst case.

However, in response to this observation and in contradiction to the Agency's own guidance document, Wedgewood Connect has changed the position of the probe in BSCs and LAFs such that there will be an improved monitoring of the air coming from the HEPA filters. This has been instructed in the updated SOP 3.030 version 12: *Environmental Monitoring* (Attachment # 12)

C) **The non-viable particle monitoring probes within the ISO-7 cleanrooms such as rooms 120 and 121 are not pointed in the direction of the airflow. Rather these probes are hanging from the ceiling and pointed towards the floor.**

Observation 3 C) Response: We acknowledge the observation. It was discussed with the inspectors that the non-viable particle monitoring probes point towards the working area of the room to cover the worst case based on *Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing*

Practices that details their recommendation for sampling head position (Same as Attachment # 11). Based on this, it was believed that pointing the probes towards the working area of the room would be the worst and most appropriate case. Additionally, having the probes facing toward the filter would not be the worst case.

However, in response to this observation and in contradiction to the Agency's own guidance document, Wedgewood Connect has changed the position of the probes within the ISO-7 cleanrooms such that there will be improved monitoring of the air coming from the HEPA filters. The corresponding change control CC-063-2023 is attached (See Attachment # 13)

D) The ISO 7 rooms containing the ISO-5 filling BSCs and LAFs are only required to be tested for viable (surface and active air) microorganisms once per week as required by SOP 3.030 Environmental Monitoring, Version 10, Date: 09/22/2023, Table 2: Frequency of sampling in ISO-7 Classifications. The ISO-7 rooms are not required to be tested each day the ISO-5 BSC and LAFs are in use.

Observation 3 D) Response: We acknowledge the observation and have added the daily ISO 7 viable monitoring for microorganisms for surface and active air each day the ISO 5 BSC and/or LAFH are in use per updated SOP 3.030 *Environmental Monitoring* version 12 which was made effective on 12/04/2023 (Same as attachment #12 and see attachment # 14 for training record on updated SOP). The daily ISO 7 sampling began December 4.

Wedgewood Connect has and will continue to perform viable monitoring for microorganisms for surface and active air in all ISO 5 and ISO 7 sterile areas. Please note that over the last two years, Wedgewood Connect has taken over 82,000 samples in ISO 5 and ISO 7 with 0.04% recovery rate.

Observation 4:
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

Specifically,

A) Requalification of the steam sterilization process for liquid loads (1L bottle formats) in the Fedegari Autoclave, Model FOAF3/AG,Equipment ID# E-0832-W, performed 11/11/2022 failed to meet the minimum requirement of 121° C on thermocouple TC-09. Thermocouple TC-09 reported value of 120.05 during the qualification. The acceptance criteria state the minimum temperature from all the thermocouples during sterilization phase must be ≥121 ° C. Additionally, Thermocouple TC-19, failed its pre- and post- calibration check and was used during the requalification.
Although the requalification occurred 11/11/2022, to date, the final report has not been approved by the quality unit.

This autoclave is used to sterilize human and animal drug products inside 1L bottles, prior to these products being aseptically filled. Between 11/11/2022 and now, there have approximately 112 batches of drug product sterilized with this equipment.

Observation 4A) Response: We acknowledge the observation. Please note that the requalification run had a total of 36 thermocouples which were used. One of the 36 thermocouples, TC-09, reported value of 120.05 during the Maximum load run. This was investigated and a copy of the investigation report 23DR0059 was provided to the inspectors for review. Please note that all 64 biological indicators placed in this load were negative for growth. This includes a biological indicator placed at this thermocouple.

Per requalification protocol RQ-2022-012, 90% of the thermocouples must pass post calibration check (See attachment # 15). With One Thermocouple TC-19, failing pre- and post- calibration check; 97.2% of the thermocouples passed our calibration checks, which is well within our acceptance criteria. Hence, it was determined to have no impact on the qualification of autoclave.

Also, based on the fact all 64 biological indicators (during max load) resulted in negative growth, it was determined that there was no impact on the qualification status of the autoclave. Additionally, each autoclave cycle for commercial product is checked to ensure a minimum temperature of 121°C. All autoclave runs from 11/01/2021-10/31/2023 were re-checked and all runs met the minimum temperature requirement of 121°C.

We understand that the Final report should have been reviewed and approved in a more timely manner. However, it should be noted, the Quality department did review raw data and released autoclave in November 2022 on an interim basis. A copy of the final report was provided to the inspector during the audit. The Final report was signed off by QA supervisor on 12/01/2023.

While the autoclave did pass qualification, Wedgewood Connect plans to revalidate the autoclave Equipment ID# E-0832-W with one empty chamber run, three minimum load runs and three maximum load runs including BIs. The Protocol for the re-validation was approved on 12/06/2023 (See attachment # 16). The revalidation will be completed by mid-December 2023.

B) Operators were observed blocking first pass air on 11/01/2023 while filling the following drug products:

- **Tacrolimus 0.02% In Corn Oil, Ophthalmic Solution, 15 mL lot#222-05403992**

- **Cyclosporine 2%/Tacrolimus 0.2% in Corn Oil, Ophthalmic Solution, 15 mL lot #222-05400371**

Observation 4B) Response: We acknowledge the observation, however, Wedgewood Connect disagrees with this observation. We had pointed out to the inspectors that from the angle the inspectors were viewing, which was from behind the filling operators, one could not accurately assess whether first pass air was being blocked. SOP 1.060 *Aseptic Technique and Cleanroom Behavior* V2.0 step 9.1.3.3 clearly states "When handling sterile components, hand placement is critical. Hand placement should always be as far away from any critical surfaces as possible and should never block First Air" (See attachment # 17). All filling operators are trained on this procedure.

A mock video of the filling process taken from multiple angles was prepared and provided to inspectors during audit to demonstrate that what the inspector noted may not have been accurate. This included a video from behind the filling operator (the inspectors' view) and a view from parallel to the units being filled. The parallel view showed that first pass air was not blocked.
All technicians have been trained (See attachment # 18 for SOP 1.060 version 3 training record) with emphasis on section 9.1.3.3 to not block first air.

C) Airflow visualization studies are inadequate for the following reason:

1. **The generated smoke was not robust enough to show the flow of air.**
2. **Smoke was not always observed to be directly above the area where the activity was occurring during video "E-0077-W Dropper Bottles Process APR2023". Smoke appeared to be in the back corner of the BSC while operator activities were occurring in the center of the BSC.**
3. **Unidirectional airflow was interrupted with eddy currents detected at timepoint 0.31. during video "E-0078-W Dynamic Basic APR2023".**
4. **While smoke studies were performed for opening and closing droppers among the ISO-5 hoods, the entire filling process including setup and filling operations have not been evaluated within each hood under dynamic conditions as part of qualification.**

Observation 4C) Response: We acknowledge the observation. The targeted smoke outlet was placed centrally inside the BSC, and the outlet was aimed toward the direct compounding area directly below. Some angles of the video may make the smoke appear to be scant and blow toward the back corner.

Unidirectional airflow was momentarily interrupted with an eddy current at the timepoint observed due to the opening of the dropper bottles package. When the

package is opened, the air inside the package escapes, which may interrupt unidirectional airflow inside the hood briefly. The dropper bottle packages are sterilized by the manufacturer during production, so the air being expelled is sterile. During this stage of the filling process, no critical sites are open inside the hood and no product is exposed inside the hood. This brief interruption in airflow is not indicative of an equipment malfunction nor does it impact product integrity.

Only one BSC (E-0077-W) in room 121 and one LAFW (E-0082-W) in room 120 were used for dynamic smoke testing under the smoke study protocols. All other BSCs and LAFWs in the ISO 7 area experienced the standard dynamic smoke studies as defined by Controlled Environment Testing Association (CETA). Per CETA, BSC (E-0077-W) and LAFW (E-0082-W) which are closest to the entrance door of their respective rooms are considered to have worst-case smoke patterns when the door opens and closes. Further, each hood in each respective room is identical to the other hoods in that room. Velocities are checked upon regular recertification to ensure that each hood is performing in a consistent and acceptable manner.

In order to enhance our quality system, Wedgewood plans to conduct smoke studies capturing the entire process in each of the 7 hoods in rooms 121 and 120 utilizing more robust smoke generation. Wedgewood plans to complete smoke studies for all hoods no later than mid-January 2024.

Observation 5:
Employees are not given training in the particular operations they perform as part of their function.

Specifically, the visual inspection qualification program is inadequate. There is no assurance that personnel qualified for 100% visual inspection can identify all known critical defects found in your sterile products. Operators must score at least a 75% on the qualification, however, the Visual inspection Qualification test document shows 10 out 10 operators who perform visual inspection failed to identify critical defects such as particles during their qualification.

Observation 5) Response: Wedgewood Connect acknowledges the observation regarding the visual inspection qualification program. Our current training program is based on USP 1790, which uses a probability of detection rate for critical defects. Before inspecting vials for commercial products, all operators must pass 2 successive, successful test inspections using different test sets. Qualification tests are performed immediately after one hour of inspecting water-filled vials. This challenges operators' ability to inspect for the longest duration permitted without taking a break. Operators must be tested by outside, independent medical provider for visual acuity and color perception prior to qualification and at least annually thereafter. Near-vision performance must be the equivalent of 20/20 or better, uncorrected or corrected, with no impairment of color

vision. 100% of operators passed the qualification test prior to inspecting commercial products.

Although USP 1790 only requires a 70% detection limit of critical defects during qualification, we have, in an abundance of caution and to continuously improve, updated SOP 9.180 *Visual Inspection Qualification* (See attachment # 19 for SOP 9.180 version 2 and see attachment # 20 for training record), to increase the minimum test score from 75% to 80%. In addition to updating our qualification score to 80%, we have enhanced our training process by procuring an additional qualification set to include known critical defects historically found in our products and all our Operators have been re-qualified to this requirement with the new challenge set.

Observation 6:
The quality control unit lacks the responsibility and authority to approve and reject all in process materials and drug products.

Specifically,

A) **An Acceptable Quality Limit (AQL) for visual inspection is not performed for sterile Drug products.**

Observation 6A) Response: It was discussed with the inspectors that Wedgewood Connect relies on the inspection process which warrants an investigation, should >10% of the batch gets rejected due to critical defects identified by the operators.

While Wedgewood Connect is in compliance with current guidance, we had created a new SOP 9.200 Ver 1- Acceptable Quality Limit (AQL) for Visual Inspection of Sterile Products. A copy of the approved SOP was provided to the inspectors during the audit. The process of AQL for sterile products was made effective on 11/27/2023 with AQL performed on each batch of sterile product by Quality unit (See attachment # 21 for SOP 9.200)

B) **There is no test kit for the 2mL vial, rather operators are qualified using 5mL vial test kits. The 2mL vial is the size of Moxifloxacin 1mg/mL product and represents the smallest vial size used for drug products. Additionally, there are no test kits for operator qualification for any product placed in droppers, such as the Cyclosporine and Tacrolimus drug products.**

Observation 6B) Response: We acknowledge the observation. Wedgewood Connect considers that identification of defects in a 5ml vial can be detected with the same accuracy that an inspector would be able to identify in a 2ml vial, or a 15ml bottle.

Our training uses the 5mL vial as the single simulated process to qualify operators, as operators would be assessed on the ability to identify different sized particles

throughout the challenge set. The current qualification was considered worst case as it would be less challenging to detect particulate in the lower volume of a 2ml container or dropper bottle.
Although we believe a visual inspection operator can identify the same defects in a 5mL vial as in all product container forms, to enhance our current operator qualification processes we have purchased additional test sets to include all product containers produced, including 2mL vials and dropper bottles used.

C) **The visual inspection qualification challenge Set A and B contain vials pre-labeled with a "(P)" on the cap identifying them as containing particles. Personnel performing visual inspection of sterile drug products are required to correctly identify the defects during qualification. These vials pre-labeled with a "(P)" inform the operator that the vial contains a particulate.**

Observation 6C) Response: The inspection qualification vials mentioned in the observation have been addressed and the pre-labeled vials have been removed from the test set. Wedgewood connect would like to point out that the qualification set contained other vials with known particles which had no designation and were successfully found during qualification.
As mentioned in the response to observation 5 above, in addition to updating our qualification score to 80%, we have enhanced our training process by procuring an additional qualification set to include known critical defects historically found in our products and all our Operators have been re-qualified to this requirement with the new challenge set.

D) **A standard timer is not used to ensure operators visually inspect each vial and dropper for 5 seconds against white and black backgrounds. Procedure 9.170, Visual Inspection, Version: 2, Effective date: 06/26/2020 requires operator to visually inspect each unit for aminimum of 5 seconds against each background.**

Observation 6D) Response: We acknowledge the observation. Although audio timers are a part of our current operator training process, we refrained from using them after the training period due to USP 1790 stating audio timing devices can be a cause of distraction to other inspectors. (See attachment # 22 for USP). Each Wedgewood Connect inspector is trained to perform the required inspection utilizing 5 seconds against each background.

However, out of an abundance of caution, SOP 9.170 *Visual Inspection* has been updated to include requirements for a timing device to be used during inspection (See attachment # 23 for SOP 9.170 version 4). This will be made effective 12.11.2023.

wedgewood connect

Observation 7:
The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically, your firm has designated hazardous (HD, room 121) and non-hazardous (NHD, room 120) production areas, however, it was noted both forms of drug products could be compounded at the same time within separate BSCs in the formulation room (room 118). For example, on 07/06/2023 Moxifloxacin 1 mg/mL in Sterile Balance Solution (BSS) lot #222-05084791 (which is a NHD drug) was compounded at the same time as Tacrolimus 0.02% in Com Oil lot #222-05082806 (which is a HD).

Observation 7) Response: We acknowledge the observation.
Wedgewood Connect appreciates the opportunity to respond to the observation and we understand the possible concern with regard to cross contamination or mix-ups between HDs and non-HD drug products.
Our current compounding process for all products consists of compounding in an externally vented biological safety cabinet (BSC) within our formulation rooms 118 and 115, which also encounter 34-39 air changes per hour and have negative pressure to the surrounding rooms. All product batch records require operators to perform an area clearance to ensure no unrelated materials from other batches are present in the workspace. In addition, whether compounding a Non-HD or HD product, all raw materials remain contained within the BSC until the product is in its final liquid form. All operators present during the compounding of an HD product in the formulation rooms have the appropriate HD personal protective equipment, this includes the operators working on non-HD compounds. Post-compounding cleaning consists of deactivating, decontaminating, cleaning, and disinfecting the BSC and equipment used in the compounding process. Lastly, all Wedgewood Connect drug products undergo extensive testing prior to release. This includes testing for impurities, which would identify unknown contamination. To date, none of Wedgewood Connect's drug products have failed for such impurities.

Although current engineering controls and containment procedures prevent contamination or mix-ups between products, effective December 05, 2023, formulation room 115 has been designated for HD compounding. SOP 3.010 version 7 *Classified and CNC Area Requirements* has been updated and effective as of 12/05/2023 to reflect this change (See attachment # 24).

wedgewood connect

Observation 8:
The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically, the following information is not found on your drug product labels:

A) The name of the outsourcing facility.

Example of your drug product labels that do not contain this information: Moxifloxacin. 1 mg/mL in Sterile Balanced Salt Solution Injection, I mL in 2 mL vial (NDC # 79926-068-05)

Observation 8) Response: We acknowledge the observation, and we understand the complete company name was missing on the label. Wedgewood Connect updated the label for Moxifloxacin. 1 mg/mL in Sterile Balanced Salt Solution Injection, I mL in 2 mL vial (NDC 79926-068-05) on 11/16/2023 and provided a copy of the newly approved label to the inspectors on 11/17/2023 before the conclusion of the inspection. We would like to point out that the company phone number and physical address was present on the label and if there were an issue, a patient could have dialed the number to contact Wedgewood Connect. (See attachment # 25 for updated label)

Wedgewood Connect takes all the Investigators' observations and remarks seriously and it is our intent to be fully compliant with all aspects of the current 503B guidance, as well as all appropriate sections of 21 CFR 211. The enclosed responses to FDA's 483 observations demonstrate Wedgewood Connect's sincere and comprehensive focus on continuous improvement. If FDA would like to further discuss any items discussed between Wedgewood Connect and the investigators during the closeout, Wedgewood Connect welcomes a meeting with the Agency at any time.

Sincerely,

Shruti - 12/07/2023

Shruti Rao Shreehari
Quality Assurance supervisor

Copies
Craig Mastenbaum – General Manager
Christina Vega- Director of Quality
Evelyn Lopez – Operations Director
Joseph Costa – President and Chief Operating Officer
Paul Yamamoto, R.Ph. – Vice President of Pharmacy Services and Pharmacist in Charge
Anney Lin, Investigator
Jeffrey P. Raimondi, Investigator
Andrew Le, Investigator

wedgewood connect

List of Attachments:

- Attachment 1: USP 797
- Attachment 2: Retrospective ISO 5 Investigation 23DR0151
- Attachment 3: Retrospective ISO 5 Investigations 23DR0172, 23DR0173, 23DR0174, 23DR0175
- Attachment 4: Retrospective ISO 7 Investigations 23DR0149, 23DR0150, 23DR0152
- Attachment 5: Training records for SOP 3.030 *Environmental Monitoring* V11.0
- Attachment 6: OOS 00041
- Attachment 7: NCR0052
- Attachment 8: Retains Check
- Attachment 9: Re-training on SOP 5.031 - Customer Complaints V5.0
- Attachment 10: *Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act Guidance for Industry*
- Attachment 11: *Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practices*
- Attachment 12: SOP 3.030 - *Environmental Monitoring* V12.0
- Attachment 13: CC-063-2023
- Attachment 14: Training records for SOP 3.030 - *Environmental Monitoring* V12.0
- Attachment 15: Thermocouple Post calibration verification criteria
- Attachment 16: 2023 Requalification Protocol for Autoclave
- Attachment 17: SOP 1.060 - *Aseptic Technique and Cleanroom Behavior* V2.0
- Attachment 18: Training Records for SOP 1.060 - *Aseptic Technique and Cleanroom Behavior* V3.0
- Attachment 19: SOP 9.180 - *Visual Inspection Qualification* V2.0
- Attachment 20: Training Records for SOP 9.180 - *Visual Inspection Qualification* V2.0
- Attachment 21: SOP 9.200 - *Acceptable Quality Limit (AQL) for Visual Inspection of Sterile Products* V1.0
- Attachment 22: USP 1790
- Attachment 23: SOP 9.170 - *Visual Inspection* V4.0
- Attachment 24: SOP 3.010 - *Classified and CNC Area Requirements* V8.0
- Attachment 25: Approval Forms - Moxifloxacin in BSS 1mg per mL 30023-503B Primary Label V2.0

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Outsourcing __ Hospital Pharmacy Clinic Exempt Hospital ___ Wholesaler Hypodermic

Date: 5/11/2023 Inspector: Margaret Panella-Spangler

Firm: WEDGEWOOD CONNECT LLC Phone: (877) 357-6613

Address: 17 GREAT OAKS BLVD City: SAN JOSE Zip: 95119

Ownership: CORPORATION

Permit #: OSF138 Permit Exp: 7/1/2023 DEA#: RW0603236 DEA Exp: 5/31/2023

Date of Self Assessment Form: _____ Other Permit #: N/A Date of DEA Inventory: _____

Hours M-F: 0800-1630 Hours Saturday closed Hours Sunday: closed

PIC PAUL K YAMAMOTO RPH43950 Administrator _____

RPH Consultant _____

Staff	RPH Name:	License #:	Staff Name:	License #:
	CHRISTINA L VEGA	RPH69993	CRAIG MASTENBAUM	CORP OFFICER
	MYHONG T PHAN	RPH69988	LAURA E LOPEZ	TCH91791
			ROBERT FAIRCLOUGH	TCH174838

Inspector Remarks:

Resident outsourcing renewal inspection
Conducted on (in person): May 9, 10, 11 2023
Completed by Inspectors: Peg Panella-Spangler, Alyce Petrutiu and Lesa Fitzpatrick. Inspector Rachel Powell observed during the inspectional walk-through as a training exercise
Assisted in full or in part by: Craig Mastenbaum, General Manager, Christina Vega PharmD, Quality Director, Evelyn Lopez, Operations Director, Paul Yamamoto RPh, VP of Pharmacy Services, Myhong Phan PharmD, Audit Scribe, R&D, and subject matter experts as required.

Product line consists of ophthalmic preparations in both oil and aqueous matrixes and injectables. Current Max BUD is up to 270 days. Completed over 20 stability protocols in the last year. Hazardous and non-hazardous preparations are compounded on-site. Products are almost exclusively distributed to veterinary customers. Shipping records provided for a non-veterinary customer. Container closure types include at least the following:

- **5 ml, 10ml, 50mL - Glass vial**
- **7ml, 15mL- Dropper bottle; 5ml, 10ml or 15mL fill volume.**

Largest formulated sterile batch size is 33 liters, largest unit batch size is 3000 units. All aseptic filling operations occur within 10-12 hours. Formulated solutions that have been prefiltered are filled same day up to 48 hours post formulation (product specific hold times).
The firm began manufacturing tablet dosage forms in 2022:

- **Quad Tabs®**

• **Tiny tabs®**
Tablets are produced in 100 and 500 count final container closures.
Products are hazardous and non-hazardous, and controlled room temperature storage and refrigerated storage. One controlled substance commercially available. Products are produced by manual and/or automated methods.
Products are prepared from API. Firm maintains licenses in all 49 states (not Hawaii) and Washington DC

Review of last California Inspection:

1. Observation I: Updated Deviations SOP;
2. Observation 2: Updated SOP 6.030 Receipt and Quarantine of Materials and SOP 6.050 Approval and Rejection of Materials by 06/01/2022
3. Observation 3: Wedgewood Connect committed to completing a site Master Validation Plan by end of Q2 2022, which will describe the required type of validation for each piece of equipment used at the site. Listed equipment was validated by 8/30/2022:
4. Observation 4: regarding drugs not on the 503B bulks list, the following are not acceptable for the compounding for human products under the exemptions for 503B: doxycycline, desmopressin, buprenorphine, apomorphine, demecarium bromide, prednisolone ophthalmic drops, cidofovir, idoxuridine, buprenorphine, ketoconazole, theophylline.
5. Observation 5: Annual product reviews were produced throughout the year and provided for review
6. Observation 6: Sodium metabisulfite, sodium hydroxide, MCT Oil and Corn Oil used in sterile products were food grade. Wedgewood did not provide sufficient data to show alternate sources were explored and continued to use these products. Please note NF and pharmaceutical use are not synonymous with, for use in a sterile product.
7. Observation 7: Impurities from the plastic bottles used were explored.
8. Observation 8: See observation 3
9. Observation 9: Complaint reporting was instituted per CA law
10. Observation 10: Complaint procedure was reviewed and training as appropriate provided
11. Observation 11: Wedgewood Connect committed to performing cleaning validations on the bin blender and other Natoli press product-contacting surfaces, to eliminate cross contamination
12. Observation 12: Site wide awareness training to reduce errors in the receiving and fulfillment area.

Quality: Subpart B
Personnel and organization: Onsite personnel consists of a general manager (Craig Mastenbaum) who oversees Operations/Production (Evelyn Lopez) and separate QA/QC (Christina Vega). New production supervisor hired in 2/2022. Employee census is 58. Quality unit consists of QA/QC/R&D validation and engineering.
Policies and Procedures: provided when requested. Reviewed during inspection. SOPS appear to be the main training source for staff.
Personnel training and PPE: Staff had masks on backwards. Staff are required to wash their hands in a rest room and then change into facility scrubs and shoes.
Media Fill process: No new processes
CAPAs, deviations, and customer complaints: Reviewed during inspection
ADEs: Evaluated and referred through the FDA SRP portal via an in-place process
Recalls: Process is available
Essential Copies / Drug Shortages: Processes in place to evaluate
Validations/Qualifications: New R&D staff, new facilities manager. Multiple validations were completed in the last year. No in person vendor audits have been completed at the time of inspection. They are being scheduled.

Facilities: Subpart C
Firm is located within a commercial space consisting of areas for offices, shipping & receiving, finished goods,

storage, quarantine/release of materials, and sampling. There is not sufficient space for all components to be stored together or for finished goods and quarantine products to be physically separate in the warehouse space. Approx. 22,000 sq ft facility with 3000 sq ft of ISO 8 areas and 1700 sq ft of ISO 7 areas. Last year several areas were committed to tablet production. A new tableting room was constructed and is undergoing validation.
Critical Utilities: Facilities supervisor Robert Fairclough has responsibility for:
• DI water -Currently not used for commercial production processes. Per firm water is intended to meet USP purified water specifications. Testing intervals are not defined and not described in any procedure. Water is used for the dishwasher and the autoclave
• Steam generator (autoclave) - Critical process parameters 121 C for 15 mins. Autoclave is used for terminal sterilization of in-process material
• HVAC -Multiple air handlers of -5-8 tons each to supply cleanrooms and other non-cleanroom spaces. Firm has equipment list that describes area(s) of service for each unit. All classified areas are terminally HEPA filtered via fan filter units on the ceilings.
• Compressed Air-Multiple drops throughout the facility. Current application of compressed air is used for rotary tablet press, deduster, filter integrity tester, auto-labeler and autoclave Source air is derived from an oilless compressor with separate dryer.
Please see observation regarding cleaning of the manufacturing area.

Equipment: Subpart D
Calibration and Equipment Maintenance: Master list provided
Smoke studies for 10ml and 50 ml vials provided as remediation from last year's inspection
Certification of sterile cleanrooms and ISO classified areas
Sterile ISO 7 and ISO 5 PECs located in those rooms are recertified semi-annually. Performed last by TSS on 4/24/23- 4/27/23. Only room 120 was done under operational/dynamic conditions, all other areas were performed at rest/static conditions. Per the facility during the inspection, they are in the process of scheduling TSS to come out again to perform it under operational/dynamic conditions.

- Area 119 (referred to as sterile hallway) ISO 7 room which contains racks with supplies and a pass thru that leads to area 122 (ISO 7 sterile garb room) and has 2 doors that lead into 1. Non-HD ISO 7 (room 120), 2. HD ISO 7 (room 121). ACPH criteria met, and HEPA filters leak test passed
- Area 120- non-HD ISO 7 room, positive pressure with 3 ISO 5 Labconco clean benches, ACPH criteria met, HEPA filters passed leak test
- Area 121- HD ISO 7 room negative pressure with 4 ISO 5 Labconco Class II A2 BSCs, ACPH criteria met, HEPA filters passed leak test
- Area 122- ISO 7 sterile garb room that leads into the room 119 (referred to as sterile hallway) HEPA filters passed leak test, ACPH criteria met, HEPA filters passed leak test
- Area 123- ISO 7 clean storage room, ACPH criteria met, HEPA filters passed leak test
- Area 124- ISO 7 room referred to as a sterile hallway
- Area 124A- ISO 7 room, non-operational at the time of the inspection

ISO 8 areas used for non- sterile compounding and PECs in those areas are recertified annually. Last done October of 2022
Sterilizing Filter selection & compatibility: Viewed C of C for filters used in oil-based products

Control of Components and Drug Product Containers and Closures: Subpart E
Identification and Inventory: All done by hand, no electronic inventory control
Quarantine and release: Through quality and done with stickers
Component/API testing: All API must have identity, bioburden and endotoxin at a minimum for each lot. Firm continues to use food grade materials to make injections. Original CofA for MCT is consistent with EP

monograph, not NF. Corn Oil is an EP monograph and purported" not regulated in the USA". NaOH used is food grade only
Container Closure Suitability and Integrity: Noted in stability reports

Production and Process Controls: Subpart F
Master & Batch records: reviewed a few selected sample batches

- Components, bill of materials, equipment identification, personnel identification: All hand done, no ERP system in place. Components are stored in multiple areas and in multiple buildings.
- Production processing steps with verification steps; The batch record was missing a step which occurred during production. Staff stated they discard excess API however, it was observed during inspection, staff returned API back into the stock bottle.
- Specification sheet & laboratory COAs / raw materials: Provided upon request
- Production environmental monitoring and personnel monitoring sampling
    - Continuous non-viable particulate monitoring & volumetric viable air sampling during batch production in ISO-5
- Post-production evaluation – inspection, labeling, sampling: Not all examples of labels were contained in the batch record
- Processing start / end times noted: In the batch record as appropriate
- In-Process controls – bubble point testing of filter, pre-filtration bioburden
- Limits of production time / hold time of intermediates – reviewed
- Yield calculations of Protirelin are incorrect and do not reflect actual yield. Discussed actual versus theoretical yield.

Method Suitability and Container Closure Integrity: reviewed a few selected validations

Packaging and Labeling Control: Subpart G
Acceptance of packaging and labeling materials: Done by quality, all hand done, not electronic
Control of labels: Not all labels are contained in the batch record
Line clearance: Noted in the batch record
Visual inspection of product postproduction: Viewed during the inspectional walk through. Deferred the review of the defect library
Examination of finished labeled product: Noted in the SOP and the batch record

Holding and Distribution: Subpart H
Warehousing procedures: Temperature controlled area, media is stored here. Secondary warehouse does not have temperature mapping during extreme temperatures.
Distribution procedures: Deferred
Pack-out procedures: Shipping studies have been provided in the past.

Laboratory Controls: Subpart I
Stability studies: Discussed water activity in tablets for stability concerns
Release testing: Wedgewood owns Front range Labs and will slowly transition to using them exclusively. Currently using CIAL for metronidazole oral susp, buprenorphine Inj, except osmolality which is done at Front Range
Prompt Praxis: Protirelin chemistry, demacarium eye drops
Equipment & facility: Currently have only incubators at the facility for environmental and personnel monitoring. All other testing is sent out to three labs: Prompt Praxis, Front Range and CIAL

Sampling Plan: Deferred
Reserve samples: Are stored in the warehouse in zip tied totes co-mingled with other products and supplies
Environmental Sampling: Provided with the batch records
Media control: GFT neutralized media, all media is growth promoted

Records and Reports: Subpart J
Batch records: Reviewed at length: Noticed inconsistencies in the batch record. Beakers were covered but it was not stated in the batch record.
Drug Master Formulas: Firm stated they do not have drug master formulas as described in CFR 211.186.
Usage and cleaning logs: Difficult to read and interpret. Discussed with staff during inspection
Distribution records: Deferred
Annual product reviews: Provided throughout the past year as the program was being completed.

Education:
1. Provided advisory on CA BoP subscriber alerts for the organization and each licensee is required to be subscribed to the email alerts.
2. Provided education on Assembly Bill 1533 (AB 1533) and BPC 4129(e) "an outsourcing facility licensed by the board dispensing patient-specific compounded preparations pursuant to a prescription for an individual patient shall not be required to be licensed as a pharmacy but shall otherwise comply with the same requirements of a pharmacy."
3. The CA State Board of Pharmacy grants its inspectors the authority to inspect per CFR 210 and 211 for compliance with current Good Manufacturing Practices [BPC 4129.2(b)]
4. The deviations and observed non-compliances referenced in this report are not intended to be an all-inclusive list of deviations and non-compliances that may exist at your firm. Your firm is responsible for investigating and determining the causes of any deviations and observed non-compliances and for preventing their recurrence or the occurrence of any other non-compliances and deviations.

5. BPC 4129.1 (e) An outsourcing facility licensed pursuant to this section shall provide the board with all of the following:
   1. A copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.
   2. Notice within 24 hours of any recall notice issued by the outsourcing facility.
   3. A copy of any clinically related complaint it receives involving an outsourcing facility's compounded products from or involving any provider, pharmacy, or patient in California within 72 hours of receipt.
   4. Notice within 24 hours after learning of adverse effects reported or potentially attributable to the outsourcing facility's products

Notice within 24 hours after learning of adverse effects reported or potentially attributable to a non-resident outsourcing facility's product

***Notification of recalls, ADRs, and complaints to the Board's email address: compounding.report@dca.ca.gov**

Please send all remark and observation responses to Peg Panella-Spangler: peg.panella-spangler@dca.ca.gov no later than May 25, 2023.

Licensee Remarks:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

I have reviewed, discussed,understand and received a copy of this form .

Quality (sign) _____
Quality (print) Christina Vega

Inspector (sign) _____
Inspector (print) PEG PAMELA SPANGLER

Other(sign) _____
Other(print) _____

Lesa Fitzpatrick / Lesa Fitzpatrick

ALYCE PETRUTIU

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

OBSERVATION

Date: 5/11/2023 Permit #: OSF138

Name as shown on permit: **WEDGEWOOD CONNECT LLC**

Address: 17 GREAT OAKS BLVD City: SAN JOSE

1. CFR 211.186(a)	Master production and control records.. To assure uniformity from batch to batch, master production and control records for each drug product, including each batch size thereof, shall be prepared, dated, and signed (full signature, handwritten) by one person and independently checked, dated, and signed by a second person. The preparation of master production and control records shall be described in a written procedure and such written procedure shall be followed. During inspection master production records were not provided for review. According to comments made by facility administration, blank templates of batch control records are used in place of master production records.
2. CFR 211.100(a)	Written procedures; deviations.. There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit. During inspection it was observed upon review of multiple SOPS, the parameters were not well delineated, limits were not required for changes and logs provided did not support the following of SOPs . This includes but is not limited to SOP 4.091, SOP 3.022, 8.4.7, 7.010 and SOP 1.060 . This includes cleaning, aseptic technique and significant figures, how long can a product beheld when wiped before being placed in the ISO 5, procedures for the handling of hazardous drugs.

3. CFR 211.100(a)	Written procedures; deviations.. There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit. During inspection it was observed when reviewing Out of Specification report OOS00034, metronidazole oral suspension, the propylparabens label claim tolerance was changed without a change control. Root cause was attributed to a rounding and significant figure discrepancy. The lab which measured the propylparabens levels was arbitrarily told to use only 2 significant digits instead of two decimal places. The changes were not reviewed and approved by the appropriate organizational units. Staff was not trained on the changes.
4. CFR 211.22(a)	Responsibilities of quality control unit.. There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. During inspection it was observed, doxycycline tablets lot # 222-04726387, had extra active ingredient added without the excipient amount being adjusted accordingly. This flaw in the master formula led to a CAPA for testing out of specifications for doxycycline made with formula. CAPA number 23CAPA001 is still open, however product has been released for sale (lot# 222-04726387) and no recall has been initiated to recall product made with the flawed formula. At no time during production was this flaw discovered or discussed.
5. CFR 211.100(b)	Written procedures; deviations... Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified. During inspection it was observed, written production procedures for aseptic technique were not followed: primary operator was observed ceasing filling operations to open and unpack trays of sterile dropper bottles and then continue filling operations without sanitizing gloves as required per SOP 1.060, section 9.1.2.5
6. CFR 211.80(a)	General requirements.. There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures; such written procedures shall be followed. During inspection it was observed, there was no specific policy for inventory and transfer of product form the Great Oaks site to the Las Colinas site, It was unclear as to which component in which facility would be used first to ensure, FIFO. No temperature testing has been completed in the winter or summer to ensure appropriate storage of components in the Las Colinas site. Documents provided stated temperature mapping was to have been completed in August 2022, however there was no evidence to support this statement.

7. CFR 211.42(c)(10)(	Design and construction features. . Operations shall be performed within specifically defined areas of adequate size. There shall be separate or defined areas or such other control systems for the firm's operations as are necessary to prevent contamination or mixups during the course of the following procedures: Aseptic processing, which includes as appropriate: Floors, walls, and ceilings of smooth, hard surfaces that are easily cleanable; During inspection it was observed the negative pressure clean room had multiple areas of damage on the floor sealed with epoxy paint, the PEC in the room had multiple areas of damage sealed with epoxy paint which had raised non smooth surfaces, the walls had areas of damage which were patched with non smooth surfaces, and the corner of the wall appeared to have damage which was not repaired. Sprinklers in the negative pressure clean room were not sealed and were not cleaned.
8. CFR 211.28(a)	Personnel responsibilities.. Personnel engaged in the manufacture, processing, packing, or holding of a drug product shall wear clean clothing appropriate for the duties they perform. Protective apparel, such as head, face, hand, and arm coverings, shall be worn as necessary to protect drug products from contamination. During inspection on May 10 2023, two staff members were observed having their face masks on backwards.
9. CFR 211.113(b)	Control of microbiological contamination.. Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of all aseptic and sterilization processes. During inspection it was observed, the only place to perform hand washing was in a restroom. Hand hygiene is performed without water in the ante area at later time during gowning.
10. CFR 211.67(b)(2)	Equipment cleaning and maintenance.. Written procedures shall be established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product. These procedures shall include, but are not necessarily limited to, the following: Maintenance and cleaning schedules, including, where appropriate, sanitizing schedules; During inspection it was observed, SOP 3.022, section 8.4.7, stated that Decon Spore 200 Plus must be used before and after each batch of hazardous drug produced in BSCs located in ISO 8 environments. LUMAC reviewed for E-0232-W, BSC located in Room 118 (ISO 8 environment), revealed that hazardous drugs, cyclosporine and tacrolimus ophthalmic, were produced without the use of Decon Spore prior to their production. This occurred at least on 5/8/23, 3/1/23, 2/28/23, 2/26/23, 2/15/23, and 2/14/23.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

11. **BPC 4129.1(b)** Outsourcing Facilities. An outsourcing facility shall compound all sterile products and nonsterile products in compliance with regulations issued by the board and with federal current good manufacturing practices applicable to outsourcing facilities.

In conjunction with the requirements of USP Chapter 800 and CFR 211.42, during inspection it was observed, two chemicals used to produce sterile eye drops were deemed hazardous per the batch record, tacrolimus and cyclosporine. The production of hazardous drug products was performed without respect to the following elements of USP 800: Sink must be available for handwashing; Eyewash station must be readily available; Improper use of PPE to prevent contamination (no removal of PPE when exiting and re-entering the HD buffer room); Non-existent wipe down of finished product and lack of hazardous labeling to minimize risk of occupational exposure; 9.3.11 shoe covers must be doffed when exiting the SEC, shoe covers must not be worn to other areas; 9.3.16 PPE must be placed in appropriate waste container before leaving SEC, after leaving the clean room the product is never treated as hazardous,nor labeled as such.

12. **CFR 211.188(b)(8)** Batch production and control records.. Batch production and control records shall be prepared for each batch of drug product produced and shall include complete information relating to the production and control of each batch. These records shall include: Documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including: Complete labeling control records, including specimens or copies of all labeling used;

During inspection it was observed for cyclosporine compounding, the beaker of formulation was covered with foil but this step was not listed in the batch record. Also the batch record for this product and cidofovir did not have specimens of all the labeling which includes but is not limited to the in-process labels and autoclave labels.

I have reviewed, discussed, understand and received a copy of this form.

Inspector (sign) [signature]
Inspector (print) PEG PANELLA SPANGLER
Date 5/11/2023

Signed [signature]
Print Name Christina Vega
Title Quality Director 05/11/2023

wedgewood connect

Wedgewood Connect
17 Great Oaks Blvd
San Jose, CA 95119

May 25, 2023

Peg Panella-Spangler, RPh
Supervising Inspector
California State Board of Pharmacy
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834

Ref: Inspection Report dated May 11th, 2023

Dear Ms. Peg Panella-Spangler,

This letter is in response to the Inspection Report issued to Wedgewood Connect, a 503B outsourcer, on May 11th, 2023. As an introductory comment, Wedgewood Connect takes all the Investigators' remarks seriously and it is our intent to be fully compliant with all aspects of California State Regulations; current 503B guidance; as well as all appropriate sections of 21 CFR 211 and are steadfast in our determination to ensure that our products are safe and of the highest quality.

In regard to the inspection that occurred between May 9th and May 11th, 2023, we appreciate the professionalism of Inspectors Peg Panella-Spangler, Alyce Petrutiu, Lesa Fitzpatrick and Rachel Powell. We acknowledge the California State Board of Pharmacy's observations in the Inspection Report that was issued on May 11th, 2023. We recognize that the Report only touched on specific aspects and that it is the responsibility of Wedgewood Connect to be in full compliance with the regulations and 503B guidance.

Wedgewood Connect responds as follows to the specific observations from the Inspection Report in the same order found in the report as well as the remarks noted in the Inspection Report.

Observation 1:
CFR 211.186(a)
Master production and control records. To assure uniformity from batch to batch, master production and control records for each drug product, including each batch size thereof, shall be prepared, dated, and signed (full signature, handwritten) by one person and independently checked, dated, and signed by a second person. The preparation of master production and control records shall be described in a written procedure and such written procedure shall be followed.

During inspection master production records were not provided for review. According to comments made by facility administration, blank templates of batch control records are used in place of master production records.

wedgewood connect

Observation 1 Response:
We acknowledge the observation of not having a master production record. As background, controlled batch manufacturing records are created and approved per SOP 1.010 *Standard Operating Procedures and Batch Records.* Batch manufacturing records are stored as a hardcopy (master copy), only accessible by delegated Quality Department personnel. All reviewer and approval signatures for any document including batch manufacturing records are taken on DCR form per SOP 1.010. Wedgewood Connect will make the following improvement:

SOP 1.010 will be updated to include procedure for master production record creation, approval, and maintenance by end of Q3 2023.
Updated SOP and training records for all staff will be provided by 10/31/2023.

Observation 2:
CFR 211.100(a)
Written procedures; deviations.. There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.

During inspection it was observed upon review of multiple SOPs, the parameters were not delineated, limits were not required for changes and logs provided did not support the following of the SOPs. This includes but is not limited to SOP 4.091, SOP 3.022,8.4.7, SOP 7.010 and SOP 1.060. This includes cleaning, aseptic technique and significant figures, how long can a product be held when wiped before being placed in the ISO 5, procedures for the handling of hazardous drugs.

Observation 2 Response:
We acknowledge the observation regarding the lack of clear specific instructions in the indicated SOPs. These following SOPs were reviewed thoroughly by applicable departments and updated to include the following:

- SOP 4.091 *Significant Figures and Rounding*, - the meaning of significant figures and the number of significant figures to report when documenting values on the batch record. For evidence of SOP update, see Attachment # 1.
- SOP 3.022 *Cleaning and Disinfection of the ISO 5 Cabinets (Primary Engineering Control)*, - cleaning and disinfection of the BSCs located in ISO 8 areas with Decon Spore 200 and Sterile 70% IPA before and after each batch for all drug formulation. For evidence of SOP update, see Attachment # 2.
- SOP 7.010 *Handling of Cytotoxic or Hazardous Drug Compounds* – Please refer to response to Observation # 11.

- SOP 1.060 *Aseptic Technique and Cleanroom Behavior* –more definite verbiage outlining the process to decontaminate items and pass them promptly into the ISO 5 space. For evidence of SOP update, see Attachment # 3.

All Staff training records on updated SOPs will be provided by 06/30/23.

Observation 3:
CFR 211.100(a)
Written procedures; deviations. There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.

During inspection it was observed when reviewing Out of Specification report OOS00034, metronidazole oral suspension, the propylparabens label claim tolerance was changed without a change control. Root cause was attributed to a rounding and significant figure discrepancy. The lab which measured the propylparabens levels was arbitrarily told to use only 2 significant digits instead of two decimal places. The changes were not reviewed and approved by the appropriate organizational units. Staff was not trained on the changes.

Observation 3 Response:
We acknowledge the observation that the propylparabens label claim tolerance was changed without a change control. Compounder's lab (CIAL), which performed testing on metronidazole oral suspension including measuring propylparabens levels were notified of label claim change through a formal memo that was approved by Quality (See Attachment # 4).

The changes were reviewed and approved by the affected department, Quality. Product impact assessment was performed as part of Out of Specification investigation and it was concluded that there was no product impact.

Change control (CC-014-2023) was initiated to retrospectively document the change in the propylparabens label claim and further evaluate potential impact. Change control has been closed and concluded to have no impact on product. (See Attachment # 5).

Impacted departments have been trained on the new label claim and attached to change control.

Observation 4:
CFR 211.22(a)
Responsibilities of quality control unit. There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the

authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.

During inspection it was observed, doxycycline tablets lot # 222-04726387, had extra active ingredient added without the excipient amount being adjusted accordingly. This flaw in the master formula led to a CAPA for testing out of specifications for doxycycline made with the formula. CAPA number 23CAPA001 is still open, however product has been released for sale (lot# 222-04726387) and no recall has been initiated to recall product made with flawed formula. At no time during production was this flaw discovered or discussed.

Observation 4 Response:
We appreciate the opportunity to reply to this observation. As with all the products we produce, Wedgewood Connect conducted stability studies on our doxycycline 400mg quad tablets. After completion of the stability studies, the results were analysed and approved by our Quality team. Based on the stability results and analysis, commercial production was initiated for doxycycline 400mg quad tablets and is an active product today.

However, during routine batch reconciliation review, it was discovered that a few of the manufactured lots produced a batch yield that exceeded the acceptance criteria. Because of this, deviations were opened in May and June of 2022. The investigation of these deviations uncovered a procedural error and 23CAPA-001 was approved by quality to execute further actions. The investigation discovered the batch record did not have a process to adjust the batch when the amount of API used differed from theoretical quantity. Following the batch record correction, 2 batches of doxycycline 400mg quad tablets were produced with results pending.

Observation 5:
CFR 211.100(b)
Written procedures; deviations. Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified.

During inspection it was observed, written production procedures for aseptic technique were not followed: primary operator was observed ceasing filling operations to open and unpack trays of sterile dropper bottles and then continue filling operations without sanitizing gloves as required per SOP 1.060, section 9.1.2.5

Observation 5 Response:
We acknowledge the observation of production procedures not being followed by operator.

On 5/19/2023, there was verbal discussion with the Production team, that sterile 70% IPA must be applied to gloved hands prior to beginning the filling of staged units and to allow

gloves to dry before resuming aseptic manipulations. It was also discussed that while preparing items to enter the ISO 5 space that items need to be decontaminated per SOP 1.062 and should not be prepared ahead of time when needed, so it does not sit in the ISO 7 environment after decontamination is complete.

SOP 1.060 *Aseptic technique and cleanroom behavior* was reviewed and updated with more precise instructions regarding sanitization of gloves.

For evidence of SOP update, see Attachment # 3.
All Staff training records on updated SOP will be provided by 06/30/23.

Observation 6:
CFR 211.80(a)
General requirements. There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures; such written procedures shall be followed.

During inspection it was observed, there was no specific policy for inventory and transfer of product from the Great Oaks site to the Las Colinas site. It was unclear as to which component in which facility would be used first to ensure, FIFO. No temperature testing has been completed in the winter or summer to ensure appropriate storage of components in the Las Colinas site. Documents provided stated temperature mapping was to have been completed in August 2022, however there was no evidence to support this statement.

Observation 6 Response:
We acknowledge the observation of not having a process for inventory management and transfer of material from the Great Oaks site to the Las Colinas warehouse and not completing temperature mapping for Las Colinas warehouse in August 2022.

Sop 3.090 *Las Colinas Warehouse Operations* was updated to include inventory management method "first to expire, first out" (FEFO) and transfer of material to and from the Las Colinas warehouse.

For evidence of SOP update, see Attachment # 6.
All Staff training records on updated SOP will be provided by 06/30/23.

Temperature mapping study results from April 2022 supports a current operating temperature of 15°C to 25°C for the Las Colinas warehouse. Temperature mapping study will be performed in August 2023 to address hot summer season effects. Temperature and relative humidity are continually monitored through the Dickson One temperature monitoring system. Two (2) temperature/relative humidity sensors are located in the Las Colinas warehouse: one on the wall roughly 6 feet high at Row 8, and the other low-mounted on a pallet rack vertical beam at Row 9. These sensor locations were identified as worst-case from the temperature mapping study performed in April 2022 (refer to FR-014-2022).

wedgewood connect

Observation 7:
CFR 211.42(c)(10)
Design and construction features. Operations shall be performed within specifically defined areas of adequate size. There shall be separate or defined areas or such other control systems for firm's operations as are necessary to prevent contamination or mixups during the course of the following procedures: Aseptic processing, which includes as appropriate floors, wall, and ceilings of smooth, hard surfaces that are easily cleanable.

During inspection it was observed the negative pressure cleanroom had multiple areas of damage on the floor sealed with epoxy paint, the PEC in the room had multiple areas of damage sealed with epoxy paint which had raised non smooth surfaces, the walls had areas of damage which were patched with non smooth surfaces, and the corner of the wall appeared to have damage which was not repaired. Sprinklers in the negative pressure clean room were not sealed and were not cleaned.

Observation 7 Response:
We appreciate the opportunity to reply to this observation.

We understand the concern of raised non-smooth surfaces. As an immediate action, each repaired surface was inspected by the facility supervisor. Epoxy repairs will be made and stainless-steel bumper rail will be installed to repair and protect the corner wall. These repairs will be completed by 06/30/2023. QC will take microbial samples of repaired surfaces to ensure surfaces are easily cleanable.

A new SOP outlining the procedure for necessary actions to be taken during clean room damage repairs at Wedgewood Connect will be implemented by 06/30/2023.

While it may have appeared during inspection that the sprinklers in the negative pressure room were not sealed, we affirm that the sprinklers are sealed where the sprinkler trim meets the ceiling tile. Additionally, we acknowledge the concern with not cleaning the sprinklers and we have updated SOP 3. 020 *Cleaning and Disinfection of the ISO 7 and ISO 8 Areas* to include cleaning of sprinklers with our routine scope of weekly and monthly cleaning and sanitization.

For evidence of SOP 3. 020 update, see Attachment # 7.
All Staff training records on updated SOP will be provided by 06/30/23.

Observation 8:
CFR 211.28(a)
Personnel engaged in the manufacture, processing, packing, or holding of a drug product shall wear clean clothing appropriate for the duties they perform. Protective apparel, such as head, face, hand, and arm coverings, shall be worn as necessary to protect drug products from contamination.

wedgewood connect

During inspection on May 10,2023, two staff members were observed having their face masks on backwards.

Observation 8 Response:
We acknowledge the observation of not having specific instructions of having one way to wear masks.

SOP 9.130 *Required Garb for Non-Sterile Compounding Area* was updated to include specific instructions such that surgical masks are worn consistently.

SOP now includes: *Place the colored side of the surgical face mask away from the face and the white side toward the face. Pinch the top metal tab against the bridge of your nose to create a snug fit. Ensure ear loops are behind the ears and mask covers your mouth and chin.*

For evidence of SOP update, see Attachment # 8.
All Staff training records on updated SOP will be provided by 06/30/23.

Observation 9:
CFR 211.113(b)
Control of microbiological contamination. Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of all aseptic and sterilization processes.

During inspection it was observed, the only place to perform hand washing was in a restroom. Hand Hygiene is performed without water in the ante area at later time during gowning.

Observation 9 Response:
We appreciate the opportunity to reply to this observation. Wedgewood Connect believes in continuous quality improvement and constantly strives to achieve it.

In order to assess the potential concern, glove monitoring results from period of 04/01/2022-04/30/2023 were reviewed. Approximately 0.17% reached alert level and none reached action level. The glove monitoring EM data proves the efficiency of PPE procedure.

SOP 9.130 *Required Garb for Non-Sterile Compounding Area* was reviewed and updated to remove hand washing outside of the clean rooms, as one of the critical steps in our hand hygiene procedures appropriately includes use of foam sanitizer during gowning into ISO 7 areas.

For evidence of SOP update, see Attachment # 8.
All Staff training records on updated SOP will be provided by 06/30/23.

wedgewood connect

Observation 10:
CRF 211.67(b)
Equipment cleaning and maintenance. Written procedures shall be established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product. These procedures shall include, but are not necessarily limited to, the following: maintenance and cleaning schedules, including where appropriate, sanitizing schedules

During inspection it was observed, SOP 3.022, section 8.4.7 stated that Decon Spore 200 plus must be used before and after each batch of hazardous drug produced in BSC located in ISO 8 environments. LUMAC reviewed for E-0232-W, BSC located in room 118 (ISO 8 environment), revealed that hazardous drugs, cyclosporine, and tacrolimus ophthalmic were produced without use of Decon spore prior to their production. This occurred at least on 5/8/23, 3/1/23, 2/28/23, 2/26/23, 2/15/23, and 2/14/23.

Observation 10 Response:
We acknowledge the observation of not cleaning BSC located ISO 8 environment with Decon spore prior to production of hazardous drugs, as stated in SOP 3.022 section 8.4.7.

SOP 3.022 was reviewed and it was decided to standardize cleaning and disinfection procedures across all environments and all product types.

SOP 3.022 was updated to include cleaning and disinfection of the BSCs located in ISO 8 areas with Decon Spore 200 and Sterile 70% IPA before and after each batch for all drug formulation. This process is consistent with cleaning and disinfection procedures in ISO 7 areas.

For evidence of SOP update, see Attachment # 2.
All Staff training records on updated SOP will be provided by 06/30/23.

Observation 11:
BPC 4129.1(b)
outsourcing facilities. An outsourcing facility shall compound all sterile products and nonsterile products in compliance with regulations issued by the board and with federal current good manufacturing practices applicable to outsourcing facilities.

In conjunction with the requirements of USP chapter 800 and CFR 211.42 during inspection it was observed two chemicals used to produce sterile eye drops were deemed hazardous per batch record, tacrolimus and cyclosporine. The production of hazardous drug products was performed without respect to the following elements of USP 800: sink must be available for hand washing; eyewash station must be readily available; improper use of PPE to prevent contamination (no removal of PPE when exiting and re-entering the HD buffer room);non-existent wipe down of finished

product and lack of hazardous labelling to minimize risk of occupational exposure; 9.3.11 shoe covers must be doffed when exiting the SEC, shoe cover must be worn to other area;9.3.16 PPE must be placed in appropriate waste container before leaving SEC, after leaving the clean room the product is never treated as hazardous nor labelled as such.

Observation 11 Response:
Wedgewood Connect currently classifies four drugs as hazardous due to their classification on the NIOSH list (Table 2, Group 2, Non-antineoplastic Agent): apomorphine, cidofovir dihydrate, cyclosporine, and tacrolimus. These drugs are APIs used for the formulation of sterile ophthalmic and injectable products.

Wedgewood Connect will re-assess these four drugs to confirm if the drugs are hazardous, if alternative containment strategy is required and the extent of applicability to USP 800. We will consult an expert, complete the analysis and identify an action plan by end of Q3 2023. At a minimum, we expect to update the following SOPs based on the outcome of the analysis:

- SOP 7.010 *Handling of Cytotoxic or hazardous Drug Compounds*
- SOP 7.020 *Disposing of Waste in Production* Areas
- SOP 7.030 *Cytotoxic or Hazardous Drug Spills*
- SOP 7.050 *Hazardous Chemical Storage*
- SOP 7.070 *Respiratory Protection Program*

Observation 12:
CRF 211.188(b)(8)
Batch production and control records Batch production and control records shall be prepared for each batch of drug product produced and shall include complete information relating to the production and control of each batch. These records shall include:
Documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including: Complete labeling control records, including specimens or copies of all labeling used;

During inspection it was observed for cyclosporine compounding, the beaker of formulation was covered with foil, but this step was not listed in the batch record. Also, the batch record for this product and Cidofovir did not have specimens of all the labeling which includes but is not limited to the in-process labels and autoclave labels.

Observation 12 Response:
We acknowledge the observation of certain steps being performed that were not instructed in the batch record. We have reviewed our procedures and identified areas where we better define processing and handling steps during formulation, including light protective measures.

wedgewood connect

SOP 6.070 *Storage and Handling of Materials* was updated to include specific instructions for handling light sensitive materials during the formulation process. For evidence of SOP update, see Attachment # 9.

SOP 6.020 *503B labelling* has been updated to include new attachment for documenting copy of specimen of all other labels generated during production of batch including in-process labels and autoclave labels. For evidence of SOP update, see Attachment # 10.

All Staff training records on updated SOP will be provided by 06/30/23.

Wedgewood Connect takes all the Investigators' observations seriously and it is our intent to be fully compliant with all aspects of California regulations; the current 503B guidance; as well as all appropriate sections of 21 CFR 211.

Sincerely,

Christina Vega, Pharm.D.
Site Quality Director

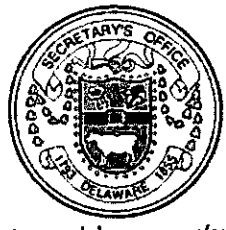
Copies
Craig Mastenbaum – General Manager
Evelyn Lopez – Operations Director
Joseph Costa – President and Chief Operating Officer
Paul Yamamoto, R.Ph., Vice President of Pharmacy Services and Pharmacist in Charge
Peg Panella-Spangler, R.Ph., Supervising Inspector
Alyce Petrutiu, R.Ph., Inspector
Lesa Fitzpatrick, R.Ph., Inspector

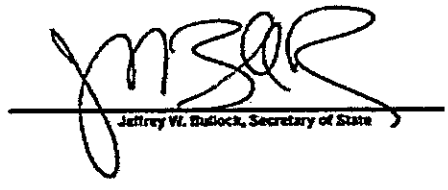
Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "WEDGEWOOD CONNECT, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-NINTH DAY OF MARCH, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.





3219181 8300

SR# 20241221389

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203142179

Date: 03-29-24

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	WEDGEWOOD CONNECT, LLC
Entity No.:	202019510105
Registration Date:	07/10/2020
Entity Type:	Limited Liability Company - Out of State
Formed In:	DELAWARE
Status:	Active

The above referenced entity is active on the Secretary of State's records and is qualified to transact intrastate business in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of March 18, 2024.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 192102321

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway #206
Reno, NV 89521

April 22, 2024

California State Board of Pharmacy License Verification

This document reflects the license status of the person or entity identified below on this date with the California State Board of Pharmacy. It may be used as prima facie evidence of the facts recited below pursuant to California Business and Professions Code section 162.

Licensee Name: WEDGEWOOD CONNECT LLC

License Type: OUTSOURCING FACILITY

License Number: OSF 138

Status: ACTIVE

Issue Date: 07/15/2020

Expiration Date: 07/01/2024

Address of Record: 17 GREAT OAKS BLVD SAN JOSE, CA 95119

Disciplinary Action: NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren
Executive Officer

By

Ann Altamirano
Public Inquiry Analyst
(916) 518-3045
Pharmacy.PublicRecords@dca.ca.gov

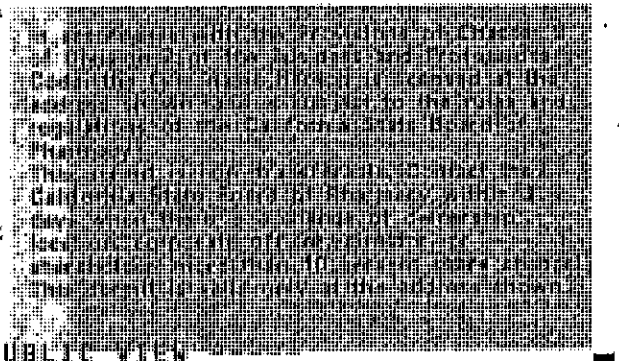
BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Renewal Certificate

Outsourcing Facility License

LICENSE NO. OSF 138 VALID UNTIL JULY 01, 2024
RECEIPT NO. 00186214

WEDGEWOOD CONNECT LLC
17 GREAT OAKS BLVD
SAN JOSE CA 95119



06/28/23
06/28/23

The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW

FORM WPHOSF (09/30/19)

Corporate Information
Wedgewood Pharmacy LLC
Wedgewood Connect LLC

Officers:

President:	Joseph Costa
CFO & Treasurer	Maria Kraus
Secretary	Marcy Bliss

Parent Companies:

Wedgewood Holdings Inc. (100% owner of Wedgewood Pharmacy LLC)
Specialty Pharma III Inc. (100% owner of Wedgewood Holdco Inc)
Specialty Pharma II Inc. (100% owner of Specialty Pharma III Inc.)
Specialty Pharma I Inc. (100% owner of Specialty Pharma II Inc.)
Specialty Pharma Holdings LP (100% owner of Specialty Pharma I Inc.)

Address:

405 Heron Drive, Suite 200
Swedesboro, NJ 08085

Officers:

President & COO:	Joseph Costa
CFO:	Maria Kraus
CEO & Sec.:	Marcy Bliss

Directors:

Marcy Bliss
Sofia Gerard
Dennis Maloney
Kevin Vasquez
David Kamenetzky
Peter Berweger

Shareholders:

There are no individual shareholders in Wedgewood Connect/Village Pharmacy as both entities are member managed limited liability companies.

All shares in Wedgewood Holdings Inc. are held by Specialty Pharma III Inc.

Marcy Bliss, Maria Kraus and Joseph Costa have served as officers at the following pharmacy locations:

Wedgewood Pharmacy LLC (f/k/a Wedgewood Village Pharmacy LLC)
405 Heron Drive, Suite 200
Swedesboro, NJ 08085

Wedgewood Pharmacy LLC (f/k/a Wedgewood Village Pharmacy LLC)
7631 E. Indian School Road, Suite 105
Scottsdale, AZ 85251

ZooPharm LLC (now closed)
3131 Grand Ave., Unit C, Laramie, WY 82070

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RW0603236	05-31-2024	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,4	MANUFACTURER	04-07-2023

WEDGEWOOD CONNECT
WEDGEWOOD CONNECT
17 GREAT OAKS BLVD
SAN JOSE, CA 95119

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RW0603236	05-31-2024	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,4	MANUFACTURER	04-07-2023

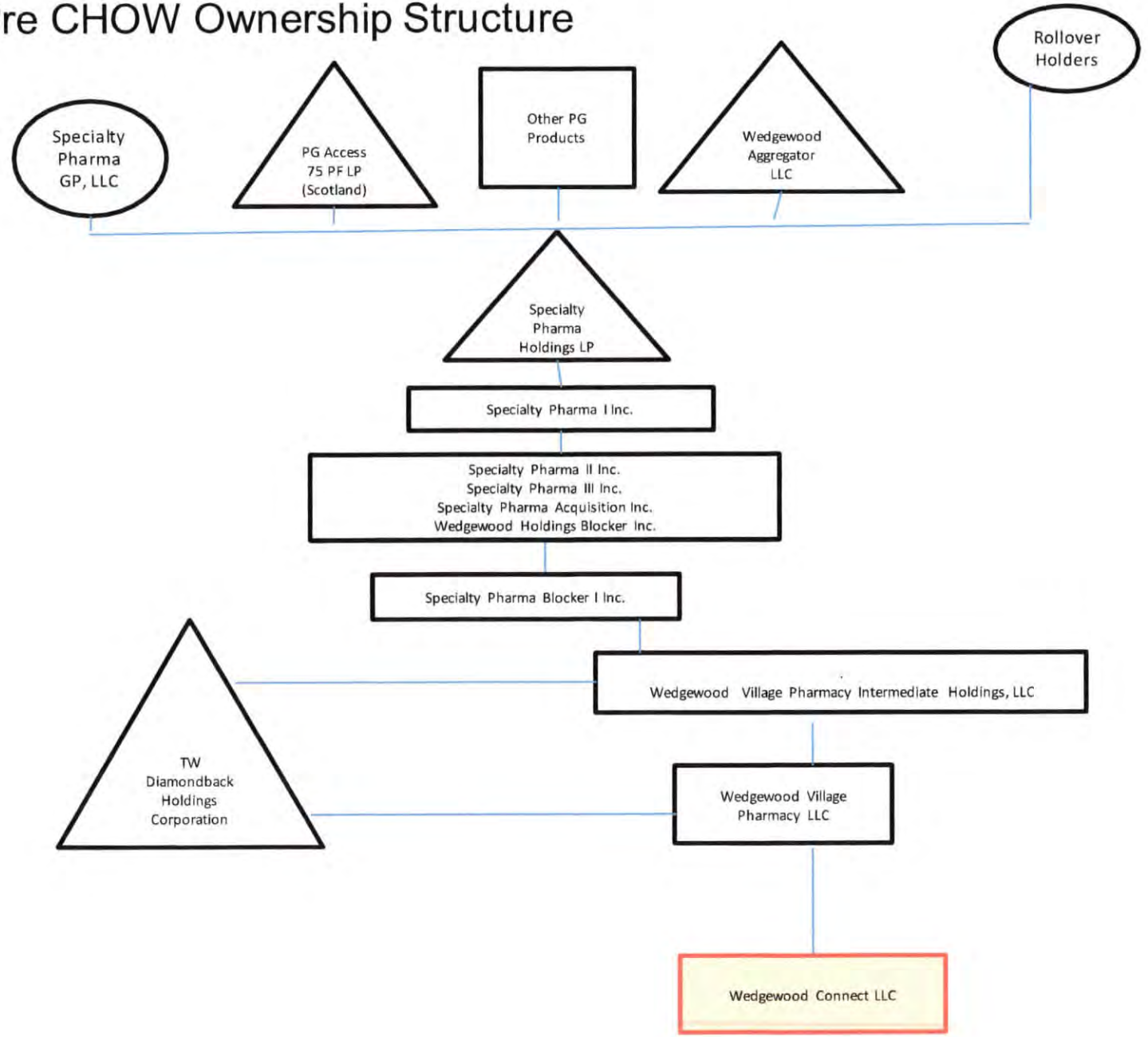
WEDGEWOOD CONNECT
WEDGEWOOD CONNECT
17 GREAT OAKS BLVD
SAN JOSE, CA 95119

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

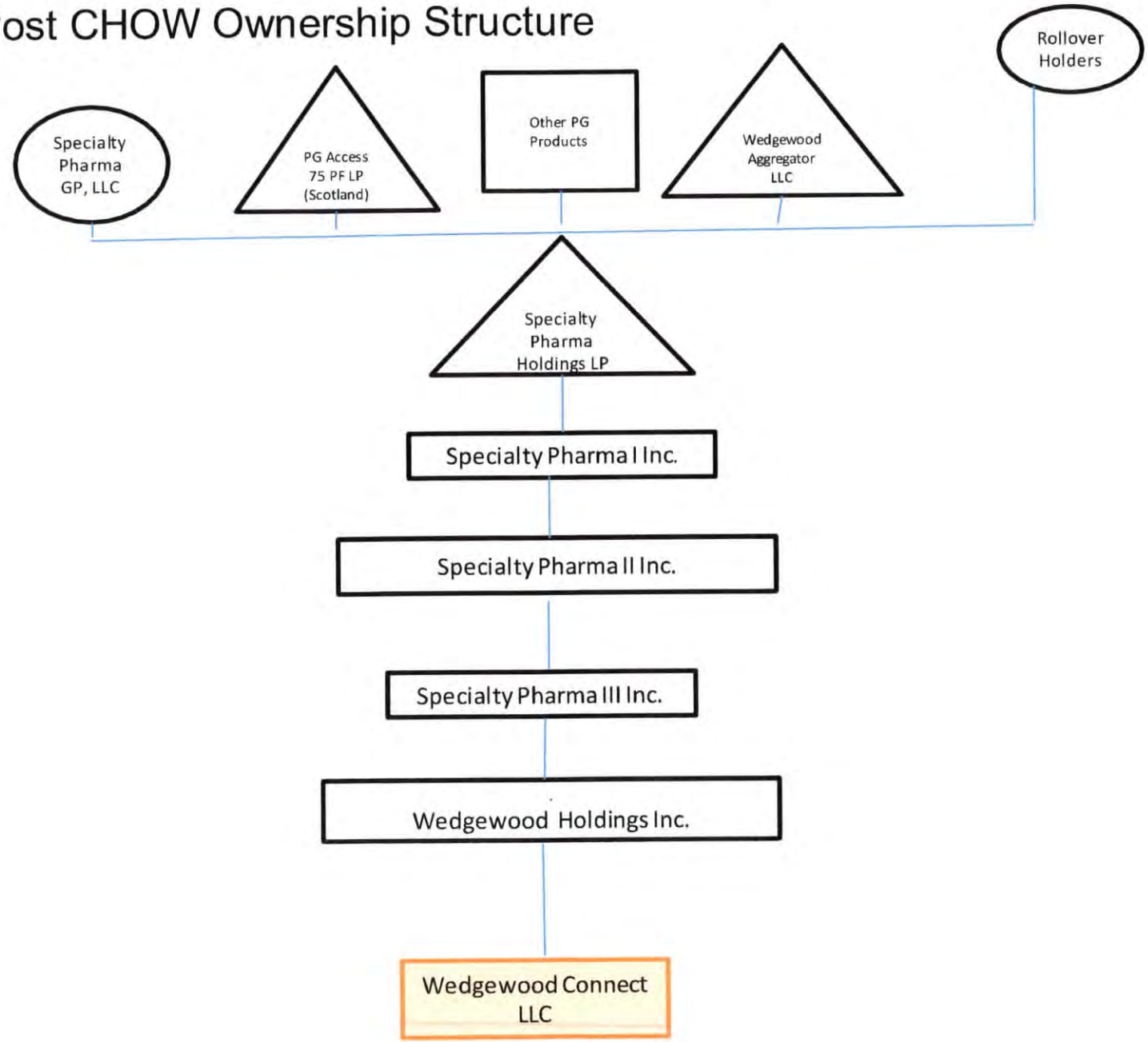
THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

Pre CHOW Ownership Structure



Post CHOW Ownership Structure



Within the last five (5) years:
3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry?

Wedgewood Pharmacy LLC

The list includes prior matters that have previously been reported to the Board in an effort to provide full transparency with the application.

I. Discipline and Closed Matters for Wedgewood Village Pharmacy LLC, Swedesboro, NJ Location

6/17/2021 – California Citation & Fine

Received notification of a non-disciplinary, Administrative Citation which was finalized on 07/29/2021. A fine was paid as part of the final citation. The basis for the citation was that Wedgewood did not have the necessary data to support the "beyond use dates" Wedgewood used.

3/22/24 – California Stipulation Settlement and Disciplinary Order for Public Reproval

On February 21, 2024, the California Board of Pharmacy (the "Board") approved a Stipulated Settlement and Disciplinary Order for Public Reproval entered into with Wedgewood Village Pharmacy LLC relating to claims made by the Board regarding assignment of unsupported beyond use dates and other matters. The Order became effective on March 22, 2024 and Wedgewood agreed to pay the Board $11,054.75 as reimbursement of its costs in connection with this matter.

Rachel Taggs
Sr. Compliance Specialist
Wedgewood Pharmacy

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

June 17, 2021

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2020 90874
WEDGEWOOD VILLAGE PHARMACY LLC
NRP 1826

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- July 01, 2021: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- July 17, 2021: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Stephanie Koenig, Associate Enforcement Analyst at (916) 518-3012.

Anne Sodergren
EXECUTIVE OFFICER

By: Skoenig

Stephanie Koenig
Associate Enforcement Analyst

Attachments

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826
Citation and Fine CI 2020 90874

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On, June 17, 2021 I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR SUITE 200 SWEDESBORO, NJ 08085	7020 0640 0002 1075 9670

I declare under penalty of perjury that the forgoing is true and correct.

Executed on June 17, 2021

DECLARANT

Stephanie Koenig
Associate Enforcement Analyst

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2020 90874	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1735.2 subd. (i)(3)	**Compounding Limitations & Requirements- Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding; extension of a beyond use date is only allowable when...**

CONDUCT:

Assigning an extended beyond use date without the required data: California code of regulations section 1735.2(i)(3) states every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding. (3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following: (A) Method Suitability Test, (B) Container Closure Integrity Test, and (C) Stability Studies. Wedgewood Village Pharmacy Llc located at 405 Heron Drive, Suite 200, Swedesboro, NJ 08085 was not compliant. Specifically, from at least 5/19/20 to at least 6/1/20 Wedgewood Village Pharmacy Llc assigned a beyond use date of approximately 120 day without first having at least a method suitability test, container Closure integrity test, and stability studies. This investigation found this to be true for at least the following 5 lots and 281 units (3.5gms each).

Date made	Lot number	units made	units recalled	BUD assigned
5/19/20	000-02188529	485	89	9/26/20
5/22/20	000-02196777	492	62	9/19/20
5/28/20	000-02205573	473	77	9/25/20
5/29/20	000-02210219	481	29	9/26/20
6/1/20	000-02214825	482	24	9/29/20
Grand Total			281	

This is a violation of Pharmacy law.

CITATION ISSUED ON: June 17, 2021

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

June 17, 2021

DATED MATERIAL ENCLOSED

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR, SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2020 89042
WEDGEWOOD VILLAGE PHARMACY LLC
NSC 100970

The attached Citation and Fine, Order of Abatement ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation and indicates, within the Order of Abatement, information and/or material to be submitted to the Board.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- July 17, 2021: Unless the Citation is contested, Proof of Abatement and payment of fine(s) must be received by the Board, or as directed in Order of Abatement at the bottom of your citation.
- July 01, 2021: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- July 17, 2021: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), timely payment of any fine(s) and the submission of Proof of Abatement shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations title 16 section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Stephanie Koenig, Associate Enforcement Analyst at (916) 518-3012.

Anne Sodergren
EXECUTIVE OFFICER

By: Skoenig

Stephanie Koenig
Associate Enforcement Analyst

Attachments

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970
Citation and Fine CI 2020 89042

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On, April 28, 2021 I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Order of Abatement, Proof of Abatement, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
WEDGEWOOD VILLAGE PHARMACY LLC ATTN: MARCY ANN BLISS, CEO 405 HERON DR, SUITE 200 SWEDESBORO, NJ 08085	7020 0640 0002 1075 9687

I declare under penalty of perjury that the forgoing is true and correct.

Executed on April 28, 2021

DECLARANT

Stephanie Koenig
Associate Enforcement Analyst

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE
ORDER OF ABATEMENT

Citation Number	Name, License No
CI 2020 89042	WEDGEWOOD VILLAGE PHARMACY LLC, NSC 100970

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1735.2 subd. (i)(3)	Compounding Limitations & Requirements- Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding; extension of a beyond use date is only allowable when...	$2,500.00

CONDUCT:

Assigning an extended beyond use date without the required data: California code of regulations section 1735.2(i)(3) states every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding. (3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following: (A) Method Suitability Test, (B) Container Closure Integrity Test, and (C) Stability Studies. Wedgewood Village Pharmacy Llc located at 405 Heron Drive, Suite 200, Swedesboro, NJ 08085 was not compliant. Specifically, from at least 5/19/20 to at least 6/1/20 Wedgewood Village Pharmacy Llc assigned a beyond use date of approximately 120 day without first having at least a method suitability test, container Closure integrity test, and stability studies. This investigation found this to be true for at least the following 5 lots and 281 units (3.5gms each).

Date made	Lot number	units made	units recalled	BUD assigned
5/19/20	000-02188529	485	89	9/26/20
5/22/20	000-02196777	492	62	9/19/20
5/28/20	000-02205573	473	77	9/25/20
5/29/20	000-02210219	481	29	9/26/20
6/1/20	000-02214825	482	24	9/29/20
Grand Total			281	

This is a violation of Pharmacy law.

ORDER OF ABATEMENT

By the Abatement date/payment date submit to the Board the following:

In addition to the issued citation, Wedgewood Village Pharmacy shall provide (1) payment in the amount of $2,500.00 and (2) justification for extended Beyond Use Dates (BUD's) for antibacterial eye ointment within 30 days from the date the citation was issued.

If Wedgewood Village Pharmacy fails to provide justification for extended Beyond Use Dates (BUD's) for antibacterial eye ointment within 30 days from the date the citation was issued, this shall constitute a ground for revocation or suspension of your license, permit, or registration.

CITATION ISSUED ON: June 17, 2021	TOTAL AMOUNT OF FINE(S): $2,500.00

PROOF OF ABATEMENT AND PAYMENT OF FINE(S) DUE BY: July 17, 2021

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

July 29, 2021

WEDGEWOOD VILLAGE PHARMACY LLC
ATTN: MARCY ANN BLISS, CEO
405 HERON DR, SUITE 200
SWEDESBORO, NJ 08085

RE: CI 2020 89042
WEDGEWOOD VILLAGE PHARMACY LLC
NSC 100970

This is in response to the administrative fine and proof of abatement provided to the board for the above referenced citation. The payment and documentation have been received and accepted as satisfactorily resolving the matter.

Please be advised that this citation has become a part of the board's records and constitutes a public record for purposes of disclosure.

If you have any questions regarding this matter, please contact the Enforcement Manager, Susan Cappello at (916) 518-3008.

Sincerely

Julia Ansel
Chief of Enforcement
Board of Pharmacy

3/22/24 – California Stipulation Settlement and Disciplinary Order for Public Reproval

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

February 21, 2024

CERTIFIED MAIL

Wedgewood Village Pharmacy
Attn: Marcy Ann Bliss, CEO
405 Heron Drive
Swedesboro, NJ 08085

RE: Administrative Case No. 7286
Wedgewood Village Pharmacy LLC, dba Wedgewood Village Pharmacy,
NRP 2526, NRP 1826, NSC 101673 & NSC 100970

Dear Ms. Bliss:

Attached is the Board of Pharmacy's Stipulated Settlement and Disciplinary Order for Public Reproval regarding the above-referenced matter. Your attention is directed to pages 5 – 6 of the document.

Effective at 5:00 p.m. on March 22, 2024, Nonresident Pharmacy Permit Nos. NRP 2526 & NRP 1826 and Nonresident Sterile Compounding Permit Nos. NSC 101673 & NSC 100970 issued to Wedgewood Village Pharmacy, shall be publicly reproved by the Board and shall also be subject to terms and conditions in the decision.

If you wish to file a petition for reconsideration pursuant to Government Code section 11521, the petition must be received prior to the effective date of the decision. However, please be aware the Board needs approximately five days to process a petition for reconsideration. Attached is a copy of the Government Code section for your review. **Please note that reconsideration is NOT available to you if you entered into a stipulated settlement with the Board.**

If you have any questions concerning this matter, you may contact Lupe Baltazar, at lupe.baltazar@dca.ca.gov or (916) 518-3009. Should you have any questions related to litigation of this matter, please contact the Deputy Attorney General handling this matter.

Sincerely,

ANNE SODERGREN
Executive Officer

By

Susan Cappello
Enforcement Manager

SC:lb
Enclosure(s)

cc: Kristina T. Jarvis, DAG
Derek Shaffer, Esq.

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Administrative Case No. 7286
Wedgewood Village Pharmacy,
NRP 2526, NRP 1826, NSC 101673 & NSC 100970

I am over 18 years of age, and not a party to the within cause; my business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. I served a copy of the:

LETTER AND DECISION

on each of the following, by placing same in an envelope(s) addressed to as follows:

NAME	CERTIFIED NO.
Wedgewood Village Pharmacy Attn: Marcy Ann Bliss, CEO 405 Heron Drive Swedesboro, NJ 08085	9589 0710 5270 0843 9755 17
Quinn Emanuel Urquhart & Sullivan, LLP Attn: Derek Shaffer, Esq. 1300 I St., NW., Ste. 900 Washington, D.C. 20005	9589 0710 5270 0843 9755 24

and that said envelope was then sealed and deposited and certified in the United States Post Office at Sacramento, California, on February 21, 2024, as certified mail with postage fully prepaid thereon and return receipt service by United States mail between the place of mailing and the place so addressed.

I declare under penalty of perjury that the foregoing is true and correct. Executed on February 21, 2024, at Sacramento, California

Lupe Baltazar, Administrative Case Analyst

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:

WEDGEWOOD VILLAGE PHARMACY LLC; dba
WEDGEWOOD VILLAGE PHARMACY;
INTERMEDIATE HOLDINGS LLC 59% SHAREHOLDER;
TW DIAMONDBACK HOLDINGS CORPORATION, 41%
SHAREHOLDER;
MARCY ANN BLISS, CEO; JOSEPH COSTA, COO; ALISON LYNCH, PIC,
Nonresident Pharmacy Permit No. NRP 2526,
Nonresident Sterile Compounding Permit No. NSC 101673; and

WEDGEWOOD VILLAGE PHARMACY LLC;
WEDGEWOOD VILLAGE PHARMACY
INTERMEDIATE HOLDINGS LLC 59% SHAREHOLDER;
TW DIAMONDBACK HOLDINGS CORPORATION, 41%
SHAREHOLDER;
MARCY ANN BLISS, CEO; ALISON LYNCH, PIC,
Nonresident Pharmacy Permit No. NRP 1826,
Nonresident Sterile Compounding Permit No. NSC 100970

Respondents

Agency Case No. 7286

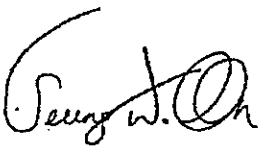
DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 22, 2024.

It is so ORDERED on February 21, 2024.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
KRISTINA T. JARVIS
Deputy Attorney General
State Bar No. 258229
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-6088
Facsimile: (916) 327-8643
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **WEDGEWOOD VILLAGE PHARMACY LLC; WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% shareholder; TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder; MARCY ANN BLISS, CEO; JOSEPH COSTA, COO; ALISON LYNCH, PIC; 405 Heron Drive Swedesboro, NJ 08085** **Nonresident Pharmacy Permit No. NRP 2526, Nonresident Sterile Compounding Permit No. NSC 101673** **and** **WEDGEWOOD VILLAGE PHARMACY LLC; WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% Shareholder; TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder; MARCY ANN BLISS, CEO; ALISON LYNCH, PIC; 405 Heron Drive, Suite 200 Swedesboro, NJ 08085**	Case No. 7286 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL** **[Bus. & Prof. Code § 495]**

Nonresident Pharmacy Permit No. NRP 1826, Nonresident Sterile Compounding Permit No. NSC 100970

Respondents.

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Kristina T. Jarvis, Deputy Attorney General.

2. On or about June 6, 2016, the Board issued Nonresident Pharmacy Permit Number NRP 1826 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 100% shareholder, doing business as (dba) Wedgewood Village Pharmacy LLC, Marcy Ann Bliss, CEO; and Alison Lynch, Pharmacist-in-Charge (Respondent Original Licensee). On or about July 17, 2018, the Board was notified and updated its records to reflect a change in ownership such that Wedgewood Village Pharmacy Intermediate Holdings LLC became a 59% shareholder and TW Diamondback Holdings Corporation became a 41% shareholder, still dba Wedgewood Village Pharmacy LLC; Marcy Ann Bliss, CEO; and Alison Lynch, Pharmacist-in-Charge, (Respondent Successor Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 4, below.

3. On or about June 6, 2016, the Board issued Nonresident Sterile Compounding Pharmacy Permit Number NSC 100970 to Respondent Original Licensee. The Nonresident Sterile Compounding Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 5, below.

///

4. On or about April 1, 2021, due to a change of ownership application, the Board issued Nonresident Pharmacy Permit Number NRP 2526 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 59% shareholder, and TW Diamondback Holdings Corporation, 41% shareholder dba Wedgewood Village Pharmacy LLC; Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge; (Respondent Successor Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

5. On or about April 1, 2021, the Board issued Nonresident Sterile Compounding Permit Number NSC 101673 to Respondent Successor Licensee. The Nonresident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

6. Respondent is represented in this proceeding by attorney Derek Shaffer whose address is: 1300 I Street NW, Suite 900, Washington D.C. 20005.

JURISDICTION

7. Accusation No. 7286 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on April 27, 2023. Respondent timely filed its Notice of Defense contesting the Accusation. On July 26, 2023, Complainant filed a First Amended Accusation. A copy of First Amended Accusation No. 7286 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

8. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 7286. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

9. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to be

represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Proccdure Act and other applicable laws.

10. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

11. NRP 1826 and NSC 101673 have been cancelled, and the Board confirms that there are no pending allegations or investigations against these licenses, and therefore no future administrative or disciplinary action is contemplated.

CULPABILITY

12. Respondent understands and agrees that the charges and allegations in Accusation No. 7286, if proven at a hearing, constitute cause for imposing discipline upon its Nonresident Pharmacy Permits and Nonresident Sterile Compounding Permits.

13. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent hereby gives up its right to contest those charges.

14. Respondent agrees that its Nonresident Pharmacy Permit and Nonresident Sterile Compounding Permit are subject to discipline and they agree to be bound by the Disciplinary Order below.

CONTINGENCY

15. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action

between the parties, and the Board shall not be disqualified from further action by having considered this matter.

16. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

17. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

18. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Nonresident Pharmacy Permit No. NRP 1826, Nonresident Sterile Compounding Permit No. NSC 100970, Nonresident Pharmacy Permit No. NRP 2526 and Nonresident Sterile Compounding Permit No. NSC 101673 issued to Respondents shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 7286, attached as exhibit A.

Cost Recovery. No later than 1 YEAR from the effective date of the Decision, Respondent shall pay $11,054.75 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code Section 125.3. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew their Nonresident Pharmacy Permit NRP 2526, or Nonresident Sterile Compounding Permit No. NSC 101673 until Respondent pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

Full Compliance. As a resolution of the charges in Accusation No. 7286, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Nonresident Pharmacy Permit No. NRP 2526 and Nonresident Sterile Compounding Permit No. NSC 101673.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Derek Shaffer. I understand the stipulation and the effect it will have on my Nonresident Pharmacy Permits and Nonresident Sterile Compounding Permits. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 1/2/2024 | 1:23 PM PST

WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, and TW DIAMONDBACK HOLDINGS CORPORATION, dba WEDGEWOOD VILLAGE PHARMACY LLC;

DocuSigned by:

By: MARCY ANN BLISS Marcy Ann Bliss

25BA168EA269425...

Title: CEO
Respondent

I have read and fully discussed with Respondent Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation, dba Wedgewood Village Pharmacy LLC, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 1/4/2024 | 7:34 AM PST

DocuSigned by:

Derek Shaffer

DEREK SHAFFER
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: January 11, 2024

Respectfully submitted,

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General

KRISTINA T. JARVIS
Deputy Attorney General
Attorneys for Complainant

SA2022301557

ROB BONTA
Attorney General of California
ANDREW M. STEINHEIMER
Supervising Deputy Attorney General
KRISTINA T. JARVIS
Deputy Attorney General
State Bar No. 258229
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-6088
Facsimile: (916) 327-8643
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:	Case No. 7286
WEDGEWOOD VILLAGE PHARMACY LLC; **WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% shareholder;** **TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder;** **MARCY ANN BLISS, CEO;** **JOSEPH COSTA, COO;** **ALISON LYNCH, PIC;** **405 Heron Drive** **Swedesboro, NJ 08085** **Nonresident Pharmacy Permit No. NRP 2526,** **Nonresident Sterile Compounding Permit No. NSC 101673** **and** **WEDGEWOOD VILLAGE PHARMACY LLC;** **WEDGEWOOD VILLAGE PHARMACY INTERMEDIATE HOLDINGS LLC, 59% Shareholder;** **TW DIAMONDBACK HOLDINGS CORPORATION, 41% shareholder;** **LUDMILLA MALMBERG, Chairman;** **MARCH ANN BLISS, CEO;** **JOCELYN ROSE STANLEY, Secretary;** **THOMAS J. FORMOLO, Secretary;**	**ACCUSATION**

EDWARD MICHAEL LHEE, Secretary;
ALISON LYNCH, PIC;
405 Heron Drive, Suite 200
Swedesboro, NJ 08085

Nonresident Pharmacy Permit No. NRP 1826,
Nonresident Sterile Compounding Permit No. NSC 100970

Respondent.

PARTIES

1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).

2. On or about June 6, 2016, the Board issued Nonresident Pharmacy Permit Number NRP 1826 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 100% shareholder, doing business as (dba) Wedgewood Village Pharmacy LLC, Ludmilla Malmberg, Chairman, Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge. On or about July 17, 2018, the Board was notified and updated its records to reflect a change in ownership such that Wedgewood Village Pharmacy Intermediate Holdings LLC became a 59% shareholder and TW Diamondback Holdings Corporation became a 41% shareholder, still dba Wedgewood Village Pharmacy LLC; Ludmilla Malmberg, Chairman,Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge, (Respondent Original Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 4, below.

3. On or about June 6, 2016, the Board issued Nonresident Sterile Compounding Pharmacy Permit Number NSC 100970 to Respondent Original Licensee. The Nonresident Sterile Compounding Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein until April 1, 2021, at which point the license was cancelled due to a change of ownership as set forth in paragraph 5, below.

///

4. On or about April 1, 2021, due to a change of ownership application, the Board issued Nonresident Pharmacy Permit Number NRP 2526 to Wedgewood Village Pharmacy Intermediate Holdings LLC, 59% shareholder, and TW Diamondback Holdings Corporation, 41% shareholder dba Wedgewood Village Pharmacy LLC; Marcy Ann Bliss, CEO; Joseph Costa, COO; and Alison Lynch, Pharmacist-in-Charge; (Respondent Successor Licensee, collectively "Respondents"). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

5. On or about April 1, 2021, the Board issued Nonresident Sterile Compounding Permit Number NSC 101673 to Respondent Successor Licensee. The Nonresident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein from April 1, 2021, and will expire on April 1, 2024, unless renewed.

JURISDICTION

6. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

7. Section 4011 of the Code states:

The board shall administer and enforce this chapter and the Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code).

8. Section 4300 of the Code states in pertinent part:

(a) Every license issued may be suspended or revoked.

...

(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

9. Section 4300.1 of the Code states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not

deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

10. Section 4307 of the Code states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

STATUTORY PROVISIONS

11. Section 4301 of the Code states in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofcssional conduct shall include, but is not limited to, any of the following:

...

(c) Gross negligence.

...

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

...

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

...

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency....

REGULATORY PROVISIONS

12. California Code of Regulations, title 16, (Regulations) section 1735.2 states in pertinent part:

...

(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

...

(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

...

(*l*) Packages of ingredients, both active and inactive, that lack a supplier's expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

(2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

13. Regulations section 1735.3 states in pertinent part:

(a) For each compounded drug preparation, pharmacy records shall include:

...

(2) A compounding log consisting of a single document containing all of the following:

...

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply....

COST RECOVERY

14. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DRUG PREPARATIONS

15. Tacrolimus Ophthalmic Suspension is an eye drop generally prescribed to dogs to treat dry eyes, particularly when caused by low tear production or tears of poor quality. It is a dangerous drug pursuant to Code section 4022.

16. Protirelin is an injectable drug product generally prescribed for horses as a thyrotropin-releasing hormone in order to test for certain metabolic disorders or illnesses. It is a dangerous drug pursuant to Code section 4022.

17. Cyclosporine in MCT oil solution is an eye drop generally prescribed to dogs. It is used to decrease inflammation in the eye and tear glands and increase tear production. It is a dangerous drug pursuant to Code section 4022.

18. Edetate Disodium (EDTA) is a chelating agent generally prescribed to treat corneal ulcers in dogs, cats, and horses. It is a dangerous drug pursuant to Code section 4022.

FACTUAL ALLEGATIONS

19. Respondents own and operate a nonresident pharmacy which also possesses a nonresident sterile compounding pharmacy permit, and is located in the State of New Jersey.

20. On or about April 1, 2021, due to a change in the ownership structure of certain parent corporations that own the corporations that own Respondent Original Licensee, successor licensees, both a nonresident pharmacy permit and a nonresident sterile compounding pharmacy permit, were issued to the same immediate ownership structure. Nearly all of the immediate owners and officers of Respondent Original Licensee remained with Respondent Successor Licensee. The conduct set forth in this accusation came to the attention of the Board due to the change of ownership inspection that is required by pharmacy law. Therefore, all of the actions were taken on dates on which Respondent Original Licensee was the owner and operator of the pharmacy. However, since the immediate ownership structure did not change, the owners and operators of Respondent Successor Licensee are responsible for the actions of Respondent Original Licensee.

21. Respondents specialize in veterinary compounding.

22. On January 1, 2017, the Board's sterile compounding regulations became effective.

23. In 2017, Board inspector S.P. issued a written warning to Respondents due to Respondents issuing many of its drug preparations extended beyond use dates (BUDs) without the appropriate data to support those BUDs.

24. In 2018, and again in 2020, during inspections of Respondents facility, Board inspector S.P. discussed with Respondents the documentation Respondents needed to provide, obtain, or test for, in order determine and assign extended BUDs and noted that Respondents had not obtained, tested for, or provided this documentation such that the extended BUDs were still inappropriate.

25. After the 2020 inspection, the Board issued a citation to Respondents for providing 120-day extended BUDs without having the tests and studies required to support the extended BUDs.

///

26. On and between approximately March 17, 2021, and May 28, 2021, Board Inspector M.V. conducted a change of ownership inspection regarding Respondents as discussed in additional depth, above. Due to the COVID-19 pandemic, the inspection was conducted remotely via records review. The investigation report is dated March 1, 2022 (March 1, 2022 Inspection Report).

27. On or about March 19, 2021, Board Inspector M.V. requested five specific compounding logs for review, including certificates of analyses, end-product release testing, documentation supporting any extended BUDs assigned to preparations, sample labels, and training records for Respondents' compounding pharmacist and compounding pharmacy technician. M.V.'s review of just these five compounding logs lead to the causes for discipline set forth below.

FIRST CAUSE FOR DISCIPLINE

(Assignment of Unsupported Extended Beyond Use Dates)

28. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondents violated Regulations 1735.2, subdivision (i). The circumstances are as follows:

A. On or about July 1, 2020, Respondents compounded 623 bottles of Tacrolimus 0.03% ophthalmic aqueous suspensions and gave an extended BUD of 160 days. Respondents only had data to support a 45-day BUD for this drug product.

B. On or about November 27, 2020, Respondents compounded 581 bottles of Cyclosporine 2% in MCT oil ophthalmic solutions and gave an extended BUD of 180 days. Respondents only had data to support a 45-day BUD for this drug product.

C. On or about February 8, 2021, Respondents compounded 353 vials of Protirelin Acetate 1mg/ml injectable solution and gave an extended BUD of 240 days. Respondents had no data to support an extended BUD for this product.

///

///

D. On or about March 10, 2020, Respondents compounded 53 bottles (15mL) of Edetate Disodium and gave an extended BUD of 240 days. Respondents had no data to support an extended BUD for the product.

SECOND CAUSE FOR DISCIPLINE

(Incomplete Compounding Records)

29. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondents violated Regulations section 1735.3, subdivision (a)(2). The circumstances are that Respondents' compounding logs reviewed by Board Inspector M.V. failed to list the manufacturers of the drug components Respondents used for compounding.

THIRD CAUSE FOR DISCIPLINE

(Gross Negligence)

30. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (c), in that Respondents committed acts constituting gross negligence when Respondents assigned extended BUDs without having the required data to support those BUDs.

FOURTH CAUSE FOR DISCIPLINE

(Knowingly Making or Signing a False Document)

31. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (g), in that Respondents knowingly made or signed false documents when Respondents assigned extended BUDs without having the required data to support those BUDs.

FIFTH CAUSE FOR DISCIPLINE

(Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

32. Respondents are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (g), in that Respondents committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption when Respondents continued to assign extended

BUDs and ship the compounded drugs to patients without having the required data to support those BUDs.

DISCIPLINARY CONSIDERATIONS

33. On or about June 17, 2021, Citation number CI 2020 90874 was issued to Respondent Original Licensee's Nonresident Pharmacy permit for violation of Regulations section 1735.2, subdivision (i)(3), for assigning an extended BUD without the required data. The citation did not order a fine, it was not appealed, and it is final.

34. On or about June 17, 2021, Citation number CI 2020 89042 was issued to Respondent Original Licensee's Nonresident Sterile Compounding Pharmacy permit for violation of Regulations section 1735.2, subdivision (i)(3), for assigning an extended BUD without the required data. The citation ordered a $2,500 fine, and required proof of abatement regarding justification for assigning extended BUDs for antibacterial eye ointment. The citation was not appealed and is final.

35. On or about December 5, 2018, Citation number Cl 2018 82132 was issued to Respondent Original Licensee's Nonresident Pharmacy permit f or violation of Regulations section 1735.2, subdivisions (c)(1), and (c)(4) for furnishing over 2,200 unites of compounded ophthalmic drops to a prescriber for office use. This amount exceeds the reasonable quantity that may be furnished and Respondent Original Licensee failed to have a credible basis for determining a reasonable quantity for office use. The citation was not appealed and is final.

36. On or about December 5, 2018, Citation number Cl 2016 73882 was issued to Respondent Original Licensee's Nonresident Sterile Compounding Pharmacy permit for violation of Regulations section 1735.2, subdivisions (c)(1), and (c)(4) for furnishing over 2,200 unites of compounded ophthalmic drops to a prescriber for office use. This amount exceeds the reasonable quantity that may be furnished and Respondent Original Licensee failed to have a credible basis for determining a reasonable quantity for office use. The citation was not appealed and is final.

///

///

///

37. On or about October 13, 2017, Citation number CI 2017 77042 was issued to Respondent Original Licensee's Nonresident Pharmacy permit for violation of Code section 4059.5, subdivision (b), for selling prescription items to individual. S.G. who was not authorized to purchase these items. S.G. represented himself as a physician and Respondent Original Licensee failed to note the discrepancy between S.G.'s address and the address of the physician he was impersonating. The citation ordered a $1,000 fine, it was not appealed, and it is final.

OTHER MATTERS

38. Pursuant to Code section 4307, if discipline is imposed on Nonresident Pharmacy Permit Number NRP 2526 or on Nonresident Sterile Compounding Pharmacy Permit Number NSC 101673 issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC then Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC, and if Ludmilla Malmberg, Marcy Ann Bliss, Joseph Costa, and Alison Lynch are proven to have knowledge of or have participated in the conduct, then each shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for 1) a period not to exceed five (5) years if either or both of the pharmacy permits are placed on probation; or, 2) if either or both of the pharmacy permits are revoked, the prohibition shall continue until either of the permits are reinstated.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Nonresident Pharmacy Permit number NRP 1826, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

2. Revoking or suspending Nonresident Sterile Compounding Permit number NSC 100970, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

///

3. Revoking or suspending Nonresident Pharmacy Permit number NRP 2526, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

4. Revoking or suspending Nonresident Sterile Compounding Permit number NSC 101673, issued to Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC;

5. Prohibiting Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

6. Ludmilla Malmberg from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

7. Prohibiting Marcy Ann Bliss from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

8. Prohibiting Joseph Costa from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

9. Prohibiting Alison Lynch from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

10. Ordering Wedgewood Village Pharmacy Intermediate Holdings LLC, and TW Diamondback Holdings Corporation dba Wedgewood Village Pharmacy LLC, Ludmilla Malmberg, Marcy Ann Bliss, and Joseph Costa to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

///

11. Taking such other and further action as deemed necessary and proper.

DATED: 4/5/2023

Sodergren, Anne@DCA
Digitally signed by Sodergren, Anne@DCA
Date: 2023.04.15 07:02:07 -07'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

SA2022301557
Wedgewood Acc.docx

GOVERNMENT CODE - GOV

TITLE 2. GOVERNMENT OF THE STATE OF CALIFORNIA [8000 - 22980] *(Title 2 enacted by Stats. 1943, Ch. 134.)*

DIVISION 3. EXECUTIVE DEPARTMENT [11000 - 15986] *(Division 3 added by Stats. 1945, Ch. 111.)*

PART 1. STATE DEPARTMENTS AND AGENCIES [11000 - 11898] *(Part 1 added by Stats. 1945, Ch. 111.)*

CHAPTER 5. Administrative Adjudication: Formal Hearing [11500 - 11529] *(Heading of Chapter 5 amended by Stats. 1995, Ch. 938, Sec. 22.)*

11521. (a) The agency itself may order a reconsideration of all or part of the case on its own motion or on petition of any party. The agency shall notify a petitioner of the time limits for petitioning for reconsideration. The power to order a reconsideration shall expire 30 days after the delivery or mailing of a decision to a respondent, or on the date set by the agency itself as the effective date of the decision if that date occurs prior to the expiration of the 30-day period or at the termination of a stay of not to exceed 30 days which the agency may grant for the purpose of filing an application for reconsideration. If additional time is needed to evaluate a petition for reconsideration filed prior to the expiration of any of the applicable periods, an agency may grant a stay of that expiration for no more than 10 days, solely for the purpose of considering the petition. If no action is taken on a petition within the time allowed for ordering reconsideration, the petition shall be deemed denied.

(b) The case may be reconsidered by the agency itself on all the pertinent parts of the record and such additional evidence and argument as may be permitted, or may be assigned to an administrative law judge. A reconsideration assigned to an administrative law judge shall be subject to the procedure provided in Section 11517. If oral evidence is introduced before the agency itself, no agency member may vote unless he or she heard the evidence.

(Amended by Stats. 2004, Ch. 865, Sec. 34. Effective January 1, 2005.)

4SS

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☒ Nuclear ☐ Other:	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☒ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☒ Other: radiopharmaceuticals

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: PharmaLogic Austin, LLC

Physical Address: 10600 N Lamar Blvd

City: Austin State: TX Zip: 78753

Mailing Address (if different from physical address): same as physical address

City: _____ State: _____ Zip: _____

Telephone: 737-285-0424 Toll Free # (NAC 639.708, NRS 639.23286): 877-684-5301

Fax: 512-855-4795 Contact Email: AustinPharmacy@radiopharmacy.com

Website: www.radiopharmacy.com

Nevada Business License # (if applicable) N/A; new license application

Supervising/Managing Pharmacist Name (NRS 639.220): Grant Pearson

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24192

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Grant Pearson	NV Pharmacist Registration #: 24192
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): PharmaLogic Holdings Corp

Corporation/Organization Name: PharmaLogic Austin, LLC

Mailing Address: 10600 N Lamar Blvd

City: Austin State: TX Zip: 78753

Telephone: 737-285-0424 Email: AustinPharmacy@radiopharmacy.com

Contact Person Name: Grant Pearson

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: PharmaLogic Holdings Corp

Business Name: PharmaLogic Holdings Corp

Business Address: 5301 N Federal Hwy, Suite 280

City: Boca Raton State: FL Zip: 33487

Telephone: 561-416-0085 Email: N/A

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the VP Pharmacy Quality &Regulatory (title) for PharmaLogic Austin, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Jessica Comstock

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

07/22/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jessica Comstock

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

07/22/2024

Date

Board Use Only	Date Received: 7/29/24	Amount: $500-ck 100390

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: PharmaLogic Austin, LLC

NV Pharmacy or Outsourcing facility license # (if applicable): pending; new license application

Physical Address: 10600 N Lamar Blvd

City: Austin State: Texas Zip: 78753

Mailing Address (if different from physical address): same as physical address

City: State: Zip:

Telephone: 737-285-0424 Toll Free # (NAC 639.708, NRS 639.23286): 877-684-5301

Fax: 512-855-4795 Contact Email: AustinPharmacy@radiopharmacy.com

Website: www.radiopharmacy.com

Nevada Business License # (if applicable) N/A; new license application

Supervising/Managing Pharmacist Name (NRS 639.220): Grant Pearson

Supervising/Managing Pharmacist NV Pharmacist Registration #: 24192

Name of Person with direct knowledge of compounding procedures: Grant Pearson

Email of Person with direct knowledge of compounding procedures: gpearson@radiopharmacy.com

Telephone of Person with direct knowledge of compounding procedures: 737-285-0424

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☑ Low ☐ Medium ☐ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ☑ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

F-18 FDG - repackaged into unit dose syringes from manufacturer multidose vial
Ga-68 NetSpot - prepared per package insert
GA-68 Illuccix - prepared per package insert

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☑ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

N/A

6. What laboratory performs this additional testing?

Name: N/A

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

7. What is your procedure for visual inspection of compounded sterile products?

All products are inspected before and after preparation for any visible particles, abnormal coloration, and/or turbidity. If the product does not pass visual inspection, the product is quarantined and the compounding pharmacist will reach out to the Quality and Regulatory Department for next steps/investigations as needed.

8. How often do you perform glove fingertip and medial fill testing?

In triplicate as part of the onboarding process, then annually thereafter.

9. What is your policy if an employee fails a glove fingertip or media-fill test?

If the observer notes any deviations from the acceptance criteria or procedures for glove fingertip or media-fill testing, the employee is considered to be not qualified and must repeat the qualifications.

10. Describe your initial and annual training program for all personnel performing sterile compounding:

Please see SOP 6.02 - Aseptic Qualifications, 6.03 - Gowning, Garbing, and Hand Hygiene, and 7.05 - Network Training for our initial and annual training program for all personnel performing sterile compounding.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Please see SOP 6.04 - Cleaning of Clean Rooms and SRPAs and 6.05 - Cleaning of Clean LFHs and BSCs for the cleaning of our primary and secondary engineering controls, including frequency and names of approved agents used as cleaners/disinfectants and sporicidals.

12. Who performs the sterile compounding process at your facility?

Authorized nuclear pharmacists (ANPs) perform the sterile compounding process at PharmaLogic Austin, LLC.

13. Who is responsible and accountable for the sterile compounding process at your facility?

Grant Pearson, Pharmacist-in-Charge

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

All products that are delivered/shipped follow DoT regulations and emergency procedures for handling radioactive materials. The delivery process is either initiated after quality control tests are completed, or delivered under quarantine and only released to the customer upon the successful completion of quality control tests.

Section not applicable

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility?		
2. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?		

Section Not Applicable

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

2. What sterilization methods are utilized at your facility?

3. Does your facility utilize biological indicators? ☐ Yes ☐ No

4. If yes, describe how they are utilized:

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Payton Hanby

Name of Person who Completed the Form

Pharmacy Regulatory Affairs Specialist, PharmaLogic Holdings Corp

Title

Signature (copies or stamps not accepted)

07/25/2024

Date

Board Use Only	Date Received: 7/29/24 Date Approved: _____ Approved By: _____

State Of Delaware

Entity Details

6/25/2024 10:56:12PM

File Number: 3870706
Incorporation Date / Formation Date: 10/13/2020
Entity Name: PHARMALOGIC AUSTIN, LLC
Entity Kind: Limited Liability Company
Entity Type: General
Residency: Domestic
State: DELAWARE
Status: Good Standing
Status Date: 10/13/2020

Registered Agent Information

Name: REGISTERED AGENT SOLUTIONS, INC.
Address: 838 WALKER ROAD SUITE 21-2
City: DOVER
Country:
State: DE
Postal Code: 19904
Phone: 888-716-7274

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Inspection Report

Facility Information

Name: *PHARMALOGIC AUSTIN, LLC* License Number:

Class of License: *B*

Inspection Information

Type: *Compliance* Purpose: *Pre-Inspection*

Date: *05/06/2024* Arrival Time: *11:45 AM* Departure Time: *12:30 PM*

Action Taken: *Pre-Inspection*

General Comments:

Pre-Inspection Checklist

Verify Owner/Owner's Representative ID	*Yes*
Name: *Jessica Comstock* / Title: *Owner's Representative*	
Verify PIC ID	*Yes*
Name: *Grant Pearson* / Title: *PIC*	
1. The prescription department has adequate space for the size and scope of the pharmaceutical services provided by the pharmacy.	*Yes*
2. Fixtures (i.e. shelving, countertops, etc.) for the storage of drugs, equipment, and supplies necessary to operate a pharmacy are installed.	*Yes*
3. Electrical supply exists.	*Yes*
4. A sink with hot and cold running water available exclusive of the restroom facilities.	*Yes*
5. Pharmacy arranged in an orderly fashion and kept clean.	*Yes*
6. The prescription department is complete and contains the following required equipment and supplies including, but not limited to:	*Yes*
6a. data processing system including a printer or comparable equipment;	*Yes*
6b. refrigerator to be maintained within a range compatible with the proper storage of drugs requiring refrigeration;	*Yes*
6c. adequate supply of child-resistant, light-resistant, tight, and, if applicable, glass containers;	*Yes*
6d. adequate supply of prescription labels with name, address, and telephone number of the pharmacy;	*Yes*

6e. appropriate equipment necessary for the proper preparation of prescription drug orders;	*Yes*
6f. metric-apothecary weight and measure conversion charts;	*Yes*
6g. if the pharmacy serves the public, the word "pharmacy" or similar word or symbol, as determined by the board, is displayed in a prominent place on the front of the pharmacy.	*Not Applicable*
7. A reference library is on site and current:	*Yes*
7a. Texas Pharmacy Laws and Regulations (publication year: _____) Publication Year *Online*	*Yes*
7b. Drug Interactions Reference (publication year: _____) Publication Year *Online*	*Yes*
7c. General Information Reference (publication year: _____) Publication Year *Online*	*Yes*
7d. Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations (if the pharmacy is compounding non-sterile preparations)	*Not Applicable*
7e. General reference text on veterinary drugs (if the pharmacy dispenses veterinary prescriptions)	*Not Applicable*
7f. Basic Antidote Information and telephone number of the nearest Regional Poison Control Center.	*Yes*
8.If the pharmacy is compounding sterile preparations, the following references are also required:	*Yes*
8a. United States Pharmacopeia/National Formulary or USP Pharmacist's Pharmacopeia containing USP Chapter 797, Pharmaceutical Compounding Sterile Preparations	*Yes*
8b. Chapter 71 of the USP/NF concerning Sterility Tests	*Yes*
8c. Chapter 85 of the USP/NF concerning Bacterial Endotoxins Test	*Yes*
8d. Chapter 1163 of the USP/NF concerning Quality Assurance in Pharmaceutical Compounding	*Yes*
8e. Handbook on Injectable Drugs (publication year: _____) Publication Year *Online*	*Yes*
8f. Specialty reference text appropriate for the scope of pharmacy services provided by the pharmacy (e.g., if the pharmacy prepares hazardous drugs, a reference text on the preparation of hazardous drugs)	*Yes*
9. Security Requirements can be met to assure the pharmacy will be locked by key, combination, or other mechanical or electronic means to prohibit unauthorized access when a pharmacist is not on-site.	*Yes*

10. Pharmacy has basic alarm system with the off-site monitoring and perimeter and motion sensors. (Alarm must be activated). *If your city requires an alarm permit, provide a copy of the permit.	*Yes*
11. Written policies and procedures/SOPs for the pharmacy's security system that meet the requirements of Rule 291.33(b)(2)(E)	*Yes*
12. An area suitable for confidential patient counseling, if the pharmacy serves the general public	*Not Applicable*
13. If compounding sterile preparations, the pharmacy has controlled area that meets the requirements in Rule 291.133 (d)(6)(A) if the pharmacy is compounding low-risk and medium-risk preparations or Rule291.133(d)(6)(B) if high-risk preparations are being compounded.	*Not Applicable*
14. Certified primary engineering control device (e.g., laminar airflow work benches, biological safety cabinets, compounding aseptic isolators, and compounding aseptic containment isolators).	*Not Applicable*
15. Certified clean room(s) (e.g. ante area, buffer area).	*Not Applicable*

Discussion Items

The requirements of TSBP Rule 291.11 and Section S65.0591 of the Pharmacy Act regarding the operation of a pharmacy within 6 months of becoming licensed.	*Yes*
Corresponding Responsibility and the Red Flags checklist using references from the DEA RPh Manual, the Texas Controlled Substances Act, and TSBP Rules 291.29 and 291.34 (b).	*Yes*
Pharmacy will need to conduct an opening inventory on the first day of business.	*Yes*
Pharmacy will need to report all controlled substances to the PMP as required.	*Not Applicable*

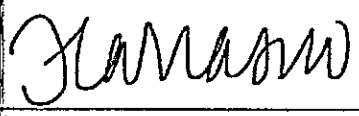
Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).



Grant Pearson



Felicia Carrasco

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Notice of Inspection

Facility Information

Name: *PHARMALOGIC AUSTIN, LLC*

License Number:

Address: *10600 N LAMAR BLVD, AUSTIN, TX 78753*

Phone: *737-285-0424*

Email:

Class of License: *B*

License Expiration:

DEA #: *N/A*

DEA Expiration:

Inspection Information

Type: *Compliance*

Purpose: *Pre-Inspection*

Date: *05/06/2024*

Arrival Time: *11:45 AM*

Acknowledgment

This is to acknowledge that Texas State Board of Pharmacy Agent has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. **I have read the Notice of Inspection and understand its contents and purpose;**
2. **I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;**
3. **I have had the purpose of the entry into the above-described facility by the Boards agent stated to me; and**
4. **I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.**

Grant Pearson *PIC* *72405*

Witness

Felicia Carrasco

TEXAS STATE BOARD OF PHARMACY

Pharmacist in Charge Attestation:

I hereby attest the following statements are true and accurate (initial each statement below):

GP — I am the Pharmacist-in-Charge (PIC) of *PHARMALOGIC AUSTIN, LLC*, pharmacy license number , and I ☑ was/ ☐ was not present during a Compliance Inspection conducted by a Texas State Board of Pharmacy Compliance Officer/Inspector on *05/06/2024*.

GP — I received and reviewed the Notice of Inspection, Inspection Report, and Warning Notice (if applicable) issued by the Compliance Officer/Inspector.

GP — I reviewed the document titled Texas State Board of Pharmacy "Red Flags" Checklist for Pharmacies YOU MIGHT BE A PILL MILL IF.

N/A — If applicable, the Warning Notice issued contains *0* deficiencies which may require corrections to resolve. I affirm that each of the deficiencies will be corrected by the date noted on the Warning Notice.

GP — I was present and completed this Attestation during the Compliance Inspection.

If not completed during the Compliance Inspection, please email this completed form to the TSBP Compliance Inspector for your area or to inspections@pharmacy.texas.gov within 7 days of the date of the inspection.

Signed: _____ **Date:** *05/06/2024*

Printed Name: *Grant Pearson* **License No.(if applicable):** *72405*

Texas State Board of Pharmacy
"Red Flags" Checklist for Pharmacies
YOU MIGHT BE A PILL MILL IF...

Check all that apply:

	(1) Your pharmacy fills a discernable pattern of prescriptions for prescribers who write essentially the same prescriptions for numerous persons, indicating a lack of individual drug therapy
	(2) Your pharmacy operates with limited hours of operation or closes after a certain threshold of controlled substance prescriptions are dispensed, and has overall low prescription dispensing volume.
	(3) Prescriptions presented to the pharmacy are for controlled substances with popularity as street drugs, such as opiates, benzodiazepines, muscle relaxants, psychostimulants, and/or cough syrups, or any combination of these drugs.
	(4) The prescriptions for controlled substances contain nonspecific or no diagnoses.
	(5) The prescriptions are commonly for the highest strength of the drug and/or for large quantities.
	(6) Dangerous drugs or OTC products (such as multi-vitamins or laxatives) are added to the controlled substance prescriptions, maintaining relatively consistent 1:1 ratio of controlled substances to dangerous drugs and/or OTC products dispensed as prescriptions.
	(7) Prescriptions are authorized by the same prescriber with what appears to be different handwriting on the hardcopy prescription drug order forms.
	(8) Upon contact with the prescriber's office, you are unable to engage in comprehensive discussion with the actual prescriber, or he/she is unconcerned about your apprehensions regarding his/her prescribing practices or unwilling to provide additional information, such as treatment goals and/or prognosis with prescribed drug therapy.
	(9) You rely solely on the prescriber's representation, or on the representation of the individual answering the phone at the number on the prescription, that prescriptions are legitimate.
	(10) The prescriber's clinic is not registered as a pain management clinic by the Texas Medical Board, despite routinely receiving prescriptions from the prescriber foropiates, benzodiazepines, and/or muscle relaxants.
	(11) Drugs prescribed are inconsistent with the prescriber's area of practice.
	(12) The prescriber of the drugs is located a significant distance from your pharmacy.
	(13) The prescriber has been subject to disciplinary action by the licensing board, had his/her DEA registration removed, or been subject to criminal action.
	(14) The Texas PMP system indicates that persons are obtaining prescriptions for the same drugs from multiple prescribers or that persons are filling prescriptions for the same drugs at multiple pharmacies.
	(15) The person's address is a significant distance from your pharmacy and/or from the prescriber's office.
	(16) Multiple persons with the same address present prescriptions from the same prescriber.
	(17) Persons pay with cash or credit card more often than through insurance.
	(18) Persons presenting controlled substance prescriptions are doing so in such a manner that varies from seeking routine pharmacy services (e.g., willing to wait in long lines to receive drugs, persons arrive in the same vehicle with prescriptions from same prescriber, one person presents to pick up prescriptions for multiple others, persons refer to drugs by "street names" and/or comment on drug's color, persons seek early refills, persons travel from outside reasonable trade area of pharmacy).
	(19) Your pharmacy charges and persons are willing to pay more for controlled substances than they would at nearby pharmacies.
	(20) Your pharmacy routinely orders controlled substances from more than one drug supplier, or your pharmacy has been discontinued by a drug supplier related to controlled substance orders.
	(21) Sporadic and non-consistent dispensing volume (including zero dispensing) varies from day to day and week to week, and your pharmacy does not maintain operational hours each week on Monday through Friday.
	(22) Your pharmacy employs or contracts security personnel during operational hours to prevent problems.
	(23) Your pharmacy has been previously warned or disciplined by the Texas State Board of Pharmacy for inappropriate dispensing of controlled substances (i.e., corresponding responsibility).

If you checked any of the above items, you should review the laws and rules regarding corresponding responsibility and non-therapeutic dispensing, especially Board rule §291.29, in the law book or on our website: www.pharmacy.texas.gov (click on Texas Pharmacy Rules and Laws). Additional educational material is available at: http://www.pharmacy.texas.gov/Nontherapeutic.asp. Failure of pharmacies and pharmacists to detect patterns of inappropriate dispensing of prescription drugs is unprofessional practice and constitutes grounds for disciplinary action.

Updated 2/2018

TEXAS STATE BOARD OF PHARMACY
1801 Congress Avenue, Suite 13.100
Austin, TX 78701-1319
(512) 305-8000

License Number: 35345

(Date PDF Version Generated: 5/6/2024)

HELPFUL PHARMACY INFORMATION

- Pharmacies are required to notify TSBP within 10 days of a discontinuance of service, change of location or closure. See the TSBP website here Pharmacy - Renew & Update (texas.gov) for changes.
- Renewals open about 60 days prior to your expiration date, renewal information can be found here Renew | Pharmacy (texas.gov).
- Change of Employment or Change of PIC information can be found here Update | Employment (texas.gov).
- Change of Ownership – Call (512) 305-8021 or see Apply | Change of Ownership (texas.gov).
- For questions or assistance regarding rules, contact TSBP Rules Queue line at (512) 305-8070 see www.pharmacy.texas.gov.
- Non-Resident Pharmacy questions call (512) 305-9127 or email NonResPhcy@pharmacy.texas.gov.

An up-to-date License Verification is always available on the Board's website: http://www.pharmacy.texas.gov/

CERTIFICATE
TEXAS
BOARD OF PHARMACY

This certifies that the pharmacy named below is hereby licensed to operate as a Class **B** pharmacy.

License No. **35345** Expiration Date: **05/31/2026**

Balances: **0**

PHARMALOGIC AUSTIN, LLC
10600 N LAMAR BLVD
AUSTIN, TX 78753

Daniel R. Carroll, Pharm.D.,
Executive Director/Secretary

MUST BE DISPLAYED IN FULL PUBLIC VIEW

TEXAS STATE BOARD OF PHARMACY

Texas Pharmacy License # 35345

PHARMALOGIC AUSTIN, LLC

License Information

License Status Active
License # 35345
Expiration Date 05/31/2026
Date License Issued 05/06/2024

Address

10600 N LAMAR BLVD
AUSTIN, TX 78753
County TRAVIS
Phone (737) 285-0424

Pharmacy Details

Prior Disciplinary Orders* No

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

Class of Pharmacy Nuclear Pharmacy
Type of Ownership LLC
Type of Pharmacy Other
# of Hospital beds

Employment Information

Pharmacist in Charge
PEARSON, GRANT

Pharmacy Profile ¥

Accessible to disabled persons?	Yes
Participates in the Texas Medicaid program?	No
Translating services (Listed Below If Available)	

¥ Please note: The data regarding accessibility, translating services, and insurance participation is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder or facility for clarification.

Remedial Plans and Inspection Reports

- 3346518 35345 PHARMALOGICAUSTINLLC 2024-05 05-2029.pdf

Remedial Plans and/or Inspection Reports (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

Services Provided

Nuclear	Yes
Out-Patient Prescriptions	No
Ship Prescription Out of State	No
Class D (Expanded Formulary)	No
Class D (Alternative Visit Schedule)	No
Compounding Sterile-Risk Level Low	Yes
Compounding Sterile-Risk Level Med	No
Compounding Sterile-Risk Level High	No
Compounding Non-Sterile	No
24 Hour Service	No
Closed Door	Yes
Compounding, Office Use	No
Home Delivery	No
Infusion	No

Pharmacist Administered Immunizations	No
Veterinary Prescriptions	No
In-Patient Medication Orders	No
Out-Patient Surgery	No
Rural Hospital	No
Tech Check Tech	No
503b Outsourcing Facility	No
Other Services	No

Texas Pharmacist Employment Information

Pharmacist Name	License #	Registr. Date	Expir. Date	Emp. Status	License Status
PEARSON, GRANT	72405	06/15/2023	05/31/2025	PIC	Active
PHATTHANAPHUTI, SADA	73280	09/28/2023	10/31/2025	Staff	Active

Page 1 of 1 20 View 1 - 2 of 2

Texas Registered Technicians/Trainees Employment Information

Technician/Trainee Name	License #	Registr. Date	Expir. Date	Emp. Status	Reg. Status

Page 0 of 0 20 No records to view

Texas Remote Pharmacy Information

Remote Pharmacy Name	Registr. #	Address	City	State	Zipcode

Page 0 of 0 20 No records to view

Texas Pharmacy Owner Information

Owner Name	Owner Title	Address	City	State	Zipcode
PHARMALOGIC AUSTIN, LLC	OWNER	,			
CHILINSKI, STEVEN	OFFICER	,			
MEDEL, ANTHONY	OFFICER	,			
HOLBROOK, SCOTT	OFFICER	,			
KENNEDY, KEITH	OFFICER	,			
PALMER, GLEN F	OFFICER	,			
ROMERO, ANTONIO	OFFICER	,			

Page 1 of 1 20 View 1 - 7 of 7

The Texas State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website, and considers the website to be a secure, primary source for license verification.

2011

Ownership



PharmaLogic Austin, LLC Managing Officer

Steven Chilinski – President, Treasurer, and Secretary
[redacted] Cedar Farm Road, Medway, MA 02053
[redacted]
No Medical Professional License
0% Ownership

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: PharmaLogic Austin, LLC

Pharmacy/Wholesaler License # (if applicable): pending; new license application

Physical Address: 10600 N Lamar Blvd

City: Austin State: Texas Zip: 78753

Mailing Address (if different from physical address): same as physical address

City: State: Zip:

Telephone: 737-285-0424 Website: www.radiopharmacy.com

Licensing Company Email: AustinPharmacy@radiopharmacy.com

Section 2: Personal Information

First: Grant Middle: Robert Last: Pearson

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Stepp Bend

City: Cedar Park State: TX Zip: 78613

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Gonzaga University		09/23-present	
Address	**City**	**State**	**Zip**
502 E Boone Ave	Spokane	WA	99258
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
University of Montana		09/96-05/03	
Address	**City**	**State**	**Zip**
32 Campus Dr	Missoula	MT	59812
Diploma/Degree obtained, if any			
RPh			

School Name		From - To (MM/YY – MM/YY)	
Sentinel High School		09/92-05/96	
Address	**City**	**State**	**Zip**
901 South Ave W #7910	Missoula	MT	59801
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/23-Present	[redacted]tepp Bend	Cedar Park	TX	78613
04/23-10/23	[redacted]Ridgline Blvd #6203	Cedar Park	TX	78613
06/20-04/23	[redacted]S. Jordan Ln	Spokane	WA	99224
06/12-06/20	[redacted]S. Myrtle St	Spokane	WA	99224
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
PharmaLogic Austin, LLC			05/23 - Present	
Business Address		**City**	**State**	**Zip**
10600 N. Lamar Blvd		Austin	TX	78753
Phone	**Title**		**Number of Employed Hours**	
(737)667-6694	Pharmacy Manager		2240	
Description of Duties				
All PIC and Pharmacy manager duties.				

Business Name			From - To (MM/YY – MM/YY)	
PetNet Solutions			02/14 - 01/23	
Business Address		**City**	**State**	**Zip**
7011 W. Flightline Blvd		Spokane	WA	99224
Phone	**Title**		**Number of Employed Hours**	
(509)455-4301	Pharmacy Manager		17,280	
Description of Duties				
All PIC, pharmacy/facility manager duties.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Grant Pearson, **certify that as the designated representative for**

PharmaLogic Austin, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. GP I am at least 21 years of age;
3. GP I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. GP I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. GP I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. GP I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. GP I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Grant Pearson

Print Name (First, Last)

GP

Original Signature (electronic, copies or stamps not accepted)

7-23-24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Grant Pearson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7-23-24

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Travis

I, Grant Pearson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7-23-24

Date

Subscribed and Sworn to before me this 23 day of July.

Notary Public Signature

Jose Luis Navarro Jr.
Notary Public, State of Texas
Comm. Expires 10-13-2024
Notary ID 13272616-6

4TT

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	☐ Retail/Community	☐ Retail/Community
☑ Out-of-Nevada	☑ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☑ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☑ Sterile Compounding
			☑ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH PH04414		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Sofie Co.

Physical Address: 5900-B Obata Way

City: Gilroy State: CA Zip: 95020

Mailing Address (if different from physical address): same

City: _____ State: _____ Zip: _____

Telephone: 408-842-0520 Toll Free # (NAC 639.708, NRS 639.23286): 866-607-6645

Fax: 408-842-0220 Contact Email: _____

Website: regulatoryaffairs@sofie.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Austin Merritt

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): N/A

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Elizabeth Hefley	NV Pharmacist Registration #: 18434
Name: Vincent Vu	NV Pharmacist Registration #: 24114
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name: NA	Credentials:	%:
Name: N/A	Credentials:	%:
Name: N/A	Credentials:	%:
Name: N/A	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Virginia

Parent Company (if any): GRD US PET Operations, Inc.

Corporation/Organization Name: SOFIE Co.

Mailing Address: 2100 Atlantic Blvd., Ste. 730

City: Sterling State: VA Zip: 20166

Telephone: 703-787-7900 Email: regulatoryaffairs@sofie.com

Contact Person Name: Kunj Patel

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President and CEO (title) for SOFIE Co. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Patrick Phelps

Print Name of Authorized Person

Patrick Phelps

Original signature of Authorized Person (copies or stamps not accepted)

3/4/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Patrick Phelps

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Patrick Phelps

Original signature of Authorized Person (copies or stamps not accepted)

3/4/2024

Date

Board Use Only	Date Received: 3/28/24	Amount: $500-check 00000478

SOFIE Co.
5900-B Obata Way, Gilroy, CA, 95020
Disciplinary Summary
"Yes" response to History of Company Question #3

Below please find a summary of discipline for Applicant SOFIE Co. and the pharmacy's officers/ owners.

State	Citation/ Case No.	Summary
California	CI 2021 92488	Failure to follow written policies and procedure as it pertained to environmental monitoring. Applicant paid a fine and the Board accepted such as a satisfactory resolution. Applicant's CA pharmacy permit remains active and in good standing.
Utah	Citation 102806	Pharmacy violation; fine paid.
Louisiana	Case No. 20-0329	New PIC not assigned within required time frame; fine paid.
Virginia	Inspection Deficiency Notice (s) and Consent Order(s)	Inspection Deficiencies noted; fines paid for inspection violations in 2013, 2016, 2020 and 2022.
Maine	Case No. 2022-PHA-18212	Failure to timely notify the Board of a change in PIC.
New Jersey	Inspection Deficiency Notice (s) and Letter(s) of Corrective Action	Inspection Deficiencies noted and fines paid for inspection violations.
FDA	Warning Letter 553833	Violations of CGMP regulations for positron emission tomography (PET) drugs. Corrective actions implemented and Close Out Letter issued by FDA.

Please note, SOFIE Co.'s Haverhill, MA pharmacy is currently under investigation by the Massachusetts Board of Registration in Pharmacy. SOFIE Co. will update the Board once there is a final outcome of this investigation.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

December 01, 2021

DATED MATERIAL ENCLOSED

SOFIE CO
ATTN: PATRICK W PHELPS, CEO
5900 B OBATA WAY
GILROY, CA 95020

RE: CI 2021 92488
SOFIE CO
LSC 101112

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- December 31, 2021: Unless the Citation is contested payment of fine(s) must be received by the Board.
- December 15, 2021: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- December 31, 2021: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

Anne Sodergren
EXECUTIVE OFFICER

By: 

Joshua Monforte
Citation and Fine Analyst

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

PAYMENT OF FINE

- Payment must be made by **December 31, 2021.**
- Make check or money order payable to the Board of Pharmacy. Do not submit cash.
- Attach the enclosed "copy" of your Citation

Mail payment to: State Board of Pharmacy
Attn: Cashier
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Unless contested, Citations are final 30 days from the date of service. Payment of a fine is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than December 15, 2021 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than December 31, 2021 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have any questions regarding any documents enclosed please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2021 92488	SOFIE CO, LSC 101112

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1735.5 subd. (a)	Compounding Policies and Procedures- Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding...	$2,000.00
CCR, Title 16, § 1751.4 subd. (j)	Facility and Equipment Standards for Sterile Compounding; Viable air sampling shall be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and shall be done at least once every six months	$2,000.00

CONDUCT:

Failure to follow written policies and procedures as it pertains to environmental monitoring: California Code of Regulations (CCR) 1735.5(a) states any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. Sofie Co (LSC 101112), located at 5900-B Obata Way, Gilroy, CA 95020, was not compliant. Policy and Procedure #PH.0005, Environmental Monitoring of Pharmacy Classified Areas, stated, "Microbial air sampling and non-viable particle counts are performed in the applicable ISO 5 Enclosures and ISO 8 areas (within the clean side of demarcation) at least every 6 months. Surface sampling of all classified areas (DHCs, ISO 7, and ISO 8 areas) will occur monthly." Specifically, on 7/13/2021, Sofie Co could not provide results of any viable air and surface sampling of the ISO 8 anteroom.

Failure to maintain facility and equipment standards for sterile compounding: California Code of Regulations (CCR) 1751.4(j) states, in pertinent part, that viable surface sampling shall be done at least every six months for all sterile-to-sterile compounding. Viable air sampling shall be done at least once every six months. Sofie Co (LSC 101112), located at 5900-B Obata Way, Gilroy, CA 95020, was not compliant. Specifically, on 7/13/2021, Sofie Co could not provide results of any viable air and surface sampling of the ISO 8 anteroom.

CITATION ISSUED ON: December 01, 2021	TOTAL AMOUNT OF FINE(S): $4,000.00

PAYMENT OF FINE(S) DUE BY: December 31, 2021

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

COPY

CITATION AND FINE

Citation Number	Name, License No
CI 2021 92488	SOFIE CO, LSC 101112

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1735.5 subd. (a)	Compounding Policies and Procedures- Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding...	$2,000.00
CCR, Title 16, § 1751.4 subd. (j)	Facility and Equipment Standards for Sterile Compounding; Viable air sampling shall be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and shall be done at least once every six months	$2,000.00

CONDUCT:

Failure to follow written policies and procedures as it pertains to environmental monitoring: California Code of Regulations (CCR) 1735.5(a) states any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. Sofie Co (LSC 101112), located at 5900-B Obata Way, Gilroy, CA 95020, was not compliant. Policy and Procedure #PH.0005, Environmental Monitoring of Pharmacy Classified Areas, stated, "Microbial air sampling and non-viable particle counts are performed in the applicable ISO 5 Enclosures and ISO 8 areas (within the clean side of demarcation) at least every 6 months. Surface sampling of all classified areas (DHCs, ISO 7, and ISO 8 areas) will occur monthly." Specifically, on 7/13/2021, Sofie Co could not provide results of any viable air and surface sampling of the ISO 8 anteroom.

Failure to maintain facility and equipment standards for sterile compounding: California Code of Regulations (CCR) 1751.4(j) states, in pertinent part, that viable surface sampling shall be done at least every six months for all sterile-to-sterile compounding. Viable air sampling shall be done at least once every six months. Sofie Co (LSC 101112), located at 5900-B Obata Way, Gilroy, CA 95020, was not compliant. Specifically, on 7/13/2021, Sofie Co could not provide results of any viable air and surface sampling of the ISO 8 anteroom.

CITATION ISSUED ON: December 01, 2021	TOTAL AMOUNT OF FINE(S): $4,000.00
PAYMENT OF FINE(S) DUE BY: December 31, 2021	

COPY

California State Board of Pharmacy

REQUEST FOR OFFICE CONFERENCE

Licensee: SOFIE CO

License No: LSC 101112

Citation Number : CI 2021 92488

I hereby acknowledge receipt of the Citation referenced above and notification of my rights to contest the Citation.

Check ☐ I contest the Citation and request an Office Conference.

Check One:

☐ I contest the entire Citation or

☐ specific violations for the following reasons (list each violation with your specific reason):

_____

_____

_____

_____

_____

_____

If more space is needed attach additional sheets of paper.

Name: _____

Signature: _____ Dated: _____

Address of Service: _____

City: _____ State: _____ Zip: _____

Telephone: (Business) (___) _____ Residence: (___) _____

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: California State Board of Pharmacy
Attn: Citation and Fine Unit
2720 Gateway Oaks Drive, Suite #100
Sacramento, CA 95833
(916) 518-3100

REQUEST FOR APPEAL

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Check ☐ I contest the Citation and request an administrative hearing before an Administrative Law Judge.

In the Matter of the Citation Against: SOFIE CO LSC 101112 Respondent	Citation Case No : CI 2021 92488 NOTICE OF APPEAL (Pursuant to sections 11505, and 11506 Government Code)

I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Citation.

I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in said Citation.

DATED _____ _____
(Respondent)

Mailing Address of Respondent:

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please complete the following:

Mailing Address of Attorney

_____
(Attorney's Name

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: SOFIE CO, LSC 101112
Citation and Fine CI 2021 92488

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On December 01, 2021, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
SOFIE CO ATTN: PATRICK W PHELPS, CEO 5900 B OBATA WAY GILROY, CA 95020	7019 1120 0000 6822 2311

I declare under penalty of perjury that the forgoing is true and correct.

Executed on December 01, 2021, at Sacramento, California.

DECLARANT
Joshua Monforte
Citation and Fine Analyst

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

December 30, 2021

SOFIE CO
ATTN: PATRICK W PHELPS, CEO
5900 B OBATA WAY
GILROY, CA 95020

RE: CI 2021 92488
SOFIE CO
LSC 101112

This is in response to the administrative fine provided to the board for the above referenced citation. The payment has been received and accepted as satisfactorily resolving the matter.

Please be advised that this citation has become a part of the board's records and constitutes a public record for purposes of disclosure.

If you have any questions regarding this matter, please contact the Citation and Fine Analyst, Suelynn Yee at (916) 518-3013.

Sincerely,

Suelynn Yee
Citation and Fine Analyst

Division of Professional Licensing

HOME / ACTIONS

Agency & Disciplinary Actions

$ PAY FINE

10974010-1708

SEARCH

SOFIE Co dba SOFIE

10974010-1708 — Pharmacy - Class D **(Active)**

ACTIONS

NO DISCIPLINARY ACTIONS, OR NO DISCIPLINARY ACTIONS WITHIN THE TIME FRAME ESTABLISHED IN UTAH CODE 63G-4-106 & 107**

CITATIONS

Citation 102806

Violation: Pharmacy Violation
Issued: 2023-07-19
Status: Paid
Amount: $750

UTAH.GOV HOME UTAH.GOV TERMS OF USE UTAH.GOV PRIVACY POLICY TRANSLATE UTAH.GOV

Copyright © 2023 State of Utah - All rights reserved

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

SOFIE CO. D/B/A SOFIE

LOUISIANA PHARMACY PERMIT NO. 6506 **Case No. 20-0329**

****

CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy (hereinafter referred to as the "Board") on December 15, 2020, at the Embassy Suites Hotel, 4914 Constitution Avenue, Baton Rouge, Louisiana 70808, in the matter of SOFIE CO. D/B/A SOFIE (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 6506, 4447 Brass Way, Dallas, TX 75236-2001, with Pharmacist Kunj Patel submitting a written response to the Committee on behalf of Respondent.

WHEREAS, on August 10, 2020, Pharmacist Adrryl Shnord Addison (PST.020358) relinquished his position as Pharmacist-in-Charge (PIC) of Sofie. The notification did not indicate a replacement for the PIC position. On September 22, 2020, the Board sent Sofie a notification regarding the failure to designate a replacement PIC with a choice of 3 possible options for the permit. On October 12, 2020, Pharmacist Victor Glen Spearman (PST.020271) signed on as the new pharmacist-in-charge for Sofie. The pharmacy permit did not have the required PIC from August 10, 2020 through October 12, 2020.

WHEREAS, the Board alleges that such actions constitute violations of the following:

La. R.S. 37:1241(A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

LAC, Title 46: LIII §2307(C). Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

LAC, Title 46: LIII §2307(I). Change of Pharmacist-in-Charge. Written notice to the board shall be required when the pharmacist-in-charge designation for a pharmacy has changed.

1. The permit holder shall notify the board within ten days of the prior pharmacist-in-charge's departure date. **The permit holder shall designate a new pharmacist-in-charge within ten days of the departure of the prior pharmacist-in-charge.** (emphasis added)

To facilitate the submission of this Consent Agreement, Respondent does not contest the allegations and agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

SOFIE CO. D/B/A SOFIE, holder of Louisiana Pharmacy Permit No. 6506, is ordered to pay a fine of $10,000.00 and to reimburse the Board $250.00 for administrative costs, and $162.24 for investigative costs with total payment due the Board of $10,412.24, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter and waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing, and to judicial review of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, Kunj Patel, authorized to act on behalf of and acting on behalf of **SOFIE CO. D/B/A SOFIE,** understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

SIGNED, AGREED TO AND ENTERED ON THIS 18 DAY OF January, 2021.

SOFIE CO. D/B/A SOFIE
Louisiana Pharmacy Permit No. 6506

Kunj Patel

BY: Kunj Patel
Authorized Representative

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

Carl Finalet

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on February 24, **2021**, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Carl W. Aron
Hearing Officer for the Board

NOV 2 6 2013
DHP

Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, VA 23233
804-367-4456
804-527-4472 (Fax)
pharmbd@dhp.virginia.gov
October 2, 2013

IBA Molecular North America, Inc.
Permit Number: 0201003602

Amended Inspection Deficiency Notice and Consent Order

During an inspection conducted on February 21, 2013, the following deficiencies were identified:

1 ($1,000) MAJOR 10: Unauthorized access to alarm or locking device for Rx department; 18VAC110-20-180 and 18VAC110-20-190

2 ($500) MAJOR 12: Storage of Rx drugs not in Rx department; 18VAC110-20-190

3 ($500) MAJOR 26: Training documentation involving media-fill tests for low and medium-risk levels not maintained for all individuals preparing CSPs, or no documentation maintained of a passing media-fill test for any individual preparing low and medium-risk CSPs >45 days after receipt of a failed media-fill test; §54.1-3410.2

If you agree that the above deficiencies were identified by the inspector, you may resolve this issue by complying with the following three conditions and submitting as one mailing to the Board within 30 days of the date of this notice:

1. sign the statement at the bottom of this notification; and
2. submit $2,000 by check or money order made payable to the "Treasurer of Virginia"; and
3. attach separate documentation of immediate action taken to correct ALL deficiencies.

DO NOT MAKE ANY CHANGES TO THIS DOCUMENT:

If you do not agree, you may submit documentation contesting the inspector's findings to the Board within 14 days, or you may request, in writing, an informal conference to further discuss this matter before a committee of the Board.

Failure to respond to this document within thirty (30) days of the date of this notice will result in an informal conference being scheduled to determine the violations of the statutes and regulations of the Board of Pharmacy. A notice of the informal conference will be mailed to the PIC and the pharmacy owner with the scheduled date and time. If it is determined at the conclusion of the informal conference that this pharmacy is in violation of the statutes and regulations of the Board of Pharmacy, the permit holder may be subject to disciplinary sanctions by the Board in addition to those listed above. If you have any questions, please contact the Board office.

Pursuant to §2.2-4023 and §54.1-2400.2 of the Code, the signed original of this Consent Order shall remain in the custody of the Department of Health Professions as a public record and shall be made available for public release, inspection, and copying upon request.

I agree that the above listed deficiencies, constituting violations of the above listed statutes and regulations, were identified during an inspection, and I further waive my right to an administrative proceeding related to this matter and agree to submit the monetary penalty listed above and to submit documentation of correction of the deficiencies.

Nasrin Pourkiand — 20 NOV 13
Signature of Owner or PIC — Date

NASRIN POURKIAND — Pharmacy Manager
Printed Name of Person Signing — Position/Title

FOR THE BOARD:

Caroline D. Juran — 12/13/13
Caroline D. Juran, Executive Director — Entered

AUG 15 2016
DHP

Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, VA 23233
804-367-4456
804-527-4472 (Fax)
pharmbd@dhp.virginia.gov
July 26, 2016

Zevacor Pharma, Inc. dba Zevacor
Permit Number: 0201003602

Notice

After an inspection conducted on July 26, 2016 at Zevacor Pharma, Inc. dba Zevacor, the deficiencies identified in the inspection summary that was provided to the facility were found. Those deficiencies constitute violations of the statutes and regulations cited below:

1. ($500) Deficiency 26: No documentation of annual fingertip testing for persons performing low risk level compounding of sterile preparations within 12 months of prior testing; §54.1-3410.2

If you wish to contest the violations cited above and in the inspection summary that was provided to the facility, you may submit documentation for the Board's consideration within 14 days of the date of this notice. In the alternative, you may request, in writing, an informal conference to further discuss this matter before a committee of the Board within 30 days of the date of this notice. Documents for consideration or a request for an informal conference should be mailed to:

Virginia Board of Pharmacy
9960 Mayland Drive
Suite 300
Henrico, Virginia 23233

If you do not want to contest the cited violations, in lieu of proceeding to an informal conference, you may sign the Consent Order below, submit a total penalty of $500 by check or money order, made payable to the Treasurer of Virginia, and provide documentation of corrective action taken to remedy all of the cited violations. The Consent Order, the penalty, and documentation of corrective action should be sent in one mailing to the address provided above within 30 days of the date of this Notice.

Failure to respond to this document within thirty (30) days of the date of this Notice will result in an informal conference being scheduled to determine whether violations of the statutes and regulations of the Board of Pharmacy have occurred. A notice of the informal conference will be mailed to the attention of the facility's Pharmacist-in-Charge [or the Owner if no PIC] with the scheduled date and time. If it is determined at the conclusion of the informal conference that the pharmacy is in violation of the laws and regulations of the Board of Pharmacy, the permit holder may be subject to disciplinary sanctions by the Board in addition to the penalty listed above. If you have any questions, please contact the Board office.

2044

Consent Order

The Virginia Board of Pharmacy ("Board") and Zevacor Pharma, Inc. dba Zevacor ("Pharmacy") enter into the following Consent Order as evidenced by the signature of the Pharmacist-in-Charge [or the Owner if no PIC] hereto. The deficiencies cited in the Notice above and the inspection summary that was provided to the facility constitute violations of the statutes and regulations as cited above in the Notice. These violations were identified during an inspection conducted on July 26, 2016.

DO NOT MAKE ANY CHANGES TO THIS DOCUMENT:

Pharmacy, by affixing the signature of the Pharmacist-in-Charge (or Owner if no PIC) hereon, agrees to the following:

1. The Pharmacist-in-Charge (or Owner if no PIC) has the right to seek advice of counsel prior to signing this document;
2. The Pharmacist-in-Charge (or Owner if no PIC) acknowledges that without his consent, no legal action can be taken against the Pharmacy except pursuant to the Virginia Administrative Process Act, § 2.2-4000 *et seq.* of the Code of Virginia;
3. The Pharmacist-in-Charge (or Owner if no PIC) acknowledges that he has the following rights, among others: the right to an informal fact finding conference before the Board, the right to reasonable notice of said hearing, the right to representation by counsel, and the right to cross-examine witnesses;
4. The Pharmacist-in-Charge (or Owner if no PIC) waives all such right to an informal conference;
5. The Pharmacist-in-Charge (or Owner if no PIC) admits to the violations cited herein and waives his right to contest such violations in any subsequent proceeding before the Board;
6. The Pharmacist-in-Charge (or Owner if no PIC) consents to the entry of the following Order affecting the permit of the Pharmacy in Virginia.

WHEREFORE, on the basis of the foregoing, the Board, effective upon entry of this Order, and in lieu of further proceedings, hereby ORDERS as follows:

1. Pharmacy shall pay a monetary penalty of $500 to the Board within 30 days of the date of the Notice.

2. Pharmacy shall submit documentation of immediate action taken to correct all violations.

3. Any violation of the terms and conditions of this Order or of any law or regulation affecting the conduct of Pharmacy in the Commonwealth of Virginia shall constitute grounds for the suspension or revocation of the permit of Pharmacy, and an administrative proceeding shall be convened to determine whether such permit shall be suspended or revoked.

Pursuant to § 2.2-4023 and § 54.1-2400.2 of the Code of Virginia, the signed original of this Notice and Consent Order shall remain in the custody of the Department of Health Professions as public record and shall be made available for public inspection or copying upon request.

Nasrin Poorkiani
Signature of PIC or Owner

11 Aug 16
Date

NASRIN POORKIANI
Printed Name of Person Signing

Site Manager
Position/Title

FOR THE BOARD:

Caroline D. Juran
Caroline D. Juran, Executive Director

8/23/16
Entered

BEFORE THE VIRGINIA BOARD OF PHARMACY

IN RE: SOFIE CO.
Permit Number: 0201-003602
Case Number: 198728

ORDER

JURISDICTION AND PROCEDURAL HISTORY

Pursuant to Virginia Code §§ 2.2-4019 and 54.1-2400(10), a Special Conference Committee ("Committee") of the Virginia Board of Pharmacy ("Board") held an informal conference on June 23, 2020, in Henrico County, Virginia, to inquire into evidence that Sofie Co. may have violated certain laws and regulations governing its permit to conduct a pharmacy in the Commonwealth of Virginia.

Nasrin Pourkiani, Pharmacist-in-Charge, as the representative of Sofie Co., appeared at this proceeding and was not represented by legal counsel.

NOTICE

By letter dated February 3, 2020, the Board sent a Notice of Informal Conference ("Notice") to Sofie Co. notifying it that an informal conference would be held on May 12, 2020. The Notice was sent by certified and first class mail to the legal address of record on file with the Board.

Upon consideration of the evidence, the Committee adopts the following Findings of Fact and Conclusions of Law and issues the Order contained herein.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. On May 4, 1999, the Board issued Permit Number 0201-003602 to Sofie Co., Sterling, Virginia, to conduct a pharmacy in the Commonwealth of Virginia. Said permit is scheduled to expire on April 30, 2021. At all times relevant to the findings herein, said permit was in full force and effect.

2. On August 29, 2019, an inspector from the Virginia Department of Health Professions conducted an inspection of Sofie Co. and found that a pharmacist failed to demonstrate competence in all core competencies for compounding, in violation of Virginia Code § 54.1-3410.2(E). Specifically, Pharmacist A's most recent media-fill testing and gloved fingertip testing competency was completed on March 7, 2019, with results finalized on

March 13, 2019. Pharmacist A's prior testing was completed on February 21, 2018, with results finalized on February 28, 2018, more than one year prior to the most recent testing.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, the Virginia Board of Pharmacy hereby ORDERS as follows:

1. Sofie Co. is assessed a MONETARY PENALTY of $500.00. This penalty shall be paid to the Board by certified check or money order made payable to the Treasurer of Virginia within 30 days from the date of entry of this Order. Failure to pay the full monetary penalty by the due date may cause the matter to be sent for collection and constitutes grounds for an administrative proceeding and further discipline.

2. Sofie Co. shall comply with all laws and regulations governing the practice of pharmacy in the Commonwealth of Virginia.

3. Any violation of the foregoing terms and conditions of this Order or any statute or regulation governing the practice of pharmacy shall constitute grounds for further disciplinary action.

Pursuant to Virginia Code § 2.2-4023 and 54.1-2400.2, the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record, and shall be made available for public inspection and copying upon request.

FOR THE BOARD

Caroline D. Juran
Executive Director
Virginia Board of Pharmacy

ENTERED AND MAILED ON:

6/30/2020

NOTICE OF RIGHT TO APPEAL

Pursuant to Virginia Code § 54.1-2400(10), Sofie Co. may, not later than 5:00 p.m., on August 3, 2020, notify Caroline D. Juran, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300, Henrico, Virginia 23233, in writing that it desires a formal administrative hearing before the Board. Upon the filing with the Executive Director of a request for the hearing, this Order shall be vacated. This Order shall become final on July 30, 2020, unless a request for a formal administrative hearing is received as described above.

Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, VA 23233
804-367-4456
804-527-4472 (Fax)
pharmbd@dhp.virginia.gov
November 18, 2022

SOFIE Co.
Permit Number: 0201003602

Notice

After an inspection conducted on November 18, 2022 at SOFIE Co., the deficiencies identified in the inspection summary that was provided to the facility were found. Those deficiencies constitute violations of the statutes and regulations cited below:

1. ($500) Deficiency 26: No documentation of annual fingertip testing for persons performing low risk level compounding of sterile preparations within 12 months of prior testing; §54.1-3410.2

If you wish to contest the violations cited above and in the inspection summary that was provided to the facility, you may submit documentation for the Board's consideration within 14 days of the date of this notice. In the alternative, you may request, in writing, an informal conference to further discuss this matter before a committee of the Board within 30 days of the date of this notice. Documents for consideration or a request for an informal conference should be mailed to:

Virginia Board of Pharmacy
9960 Mayland Drive
Suite 300
Henrico, Virginia 23233

If you do not want to contest the cited violations, in lieu of proceeding to an informal conference, you may sign the Consent Order below, submit a total penalty of $500 by check or money order, made payable to the Treasurer of Virginia, and provide documentation of corrective action taken to remedy all of the cited violations. The Consent Order, the penalty, and documentation of corrective action should be sent in one mailing to the address provided above within 30 days of the date of this Notice.

Failure to respond to this document within thirty (30) days of the date of this Notice will result in an informal conference being scheduled to determine whether violations of the statutes and regulations of the Board of Pharmacy have occurred. A notice of the informal conference will be mailed to the attention of the facility's Pharmacist-in-Charge [or the Owner if no PIC] with the scheduled date and time. If it is determined at the conclusion of the informal conference that the pharmacy is in violation of the laws and regulations of the Board of Pharmacy, the permit holder may be subject to disciplinary sanctions by the Board in addition to the penalty listed above. If you have any questions, please contact the Board office.

Consent Order

The Virginia Board of Pharmacy ("Board") and SOFIE Co. ("Pharmacy") enter into the following Consent Order as evidenced by the signature of the Pharmacist-in-Charge [or the Owner if no PIC] hereto. The deficiencies cited in the Notice above and the inspection summary that was provided to the facility constitute violations of the statutes and regulations as cited above in the Notice. These violations were identified during an inspection conducted on November 18, 2022.

DO NOT MAKE ANY CHANGES TO THIS DOCUMENT:

Pharmacy, by affixing the signature of the Pharmacist-in-Charge (or Owner if no PIC) hereon, agrees to the following:

1. The Pharmacist-in-Charge (or Owner if no PIC) has the right to seek advice of counsel prior to signing this document;
2. The Pharmacist-in-Charge (or Owner if no PIC) acknowledges that without his consent, no legal action can be taken against the Pharmacy except pursuant to the Virginia Administrative Process Act, § 2.2-4000 *et seq.* of the Code of Virginia;
3. The Pharmacist-in-Charge (or Owner if no PIC) acknowledges that he has the following rights, among others: the right to an informal fact finding conference before the Board, the right to reasonable notice of said hearing, the right to representation by counsel, and the right to cross-examine witnesses;
4. The Pharmacist-in-Charge (or Owner if no PIC) waives all such right to an informal conference;
5. The Pharmacist-in-Charge (or Owner if no PIC) admits to the violations cited herein and waives his right to contest such violations in any subsequent proceeding before the Board;
6. The Pharmacist-in-Charge (or Owner if no PIC) consents to the entry of the following Order affecting the permit of the Pharmacy in Virginia.

WHEREFORE, on the basis of the foregoing, the Board, effective upon entry of this Order, and in lieu of further proceedings, hereby ORDERS as follows:

1. Pharmacy shall pay a monetary penalty of $500 to the Board within 30 days of the date of the Notice.

2. Pharmacy shall submit documentation of immediate action taken to correct all violations.

3. Any violation of the terms and conditions of this Order or of any law or regulation affecting the conduct of Pharmacy in the Commonwealth of Virginia shall constitute grounds for the suspension or revocation of the permit of Pharmacy, and an administrative proceeding shall be convened to determine whether such permit shall be suspended or revoked.

Pursuant to § 2.2-4023 and § 54.1-2400.2 of the Code of Virginia, the signed original of this Notice and Consent Order shall remain in the custody of the Department of Health Professions as public record and shall be made available for public inspection or copying upon request.

Yeji Song — 22NOV22

Signature of PIC or Owner — Date

Helen Yeji Song — Facility Manager / PIC

Printed Name of Person Signing — Position/Title

FOR THE BOARD:

Caroline D. Juran — 12/6/2022

Caroline D. Juran, Executive Director — Entered

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
N-MOLECULAR, INC.	)	
	)	CONSENT AGREEMENT
Case No. 2022-PHA-18212	)	

PARTIES

This document is a Consent Agreement regarding disciplinary action against the mail order prescription pharmacy license of N-Molecular, Inc. ("N-Molecular") in the State of Maine. The parties to this Consent Agreement are: N-Molecular, the Maine Board of Pharmacy ("the Board"), and the Maine Office of the Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

FACTS

1. At all times relevant to this matter, N-Molecular was licensed by the Board as a mail order prescription pharmacy, license no. MO40002771, located at 25 Walker Way, Suite 3D, Colonie, New York.

2. On January 4, 2021, Courtney L. Kret replaced Thomas Lewis as the pharmacist in charge ("PIC") of N-Molecular, thereby requiring N-Molecular to submit a Change of PIC application to the Board within 7 days after the PIC change.

3. N-Molecular, however, did not file a change of PIC application with the Board until February 1, 2021.

4. On April 4, 2022, Board Administrator, Geraldine Betts, filed an administrative complaint with the Board alleging that N-Molecular had failed to file a timely change of PIC application.

5. This administrative complaint was docketed as Case No. 2022-PHA-18212.

6. Under Board Rules Chapter 11, § 3, upon a change of PIC, a mail order prescription pharmacy must file a new application with the Board by registered mail no later than seven (7) days after the change.

7. Pursuant to the Board's delegation of authority dated November 9, 2020, which authorizes Board Staff to offer prescribed consent agreements to resolve first-time violations of PIC change notification requirements, this Consent Agreement is being offered to finally resolve Case No. 2022-PHA-18212.

8. Absent acceptance of this Consent Agreement by signing and dating it and returning it to Maine Board of Pharmacy, Complaints Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333-0035 by **May 13, 2022,** the Board will resolve this matter by holding an adjudicatory hearing.

COVENANTS

9. N-Molecular admits to the facts as stated above and admits that such conduct constitutes grounds for discipline pursuant to 10 M.R.S. § 8003(5-A)(A)(5) for violating a rule of the Board, specifically Board Rules Chapter 11, § 3, by failing to file a new application with the Board by registered mail no later than 7 days after a change of PIC.

10. As DISCIPLINE for the violation admitted to in paragraph 9 above, N-Molecular agrees to accept the imposition of:

a. A WARNING; and

b. A CIVIL PENALTY in the amount of seven hundred fifty dollars ($750.00). Payment of the civil penalty shall be made by check or money order payable to the "Treasurer, State of Maine" and delivered to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35

State House Station, Augusta, Maine 04333, and must be submitted with the signed Consent Agreement.

11. This Consent Agreement is not appealable and is effective until modified or terminated by the parties hereto.

12. Violation of any of the terms or conditions of this Consent Agreement by N-Molecular shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

13. The Board and the Office of the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

14. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

15. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

16. The Board and N-Molecular agree that no further agency action will be initiated against N-Molecular's license by the Board based upon the specific violations admitted to herein, except or unless N-Molecular fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct in the event that other allegations are brought against N-Molecular, and this Consent Agreement will be introduced as evidence in any future adjudicatory hearing involving N-Molecular. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining discipline in any further complaints against N-Molecular.

17. N-Molecular acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that

it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

N-Molecular, Inc.

DATED: 5/3/22

BY: Kunj Patel
Authorized Representative

Kunj Patel
Printed Name

DATED: 6-13-22

EDWARD KANE, President
Maine Board of Pharmacy

DATED: 6-14-2022

ANDREW L. BLACK
Assistant Attorney General

PHM-2018-0980

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102

GURBIR S. GREWAL
Attorney General

PAUL R. RODRÍGUEZ
Acting Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

March 21, 2019

Andrea Lee Tremblay, RPIC
Sofie Co. (Nuclear Pharmacy)
60H Commerce Way
Totowa, New Jersey 07512

Re: Inspection #8-6057-18-467
Date of Inspection: 7/5/18

Dear Ms. Tremblay:

The New Jersey State Board of Pharmacy, at the February 27, 2019 meeting, reviewed correspondence submitted requesting mitigation relating to the above-referenced inspection.

The Board moved to remove N.J.A.C.13:39-11.24(a)9.

Please complete the attached **Certification** form, submit **$10,100.00** for fines incurred and provide a **Letter of Corrective Action** to be returned to the Board within 15 days receipt of this letter.

NEW JERSEY STATE BOARD OF PHARMACY

By: _____
Anthony Rubinaccio, RPh
Executive Director

AR/rh
(2/19)

CERTIFICATION

I, Alexander R. Micale, hereby acknowledge that I have read and reviewed the Board's letter dated March 21, 2019 regarding allegations of violations of the Board's enabling act and/or regulations.

Please Check:

[X] I acknowledge the conduct which has been charged and agree to:

1. **Cease and desist from engaging in the conduct alleged and pay a penalty in the amount of $10,100.00** (to be paid upon signing of this Certification).

2. **Send a Letter of Corrective Action,** as requested by the Board, with this Certification.

I am also aware that the action taken against me by the Board herein is a matter of public record, and that the Board's letter and this Certification are public documents.

(Signature)

Dated: 13 MAY 19

Alexander R Micale
(Print Name)

Ref: Andrea Lee Tremblay, RPIC
Sofie Co. (Nuclear Pharmacy)
60H Commerce Way
Totowa, NJ 07512
(28RS00706600)
Inspection #8-6057-18-467

MAY 20 2019

AR/rh
(2/19)

ATTACHMENT A

Sofie Co. (Nuclear Pharmacy) – 60H Commerce Way, Totowa, New Jersey 07512
Pharmacist-In-Charge: Andrea Lee Tremblay
Bureau File #8-6057-18-467, **Period:** 7/5/18
Reference: Board of Pharmacy inspection conducted per N.J.S.A.45:1-18 and N.J.S.A.45:14-48(a)11&12 and a request from the Board to inspect all pharmacies that engage in compounding sterile preparations.

Details

CITE	DESCRIPTION	FINE
N.J.A.C.13:39-11:14(b)	In performing antiseptic hand cleansing, the current surgical hand scrub failed to have the persistent activity.	**$100.00**
N.J.A.C.13:39-11.24(a)10	The pharmacy failed to notify the Board in writing within 48 hours when air sampling test results from the ISO Class 7 buffer room, taken on May 15, 2018, were out of compliance. Specifically, on May 21, 2018, the internal air sample taken on May 15, 2018, from the ISO Class 7 room, near the entrance, detected 24 colonies of growth. The limit for the ISO Class 7 room, set by USP standards, is less than or equal to 10 colonies. The ISO Class 7 buffer room was considered out of compliance. The sample was sent to Accugenix, an independent laboratory, for identification. Ten (10) different organisms were identified. Andrea Lee Tremblay, RPIC, stated that, based upon the internal root-cause analysis, the most likely route of contamination was the high traffic of operators entering and leaving the cleanroom. On May 15, 2018, there were three (3) FDG productions, one (1) PYL production, and one (1) FBB production. The room had a maximum of four (4) people present during dispensing. Particular attention was paid to cleaning techniques and agents used, as well as identifying the route of contamination, possibly from the movement of operators from the anteroom to the cleanroom.	**$10,000.00**

	The cleaning logs for the ISO Class 7 cleanroom for the week of May 7, 2018, as well as the week of May 14, 2018, were reviewed. All cleaning agents and processes were reviewed with compounders by this inspector. All cleaning agents present onsite were within their expiration date. All equipment used to conduct air sampling was examined. They were adequately calibrated and serviced. All training records for personnel working on May 15, 2018 were reviewed in detail, including gloved fingertip sampling and media fill records. It should be noted that the pharmacy conducts environmental sampling from each ISO Class 5 area daily, and from ISO Class 7 areas twice a week. The environmental monitoring bi-weekly reports for the week of May 7, 2018, as well as the week of May 14, 2018, were reviewed. No growth was seen on the days preceding and following the excursion; therefore, it appears that this excursion was an isolated event.	
	Area of Concern: The pharmacy follows General Manufacturing Practices (GMP) and has the sink outside of the cleanroom. It should be noted that the traditional sterile compounding cleanroom requires a sink in the anteroom. Gowning and garbing was observed from ambient area to controlled area. The implemented process represented a good practice of eliminating microorganisms and maintaining the integrity of the cleanroom environmental monitoring control.	
TOTAL: $10,100.00		

PRM-2019-10015

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102

GURBIR S. GREWAL
Attorney General

PAUL R. RODRÍGUEZ
Acting Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 25, 2019

Alexander R. Micale, RPIC
Sofie Co. (Nuclear Pharmacy)
60H Commerce Way
Totowa, New Jersey 07512

Re: Inspection #8-6057-19-1350
Date of Inspection: 6/24/19

Dear Mr. Micale:

This letter is to advise you that the New Jersey State Board of Pharmacy has had an opportunity to review information concerning the above inspection report.

Upon review of all available information, the Board has preliminarily found that you have violated those items listed on Attachment A.

The Board has determined that it will offer you an opportunity to settle this matter and thereby avoid the initiation of further disciplinary proceedings. Should you wish to avail yourself of this opportunity, you **MUST SIGN THE ATTACHED CERTIFICATION** and agree to the following:

PAY A PENALTY IN THE AMOUNT OF $11,000.00 and **PROVIDE TO THE BOARD A LETTER OF CORRECTIVE ACTION.** (To be paid immediately upon your signing of the attached acknowledgment.)

Alternatively you may waive your right to a hearing and submit a written statement or explanation to the Board. The Board will then consider your submission and render a final decision, which may include any of the terms set forth above. This disposition will be a public record. Please take notice that if the Board determines that the initial inspection findings require a re-inspection to ensure that cited deficiencies have been properly addressed, you may be subject to any costs associated with the re-inspection.

If you do not wish to settle this matter, you may request a hearing. In that event, this letter will serve as notice of the charges against you and a hearing will be scheduled before the

New Jersey Is An Equal Opportunity Employer • Printed on Recycled Paper and Recyclable

Board. At that hearing you may, either personally or with the assistance of an attorney, submit determination concerning the charges of unlawful activity. You should be aware that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in this letter. Additionally, the Board may, if the facts are found to so warrant, enter an order, requiring you to reimburse certain monies, direction you to cease and desist from engaging in unlawful acts and/or requiring you to pay costs incurred by the Board. Should you have any questions concerning this letter or the settlement offer herein, I suggest that you contact the Board at (973) 504-6450.

The enclosed Certification **MUST** be completed and returned to the Board within fifteen (15) days following your receipt of this letter. In the event that the Board receives no response from you within this time, the Board's settlement offer will be withdrawn, and the allegations contained herein shall be deemed admitted, and the Board will proceed to finally review that matter and enter an appropriate order.

NEW JERSEY STATE BOARD OF PHARMACY

By: _____
Anthony Rubinaccio, RPh
Executive Director

AR/rh
(1/20)

New Jersey Is An Equal Opportunity Employer • Printed on Recycled Paper and Recyclable

CERTIFICATION

I, Alexander R Micale, hereby acknowledge that I have read and reviewed the Board's letter dated October 25, 2019 regarding allegations of violations of the Board's enabling act and/or regulations.

Please Check One:

[✓] I acknowledge the conduct which has been charged and agree to:

1. **Cease and desist from engaging in the conduct alleged and pay a penalty in the amount of $11,000.00** (to be paid upon signing of this Certification).

2. **Send a Letter of Corrective Action,** as requested by the Board, with this Certification.

I am also aware that the action taken against me by the Board herein is a matter of public record, and that the Board's letter and this Certification are public documents.

[ ] I hereby waive any rights I may have to a hearing in this matter and defend myself against any charges, but ask the Board to consider my explanation before rendering its final decisions. I understand that the Board may order any of the terms specified in its letter and that the Certification are public documents.

[ ] I request a formal administrative hearing to contest the charges specified by the Board. I understand that I will be advised of the time, date and place for that hearing at another time. I am aware that I may be represented by an attorney and that at the time of the hearing I may submit to the Board testimony and documentation relevant to the charges. I understand that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in its letter and may order such other remedies as it may deem appropriate. I am also aware that this proceeding is a matter of public record and that the Board's letter and this Certification are public documents.

Alexander R Micale
(Signature)

Dated: 30DEC19

Alexander R. Micale
(Print Name)

Ref: Alexander R. Micale, RPIC
Sofie Co. (Nuclear Pharmacy)
(28RS00706600)
60H Commerce Way
Totowa, NJ 07512
Inspection #8-6057-19-1350

JAN 02 2020

AR/rh
(10/19)

New Jersey Is An Equal Opportunity Employer . Printed on Recycled Paper and Recyclable

ATTACHMENT A

Sofie Co. (Nuclear Pharmacy), Permit #28RS00706600 – 60H Commerce Way, Totowa, New Jersey 07512
Pharmacist-In-Charge: Alexander R. Micale
Bureau File #8-6057-19-1350, **Period:** 6/24/19
Reference: Board of Pharmacy inspection conducted per N.J.S.A.45:1-18 and N.J.S.A.45:14-48(a)11&12 and an email request, dated June 20, 2019, to Robert Lake, Supervising Investigator, Enforcement Bureau, requesting an inspection of the subject pharmacy in connection with an application for a **Remodeling.**

Details

CITE	DESCRIPTION	FINE
N.J.A.C.13:39-4.8(a)	The pharmacy failed to notify the Board of the remodeling at least 30 days in advance on a form prescribed by the Board. On December 21, 2018, Alexander R. Micale, RPIC, informed the Board in writing that, due to an equipment upgrade, the facility would undergo a temporary discontinuation of business. Mr. Micale acknowledged that the remodeling of the cleanroom took place between the periods of December 24, 2018 to March 31, 2019, during which a permit application of remodeling was not submitted.	**$1,000.00**
N.J.A.C.13:39-11.24(a)10	The pharmacy failed to notify the Board in writing within 48 hours when environmental monitoring tests (air and surface sampling) detected ISO Classified area excursions, which included excursions that occurred within the ISO Classified 5 Hot Cell area, and ISO Classified 7 buffer room. During the inspection, Mr. Micale was able to locate three (3) notifications sent to the Board regarding these incidents. It should be noted that the facility is a licensed pharmacy, a licensed manufacturer and a licensed wholesale distributor in NJ. Following the Good Manufacturing Practices (GMP) standards, the pharmacy conducts environmental sampling from each ISO Classified 5 area daily and from ISO Classified 7 areas twice a week. From May 2018 to December 2018, before the remodeling started, the pharmacy had a total of ten (10) environmental monitoring test failures.	**$10,000.00**
TOTAL: $11,000.00		

SOFIE
From start to clinic

NOV 13 2019

November 7, 2019

New Jersey Office of the Attorney General
Division of Consumer Affairs
Board of Pharmacy
124 Halsey St, 6th Floor
Newark, NJ 07102
Attention: Anthony Rubinaccio, RPh

Subject: **Letter of Corrective Action**
SOFIE Co. dba SOFIE
60H Commerce Way
Totowa, NJ 07512
Re: Inspection #8-6057-19-1350

To Mr. Rubinaccio,

SOFIE is committed to compliance to ensure product quality and patient safety. SOFIE acknowledges the non-compliant findings and commits to the following corrective actions and making continuous improvements.

[N.J.A.C.13:39-4.S(a)]: *The pharmacy failed to notify the Board of the remodeling at least 30 days in advance on a form prescribed by the Board. On December 21, 2018, Alexander R. Micale, RPIC, informed the Board in writing that, due to an equipment upgrade, the facility would undergo a temporary discontinuation of business. Mr. Micale acknowledged that the remodeling of the cleanroom took place between the periods of December 24, 2018 to March 31, 2019, during which a permit application of remodeling was not submitted.*

SOFIE is committed to compliance with the regulations set forth by the New Jersey Board of Pharmacy. SOFIE acknowledges the Boards requirement to be notified at least 30 days in advance and takes responsibility for the lack of notification of the temporary discontinuation of business in a timely manner. To ensure SOFIE complies with regulatory requirements in the various states in which SOFIE has pharmacies, a Corporate Pharmacist-in-Charge (CPIC) position was recently created and filled to work with site PICs to ensure regulatory compliance by holding monthly meetings to discuss network issues, regulatory changes, and compliance with USP guidelines. The current PIC will work closely with the CPIC to ensure that any changes within the facility are properly addressed per state Board of Pharmacy. In addition, any requests for facility upgrades must be captured through the internal Change Control process. Prior to granting approval, regulatory reporting is assessed. This adds an additional layer of ensuring state Board of Pharmacy compliance. SOFIE is confident that with these additional layers of oversight we will be in compliance with all state regulations going forward.

[N.J.A.C.13:39-11.24(a)10]: *The pharmacy failed to notify the Board in writing within 48 hours when environmental monitoring tests (air and surface sampling) detected ISO Classified area excursions, which included excursions that occurred within the ISO Classified 5 Hot Cell area, and*

SOFIE
From start to clinic

ISO Classified 7 buffer room. During the inspection, Mr. Micale was able to locate three (3) notifications sent to the Board regarding these incidents.

It should be noted that the facility is a licensed pharmacy, a licensed manufacturer and a licensed wholesale distributor in NJ. Following the Good Manufacturing Practices (GMP) standards, the pharmacy conducts environmental sampling from each ISO Classified 5 area daily and from ISO Classified 7 areas twice a week. From May 2018 to December 2018, before the remodeling started, the pharmacy had a total of ten (10) environmental monitoring test failures.

SOFIE acknowledges the Boards requirement to be notified in writing within 48 hours whenever an environmental monitoring excursion occurs in the classified areas. Due to staff turnover, the site failed to notify the BOP as required. Alexander R. Micale (current PIC) is aware of this requirement and has notified the BOP regarding EM excursions since registering as the PIC. In addition, other site pharmacists and site Quality Assurance Specialist are aware of this regulation and will assist with notification. Going forward, site personnel will send a notification electronically and via postal service. The site will also keep copies of notification letters onsite for easy retrievability. As of November 7, 2019, the facility has not experienced any environmental excursions (since re-opening) demonstrating that the site is in a state of environmental control. Also, as a secondary check, SOFIE internal SOPs of EM in the ISO 5 and ISO 7 areas will be updated to include a verification check for regulatory notification if excursions are observed. A change control is currently open to update procedures related to ISO 5 and ISO 7 EM. Once approved, these changes will be made to the documentation and implemented throughout the SOFIE network.

Sincerely,

Alexander R. Micale, Pharm.D.
Facility Manager and Pharmacist in Charge, Totowa, NJ
SOFIE
60H Commerce Way
Totowa, NJ 07512
Tel: +1 973 785 0029
www.sofie.com

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102

GURBIR S. GREWAL
Attorney General

PAUL R. RODRÍGUEZ
Acting Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

July 10, 2019

Sofie Co. (Nuclear Pharmacy)
60H Commerce Way
Totowa, NJ 07512
Attn: Alexander R. Micale, RPIC

RE: Inspection Report **#8-6057-19-1350** for the period: 06/24/2019

Dear Mr. Alexander R. Micale,

The New Jersey Board of Pharmacy (the "Board") has received the above mentioned inspection report, a copy of which is included with this letter, and has requested that you respond to the following items within **ten (10) days** of receipt of this letter:

1) Please provide a detailed response to the inspector's observations and any "areas of concern" noted for each citation in the "Report of Inspection" on pages **#1** through **#3**. Your response should include an explanation for each issue noted, as well as what steps you have taken (or are planning to take) to address each item.

2) Please provide a detailed response for each citation and any "areas of concern" noted on page **#1** of "Exhibit **#9**". You do not need to respond to items a second time, if you addressed a citation as part of your response to the "Report of Inspection" section. Again, your response should include an explanation for each issue noted, as well as what steps you have taken (or are planning to take) to address each item.

Feel free to include any additional supporting documentation you feel the Board should consider when reviewing your response. The Board will review this report and your response to this letter at the next available Board meeting. Please note that the Board reserves the right to take disciplinary action based on any violations, even if corrected.

Failure to respond and provide this information within ten (10) days from receipt of this letter will constitute a failure of a duty to cooperate pursuant to N.J.A.C. 13:45C-1.3 and may result in disciplinary action by the Board, including suspension of your permit to operate a pharmacy and/or to engage in sterile compounding.

Sincerely,

Anthony Rubinaccio, RPh
Executive Director
New Jersey Board of Pharmacy

New Jersey Is An Equal Opportunity Employer • Printed on Recycled Paper and Recyclable

Name of Agenda Item:	Sofie (Nuclear Pharmacy), Totowa 28RS00706600
Applicant / License type:	In-State Pharmacy
Type of Agenda Item:	Inspection Report
Why is this on the Agenda?	10-Day Letter Response

Submitted By:	Renee Hodges
Date (dd/mm/yyyy):	07/28/2019

2068 COPY

SOFIE
From start to clinic

24 July 2019

New Jersey Office of the Attorney General
Division of Consumer Affairs
Board of Pharmacy
124 Halsey St, 6th Floor
Newark, NJ 07102
Attention: Anthony Rubinaccio, RPh

Subject: SOFIE Co. dba SOFIE
60H Commerce Way
Totowa, NJ 07512

Inspection Date: 24 Jun 19; Report received 18 Jul 19

Dear Mr. Rubinaccio,

SOFIE is committed to compliance to ensure product quality and patient safety. SOFIE acknowledges the non-compliant findings and is fully committed to correcting issues and making continuous improvements. This letter will serve as communication to Inspection Report **#8-6057-19-1350.**

[13:39-4.B(a)] - *The pharmacy failed to notify the Board at least 30 days in advance on a form prescribed by the Board.*

SOFIE is committed to compliance with the regulations set forth by the New Jersey Board of Pharmacy. SOFIE acknowledges the Boards requirement to be notified at least 30 days in advance and takes responsibility for the lack of notification of the temporary discontinuation of business in a timely manner. To ensure SOFIE complies with regulatory requirements in the various states in which SOFIE has pharmacies, a Corporate Pharmacist In Charge (CPIC) position was recently created and filled to work with site PICs to ensure regulatory compliance by holding monthly meetings to discuss network issues, regulatory changes, and compliance with USP guidelines. The current PIC will work closely with the CPIC to ensure that any changes within the facility are properly addressed per state Board of Pharmacy. SOFIE is confident that with this additional layer of oversight we will be in compliance with all state regulations going forward.

JUL 29 2019

SOFIE
From start to clinic

[13:39-11.24(a)10.]-*The pharmacy failed to notify the Board in writing within 48 hours when environmental monitoring tests (air and surface sampling) detected ISO Classified area excursions, which included excursions occurred within the ISO Classified 5 Hot Cell area, and ISO Classified 7 buffer room. The pharmacy also failed to cease using these failed equipment during these incidents.*

SOFIE is committed to patient safety and compliance with the regulations. As such, SOFIE has taken more rigorous steps toward patient safety with a comprehensive contamination control program and extensive environmental monitoring. While USP <797> requires clean room sampling to be done every six months, SOFIE is taking environmental sampling from each individual ISO 5 area every day and the ISO 7 area at least twice a week. The historical data from daily Environmental Monitoring (EM) does not show any adverse trends and demonstrate the pharmacy is in a state of environmental control.

The EM program consists of monitoring the areas for non-viable particulates and microbial counts of viable air, surfaces, and personnel. Environmental monitoring performed at Totowa is extensive in terms of the number of areas monitored and in the frequency of monitoring. Between Q3 and Q4 2018, over 2,000 samples were taken from the ISO 5 areas and ISO 7 areas. Data collected from environmental monitoring is reviewed in real time by Site Quality Assurance (QA) and is included in a quarterly trend report that is approved and reviewed by Corporate Microbiologists.

Between the time an environment is sampled and when the plates are ready to be examined we, as the routine course of business, perform a cleaning of said environment with a sporicidal agent and a triple cleaning after excursions are identified. Excursions are immediately sent for microbial identification via DNA Sequencing and actions taken based on the microorganism(s) identified. During these excursions, an investigation is opened and completed. The root causes of these EM excursions and investigations were not attributed to failures of the ISO 7 cleanroom or ISO 5 equipment. No sterility positives or drug product complaints were received during this time. The site will continue to trend these events and take corrective actions as required. Please note that the site has not had experienced any EM excursions since re-opening of the facility.

SOFIE acknowledges the Boards requirement to be notified in writing within 48 hours whenever an environmental monitoring excursion occurs in the classified areas. Due to staff turnover, the site failed to notify the BOP as required. Alexander R. Micale (current PIC) is aware of this requirement and has notified the BOP regarding EM excursions since registering as the PIC. In addition, other site pharmacists and site Quality Assurance Specialist are aware of this regulation and will assist with notification. Going forward, site personnel will send a notification electronically and via postal service. The site will also keep copies of notification letters onsite for easy retrievability. As a secondary check, SOFIE internal SOPs of EM in the ISO 5 and ISO 7 areas will be updated to include a verification check for regulatory notification. Finally, SOFIE internal SOP ZEV.PH.012, *Conducting and Reporting Remedial Investigations for Reportable Environmental Monitoring (EM) Events at the MO Facilities*, will be revised to be applicable to all SOFIE Pharmacies to ensure all pharmacies appropriately report environmental monitoring excursion events to the Board in addition to any immediate corrective actions (cleaning).

SOFIE
From start to clinic

SOFIE strives to provide superior products that are both safe and effective and appreciates the feedback which helps us continuously improve. We believe that the changes committed to following this routine inspection help to achieve that goal.

Thank you for your consideration of the above. If any additional information is needed, please do not hesitate to contact me.

Sincerely,

Alexander R. Micale, PharmD, RPh
Facility Manager and Pharmacist-in-Charge, Totowa, NJ
SOFIE
60H Commerce Way
Totowa, NJ 07512
Tel: +1 973 785 0029
Alexander.Micale@sofie.com
www.sofie.com

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102

GURBIR S. GREWAL
Attorney General

PAUL R. RODRÍGUEZ
Acting Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 19, 2019

Alexander R. Micale, RPIC
Sofie Co. (Nuclear Pharmacy)
60H Commerce Way
Totowa, NJ 07512

Re: Inspection #8-6057-19-1350
Date of Inspection: 6/24/19

Dear Mr. Micale:

The New Jersey State Board of Pharmacy is in receipt of your check #307787 in the amount of $11,000.00 and your Letter of Corrective Action relative to the above-referenced.

The Board is requesting you sign and date the enclosed Certification and return it back to this office immediately so that this matter can be closed.

Yours truly,

Anthony Rubinaccio, RPh
Executive Director

Enclosure
AR/rh

JAN 02 2020

2072

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102

MATTHEW J. PLATKIN
Acting Attorney General

CARI FAIS
Acting Director

Mailing Address:
P.O. Box 45045
Newark, NJ 07101
(973) 504-6351

Certified Mail: 7020 1810 0001 5640 6045

June 6, 2022

Andrea Tremblay, RPIC
Sofie Co.
60H Commerce Way
Totowa, NJ 07512

Re: Inspection #8-6057-21-1
Date of Inspection: 11/15/2021 thru 1/7/2022

Dear Ms. Tremblay,

This letter is to advise you that the New Jersey State Board of Pharmacy has had an opportunity to review information concerning the above inspection report.

Upon review of all available information, the Board has preliminarily found that you have violated those items listed on Attachment A.

The Board has determined that it will offer you an opportunity to settle this matter and thereby avoid the initiation of further disciplinary proceedings. Should you wish to avail yourself of this opportunity, you **MUST SIGN THE ATTACHED CERTIFICATION** and agree to the following:

PAY A PENALTY IN THE AMOUNT OF $1,000.00 and **PROVIDE TO THE BOARD A LETTER OF CORRECTIVE ACTION.** (To be paid immediately upon your signing of the attached acknowledgment.)

Alternatively you may waive your right to a hearing and submit a written statement or explanation to the Board. The Board will then consider your submission and render a final decision, which may include any of the terms set forth above. This disposition will be a public record. Please take notice that if the Board determines that the initial inspection findings require a re-inspection to ensure that cited deficiencies have been properly addressed, you may be subject to any costs associated with the re-inspection.

If you do not wish to settle this matter, you may request a hearing. In that event, this letter will serve as notice of the charges against you and a hearing will be scheduled before the Board. At that hearing you may, either personally or with the assistance of an attorney, submit determination concerning the charges of unlawful activity. You should be aware that in making

its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in this letter. Additionally, the Board may, if the facts are found to so warrant, enter an order, requiring you to reimburse certain monies, direction you to cease and desist from engaging in unlawful acts and/or requiring you to pay costs incurred by the Board. Should you have any questions concerning this letter or the settlement offer herein, I suggest that you contact the Board at (973) 504-6450.

The enclosed Certification **MUST** be completed and returned to the Board within fifteen (15) days following your receipt of this letter. In the event that the Board receives no response from you within this time, the Board's settlement offer will be withdrawn, and the allegations contained herein shall be deemed admitted, and the Board will proceed to finally review that matter and enter an appropriate order.

NEW JERSEY STATE BOARD OF PHARMACY

By: _____
Anthony Rubinaccio, RPh
Executive Director

AR/em
(05/22)

CERTIFICATION

I, Andrea Tremblay, hereby acknowledge that I have read and reviewed the Board's letter dated June 6, 2022, regarding allegations of violations of the Board's enabling act and/or regulations.

Please Check One:

[X] I acknowledge the conduct which has been charged and agree to:

1. **Cease and desist from engaging in the conduct alleged and pay a penalty in the amount of $1,000.00** (to be paid upon signing of this Certification).

2. **Send a Letter of Corrective Action,** as requested by the Board, with this Certification.

I am also aware that the action taken against me by the Board herein is a matter of public record, and that the Board's letter and this Certification are public documents.

[X] I hereby waive any rights I may have to a hearing in this matter and defend myself against any charges, but ask the Board to consider my explanation before rendering its final decisions. I understand that the Board may order any of the terms specified in its letter and that the Certification are public documents.

[ ] I request a formal administrative hearing to contest the charges specified by the Board. I understand that I will be advised of the time, date and place for that hearing at another time. I am aware that I may be represented by an attorney and that at the time of the hearing I may submit to the Board testimony and documentation relevant to the charges. I understand that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in its letter and may order such other remedies as it may deem appropriate. I am also aware that this proceeding is a matter of public record and that the Board's letter and this Certification are public documents.

Andrea Tremblay
(Signature)

Dated: 06/30/22

Andrea Tremblay
(Print Name)

Ref: Andrea Tremblay, RPIC
Sofie Co.
(28RS00706600)
60H Commerce Way
Totowa, NJ 07512
Inspection #8-6057-21-1

AR/em
(05/22)

JUL 0 1 2022

ATTACHMENT A

SOFIE CO.-Totowa, Permit #28RS00706600 – 60H Commerce Way Totowa, NJ 07512
Pharmacist-In-Charge: Andrea Tremblay
Bureau File #8-6057-21-1, **Period:** 11/15/2021 thru 1/7/2022
Reference: Board of Pharmacy inspection activity conducted pursuant to N.J.S.A. 45:1-18 and N.J.S.A. 45:14-48(a)ll&12, and a request from the Board of Pharmacy to inspect all pharmacies that engage in compounding sterile preparations.

Details

CITE	DESCRIPTION	FINE
N.J.A.C.13:39-11.24(a)(6)	The SUBJECT pharmacy does not have an independent contractor (certification company) conduct environmental sampling once every six months. The SUBJECT pharmacy only conducted their own in-house viable air and surface sampling.	**$1,000.00**
TOTAL:		**$1,000.00**

SOFIE
From start to clinic

June 30, 2022

New Jersey Office of the Attorney General
Division of Consumer Affairs
Board of Pharmacy
124 Halsey St, 6th Floor
Newark, NJ 07102
Attention: Anthony Rubinaccio, RPh

Subject: **Letter of Corrective Action**
SOFIE Co. dba SOFIE
60H Commerce Way
Totowa, NJ 07512
Re: Inspection #8-6057-21-1

To Mr. Rubinaccio,

SOFIE is committed to compliance to ensure product quality and patient safety. SOFIE acknowledges the non-compliant findings and commits to the following corrective actions and making continuous improvements.

[N.J.A.C.13:39-11.24(a)(6): *The subject pharmacy does not have an independent contractor (certification company) conduct environmental sampling once every six months. The subject pharmacy only conducted their own in-house viable air and surface sampling.*

SOFIE is committed to compliance with the regulations set forth by the New Jersey Board of Pharmacy. SOFIE acknowledges the Boards requirement of having an independent certification company conduct environmental sampling once every six months. The facility scheduled ENV (independent certification company) to perform environmental sampling on 12 Mar 22 and will continue to have an independent certification company perform environmental monitoring every six months going forward.

Thank you for your consideration of the above corrective action. If any additional information is needed, please do not hesitate to contact me.

Sincerely,

Andrea Tremblay, Pharm.D.
Facility Manager and Pharmacist in Charge, Totowa, NJ
SOFIE
60H Commerce Way
Totowa, NJ 07512
Tel: +1 973 785 0029
www.sofie.com

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102

MATTHEW J. PLATKIN
Acting Attorney General

CARI FAIS
Acting Director

Mailing Address:
P.O. Box 45045
Newark, NJ 07101
(973) 504-6351

Certified Mail: 7020 1810 0001 5640 6069

June 6, 2022

Amanda Lance, RPIC
Sofie Co.
110 Clyde Road
Somerset, New Jersey 07601

Re: Inspection #8-4796A-21-2
Date of Inspection: 4/5/2021

Dear Mrs. Lance

This letter is to advise you that the New Jersey State Board of Pharmacy has had an opportunity to review information concerning the above inspection report.

Upon review of all available information, the Board has preliminarily found that you have violated those items listed on Attachment A.

The Board has determined that it will offer you an opportunity to settle this matter and thereby avoid the initiation of further disciplinary proceedings. Should you wish to avail yourself of this opportunity, you MUST SIGN THE ATTACHED CERTIFICATION and agree to the following:

PAY A PENALTY IN THE AMOUNT OF $2,000.00 and PROVIDE TO THE BOARD A LETTER OF CORRECTIVE ACTION. (To be paid immediately upon your signing of the attached acknowledgment.)

Alternatively you may waive your right to a hearing and submit a written statement or explanation to the Board. The Board will then consider your submission and render a final decision, which may include any of the terms set forth above. This disposition will be a public record. Please take notice that if the Board determines that the initial inspection findings require a re-inspection to ensure that cited deficiencies have been properly addressed, you may be subject to any costs associated with the re-inspection.

If you do not wish to settle this matter, you may request a hearing. In that event, this letter will serve as notice of the charges against you and a hearing will be scheduled before the Board. At that hearing you may, either personally or with the assistance of an attorney, submit determination concerning the charges of unlawful activity. You should be aware that in making

its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in this letter. Additionally, the Board may, if the facts are found to so warrant, enter an order, requiring you to reimburse certain monies, direction you to cease and desist from engaging in unlawful acts and/or requiring you to pay costs incurred by the Board. Should you have any questions concerning this letter or the settlement offer herein, I suggest that you contact the Board at (973) 504-6450.

The enclosed Certification MUST be completed and returned to the Board within fifteen (15) days following your receipt of this letter. In the event that the Board receives no response from you within this time, the Board's settlement offer will be withdrawn, and the allegations contained herein shall be deemed admitted, and the Board will proceed to finally review that matter and enter an appropriate order.

NEW JERSEY STATE BOARD OF PHARMACY

By: Anthony Rubinaccio, RPh
Executive Director

AR/cm
(05/22)

CERTIFICATION

I, Rushab Menon, hereby acknowledge that I have read and reviewed the Board's letter dated June 6, 2022, regarding allegations of violations of the Board's enabling act and/or regulations.

Please Check One:

[ ] I acknowledge the conduct which has been charged and agree to:

1. Cease and desist from engaging in the conduct alleged and pay a penalty in the amount of $2,000.00 (to be paid upon signing of this Certification).

2. Send a Letter of Corrective Action, as requested by the Board, with this Certification.

I am also aware that the action taken against me by the Board herein is a matter of public record, and that the Board's letter and this Certification are public documents.

[✓] I hereby waive any rights I may have to a hearing in this matter and defend myself against any charges, but ask the Board to consider my explanation before rendering its final decisions. I understand that the Board may order any of the terms specified in its letter and that the Certification are public documents.

[ ] I request a formal administrative hearing to contest the charges specified by the Board. I understand that I will be advised of the time, date and place for that hearing at another time. I am aware that I may be represented by an attorney and that at the time of the hearing I may submit to the Board testimony and documentation relevant to the charges. I understand that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in its letter and may order such other remedies as it may deem appropriate. I am also aware that this proceeding is a matter of public record and that the Board's letter and this Certification are public documents.

(Signature)

Dated: 01 Jul 22

Rushab Menon
(Print Name)

Ref: Amanda Lance, RPIC
Sofie Co.
(28RS00630200)
110 Clayde Road
Somerset, NJ 07601
Inspection #8-4796A-21-2

AR/em
(05/22)

ATTACHMENT A

SOFIE CO., Permit # 28RS00630200 – 110 Clyde Road, Somerset, NJ 07601
Pharmacist-In-Charge: Amanda Lance
Bureau File # #8-4796A-21-2, Period: 04/5/2021
Reference: Board of Pharmacy inspection activity conducted pursuant to N.J.S.A. 45:1-18 and N.J.S.A. 45:14-48(a)11&12, and a request from the Board of Pharmacy to inspect all pharmacies that engage in compounding sterile preparations.

Details

CITE	DESCRIPTION	FINE
N.J.A.C.13:39-11.24(a)(6)	Air & surface sampling for microbial organisms in ISO Class 5 primary engineering controls and in all other ISO classified areas shall be certified by an independent certification company once every six months and at any time when microbial contamination is suspected. The Subject pharmacy does not have an independent certification company to conduct environmental sampling once every six months. The Subject pharmacy conducts their in-house viable air & surface sampling.	$1,000.00
N.J.A.C.13:39-11.23(b)(1)(i)	The Subject pharmacy's risk management program within the pharmacy's Policy and Procedure manual does not include information regarding confirmed product contamination by the pharmacist-in-charge product to the NJBOP within forty-eight (48) hours of becoming aware of such.	$1,000.00
TOTAL:		$2,000.00

SOFIE
From start to clinic

June 26, 2022

New Jersey Office of the Attorney General
Division of Consumer Affairs
Board of Pharmacy
124 Halsey St, 6th Floor
Newark, NJ 07102
Attention: Anthony Rubinaccio, RPh

Subject: **Letter of Corrective Action**
SOFIE Co. dba SOFIE
110 Clyde Rod
Somerset, NJ 08873
Re: Inspection #8-4796A-21-2

To Mr. Rubinaccio,

SOFIE is committed to compliance to ensure product quality and patient safety. SOFIE acknowledges the non-compliant findings and commits to the following corrective actions and making continuous improvements.

[N.J.A.C.13:39-11.24(a)(6): *The subject pharmacy does not have an independent contractor (certification company) conduct environmental sampling once every six months. The subject pharmacy only conducted their own in-house viable air and surface sampling.*

SOFIE is committed to compliance with the regulations set forth by the New Jersey Board of Pharmacy. SOFIE acknowledges the Boards requirement of having an independent certification company conduct environmental sampling once every six months. The facility scheduled ENV (independent certification company) to perform environmental sampling on 12 Mar 22 and will continue to have an independent certification company perform environmental monitoring every six months going forward.

Thank you for your consideration of the above corrective action. If any additional information is needed, please do not hesitate to contact me.

Sincerely,

Rushab Menon, Pharm.D.
Facility Manager, Somerset, NJ
SOFIE
110 Clyde Road
Somerset, NJ 08873
Tel: +1 732 873 0245
www.sofie.com

SOFIE From start to clinic	Site Specific Pharmacy Information: Somerset, New Jersey (NJ2) PM.0001 ~~Attachment 4~~ Attachment 5 JR 02 Feb 21 Corrected attachment number.	Page 1 of 2 Revision A	TRUE COPY

A. Site Address:
   1. 110 Clyde Road
      Somerset, NJ 08873

B. Pharmacist – in – Charge:
   1. Amanda Lanze

C. Pharmacy Licenses:
   1. RAM – New Jersey State Radioactive Materials license # 439619-RAD190004
   2. State Manufacturing - New Jersey X-Ray Machine Registration Facility ID: 118651
   3. New Jersey Drug Manufacturing License # 5004838
   4. Pharmacy: New Jersey Pharmacy Permit #28RS00630200
   5. The Out-Of-State Pharmacy Permit issued by the Connecticut Board of Pharmacy is license # PCN.0002197
   6. The Out-Of-State Pharmacy Permit issued by the Maryland Board of Pharmacy is license # P07588
   7. The Out-Of-State Pharmacy Permit issued by the New York Board of Pharmacy is license # 034699
   8. The Out-Of-State Pharmacy Permit issued by the Pennsylvania Board of Pharmacy is license # NP000740

C. Products Dispensed and Compounded:
   1. [18F]-Flurodeoxyglucose (FDG)
   2. [18F]-Sodium Fluoride (NaF)

E. Prescription Retention Period (longest retention period based taking into consideration non-resident licenses):
   1. 5 years for the state of New Jersey and is the longest retention period

F. Pharmacist to Technician Ratio:
   1. 1:2.
   2. A pharmacy technician receiving in-service training is excluded from this ratio. The pharmacist can not provide in-service training for more than 2 technicians.
   3. This ratio may be exceeded if stipulations for the greater ratio is met per 13:39-6.15 (e) under Pharmacy Technician Duties and Pharmacist – Technician Ratio

G. Special Considerations for Pharmacy:
   1. Media fills and gowning validations must be completed by annually, with no grace period.

H. Board Notifications

Change in PIC (Prescription Department Manager)	Within 30 days
Disciplined in another state	Immediately upon notice
Change in Ownership	30 days
Change to Pharmacy name	30 days prior
Change in Pharmacy Location	30 days prior
Termination for Cause	15 days prior
Notification of EM excursion	48 hours
Notification of Temperature Excursions – Pharmacy ONLY Areas	48 hours (if excursion occurs for more than 24 hours). If excursion greater than 72 hours, drug may not be dispensed unless it is verified with the manufacturer that the stability of the product is not impacted.
Changes to Pharmacy Hours	30 days
Pharmacy Closure (temporary)	Notify Board and must receive Board approval. Otherwise deemed as a discontinued pharmacy.
Pharmacy Remodeling impacting size or location of prescription processing area	30 days prior

Installation of compounding aseptic isolators or compounding aseptic containment isolators not located in a buffer area (requires reinspection).	60 days prior
Pharmacy Reopening due to Closure or Remodeling	Anticipation completion date will be documented on form used for notification of remodeling/closure. Recommend following up with the board prior to completion
Notification of Possible Product Contamination	48 hours

Approval Signatures:

Name	Title	Signature	Date
Amanda Lanze	PIC / Facility Manager	Amanda Lanze Amanda Lanze (Jan 29, 2021 14:05 EST)	Jan 29, 2021
Kunj Patel	Corporate Pharmacist – in - Charge	Kunj Patel	Jan 29, 2021

Revision & Update History:

Revision	Update	Issue Date	Reference #	Details of Change
A	01	02 Feb 21	CC-2018-031 CC-2018-031-A1	Initial release.

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102

MATTHEW J. PLATKIN
Attorney General

CARI FAIS
Acting Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

CERTIFIED MAIL: 7020 1810 0001 5642 2700

March 10, 2023

Amanda Lance, RPIC
Sofie Co.
110 Clyde Road
Somerset, New Jersey 07601

Re: Inspection #8-4796A-21--2
Date of Inspection: 4/5/2021

Dear Mrs. Lance,

At the February, 2022 meeting, the New Jersey State Board of Pharmacy (the Board), reviewed correspondence submitted requesting mitigation request relating to the above-referenced inspection.

The Board moved to deny your mitigation request for N.J.A.C.13:39-11.23(b)(1)(i), as actions taken were corrective in nature.

Please complete the attached **Certification** form and submit **$2,000.00** for fines incurred to the Board within fifteen (15) days of receipt of this letter.

NEW JERSEY STATE BOARD OF PHARM ACY

By: _____
Anthony Rubinaccio, RPh
Executive Director

AR/em
(2/23)

APR 10 2023

CERTIFICATION

I, Rushab Menon, hereby acknowledge that I have read and reviewed the Board's letter dated March 10, 2023 regarding allegations of violations of the Board's enabling act and/or regulations.

Please Check:

[✓] I acknowledge the conduct which has been charged and agree to:

1. **Cease and desist from engaging in the conduct alleged and pay a penalty in the amount of $2,000.00** (to be paid upon signing of this Certification).

2. Submit an updated **Policy and Procedures Manual** (electronically) for Board review:

I am also aware that the action taken against me by the Board herein is a matter of public record, and that the Board's letter and this Certification are public documents.

(Signature)

Dated: 07 APR 23

Rushab Menon
(Print Name)

Ref: Amanda Lance, RPIC
Sofie Co.
(28RS00630200)
110 Clayde Road
Somerset, NJ 07601
Inspection #8-4796A-21--2

AR/em
(2/23)

ATTACHMENT A

SOFIE CO., Permit # 28RS00630200 – 110 Clyde Road, Somerset, NJ 07601
Pharmacist-In-Charge: Amanda Lance
Bureau File # #8-4796A-21–2, Period: 04/5/2021
Reference: Board of Pharmacy inspection activity conducted pursuant to N.J.S.A. 45:1-18 and N.J.S.A. 45:14-48(a)11&12, and a request from the Board of Pharmacy to inspect all pharmacies that engage in compounding sterile preparations.

Details

CITE	DESCRIPTION	FINE
N.J.A.C.13:39-11.24(a)(6)	Air & surface sampling for microbial organisms in ISO Class 5 primary engineering controls and in all other ISO classified areas shall be certified by an independent certification company once every six months and at any time when microbial contamination is suspected. The Subject pharmacy does not have an independent certification company to conduct environmental sampling once every six months. The Subject pharmacy conducts their in-house viable air & surface sampling.	$1,000.00
N.J.A.C.13:39-11.23(b)(1)(i)	The Subject pharmacy's risk management program within the pharmacy's Policy and Procedure manual does not include information regarding confirmed product contamination by the pharmacist-in-charge product to the NJBOP within forty-eight (48) hours of becoming aware of such.	$1,000.00
TOTAL:		$2,000.00

CLOSEOUT LETTER

N-Molecular Inc. d.b.a. SOFIE

MARCS-CMS 553833 – JULY 02, 2019

Delivery Method:

Certified Mail
Return Receipt Requested

Product:

Drugs

Recipient:

Patrick W. Phelps

President and CEO

N-Molecular Inc. d.b.a. SOFIE

SOPHIE Biosciences

6162 Bristol Parkway
Culver City, CA 90230
United States

Issuing Office:

Center for Drug Evaluation and Research

10 Waterview Blvd
3rd FL
Parsippany, NJ 07054
United States

(973) 331-4900

Dear Mr. Phelps:

The U.S. Food and Drug Administration (FDA) has completed an evaluation of your firm's corrective actions in response to our warning letter (CMS # 553833) dated September 24, 2018. Based on our evaluation, it appears that you have adequately addressed the violations contained in this warning letter.

You are expected to take all necessary steps to assure compliance with the Federal Food, Drug, and Cosmetic Act and FDA's implementing regulations. This letter will not preclude any future regulatory action should violations be observed during a subsequent inspection or through other means.

Sincerely,
/S/
Stephanie Durso, Compliance Branch Director
Office of Pharmaceutical Quality Operations, Division I

Was this helpful? Yes No

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

WARNING LETTER

N-Molecular Inc. d.b.a. SOFIE

MARCS-CMS 553833 – SEPTEMBER 24, 2018

Delivery Method:

Certified Mail

Product:

Drugs

Recipient:

Patrick W. Phelps

President and Chief Executive Officer

N-Molecular Inc. d.b.a. SOFIE

SOFIE and SOFIE Biosciences

6162 Bristol Parkway
Culver City, CA 90230
United States

Issuing Office:

Center for Drug Evaluation and Research

10 Waterview Blvd
3rd FL
Parsippany, NJ 07054
United States

(973) 331-4900

Dear Mr. Phelps:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, N-Molecular Inc. (d.b.a. SOFIE) at 11 Rogers Rd, Suite 6, Haverhill, Massachusetts, from February 12, 2018 to February 28, 2018.

This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for positron emission tomography (PET) drugs. See 21 CFR, part 212.

Because your methods, facilities, or controls for compounding, processing, packing, or holding do not conform to CGMP, your PET drug products are adulterated within the meaning of section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(C).

We reviewed your March 20, 2018, response in detail and acknowledge receipt of subsequent correspondence.

During our inspection, our investigators observed specific violations including, but not limited to, the following:

1. Your firm failed to take appropriate corrective action when a failure of a production batch or any component of the batch failed to meet any of its specifications. (21 CFR 212.20(d))

You failed to take corrective actions following bacterial contamination of an injectable product batch that you released. You opened a sterility failure investigation on May 31, 2016, after finding Bacillus pumilus/safensis in your finished sterile injectable drug product fludeoxyglucose F-18 (FDG). You failed to complete the investigation in a timely manner, and it had not been formally approved by the quality assurance vice president, as per your SOP, at the time of our inspection over a year and a half later.

Although no errors were found in laboratory testing, your investigation postulated that the FDG could have been contaminated with B. pumilus/safensis during sterility testing. You stated that the disinfection program might need to incorporate more frequent use of sporicidal agents. However, there was no indication that more frequent use of sporicidals was implemented.

Your investigation also lacked a thorough evaluation of potential manufacturing causes of the non-sterility test result. For example, your review of environmental monitoring data was minimal. You failed to address the active air sampling that found the same spore-forming genus as the sterility test isolate (Bacillus, sp.) and **(b)(4)** in the ISO 7 cleanroom location immediately adjacent to the Dispensing Hot Cell the day after the batch that failed sterility testing was produced. You had not performed active air monitoring in this area on the previous day.

In your response, you stated that you would provide training and implement director-level sign off for all investigations. You lacked evidence of your corrective actions, including but not limited to revised disinfection procedures and your remediated investigation procedure.

In response to this letter provide:
• a thorough assessment of the adequacy of your facility, equipment, and process (including both production and testing laboratory) design and controls.
• a comprehensive corrective action and preventive action (CAPA) plan that identifies microbial contamination risks throughout your operations and describes improvements to assure higher confidence in the sterility of products made at your facilities.
• a revised cleaning and disinfection program that ensures an environment suitable for aseptic processing and sterility testing.
• an assessment of your overall system for investigations into deviations, discrepancies, complaints, OOS results, failures, and verification of effectiveness of corrections. Include an action plan to fully remediate this system throughout your company's network.

2. Your firm's facilities are not adequate to ensure the prevention of contamination of equipment or product by environmental conditions that could reasonably be expected to have an adverse effect on product quality. (21 CFR 212.30(a))

Your facility was in a state of disrepair and lacked cleanliness. Floor tiles were observed to be cracked and stained in the hallway that permits access to the classified areas. The sticky floor mat at the entry to the gowning room was visibly soiled with filth, including hair. The floor beneath the door that separates ISO 7 and ISO 8 areas had black streaks and stains. PET drug manufacturing requires adequately designed, controlled, and maintained facilities to prevent contamination.

In your response, you provided a timeline for cleanroom floor remediation and stated that you will implement a procedure for changing the sticky floor mat. You also submitted environmental monitoring trend data for the fourth quarter of 2017 and indicated that there were no environmental excursions during the fourth quarter of 2017 and first quarter of 2018.

However, your data included fungal and bacterial spore formers in critical environments (e.g., operator glove, ISO 5 sterility testing hood). It is unclear whether you initiated a deviation report in response to these findings.

Your response is inadequate because you did not provide a detailed plan for remediation activities tbat will adequately control your production areas.

In response to this letter, provide:
• your alert and action levels for ISO 5 surfaces, air, and operator gloves, and improved procedures that address appropriate responses to contamination at these levels.
• your investigations for any recovery of microbes in ISO 5 hoods and on operator gloves, and any results outside alert or action levels for the ISO 7 environment since January 2017. Also include all organism identifications performed for these two clean areas during this period, and the location where microbes were recovered.
• evidence that cleaning and disinfecting agents used in all classified areas are effective.
• your firm's procedures for ensuring ongoing maintenance and control of your facility.

3. You failed to approve or reject proposed changes to existing processes, before they were implemented, to ensure that they maintain the identity, strength, quality and purity of a PET drug, and you failed to demonstrate that any change does not adversely affect the identity, strength, quality, or purity of any PET drug. (21 CFR 212.20(c))

Your firm changed your manufacturing process by **(b)(4)**. You did not adequately manage this change to ensure that it would not adversely affect the identity, strength, quality, or purity of your PET drug prior to being implemented.

Furthermore, your firm acknowledged to our investigator that you had not adequately validated this sterile filtration change. Your firm manufactured and distributed multiple batches of finished drug products using **(b)(4)**.

In your response, you stated that you have discontinued the practice of using **(b)(4)**. You provided a corporate risk assessment that included a retrospective review of this practice across all your manufacturing facilities. You concluded that patient safety was not compromised, based on the absence of patient adverse events reported during this period.

We acknowledge that you returned to the practice of using a **(b)(4)** as of February 28, 2018, upon conclusion of our inspection. However, your response is inadequate because you failed to address your deficient change management system. Further, you cannot rely on the absence of adverse events as evidence of sterility.

In response to this letter, please provide your procedures to evaluate all production and testing changes prior to implementation, including specific steps to ensure appropriate technical evaluation. Also provide a retrospective analysis to determine whether any other changes, particularly changes related to aseptic processing and sterility assurance, were implemented without adequate change management, and determine whether they adversely affected the quality of your PET drugs.

Guidance on Positron Emission Tomography (PET) Drugs

See FDA's guidance document, PET Drugs Current Good Manufacturing Practice, to help you meet the CGMP requirements when manufacturing PET drugs using aseptic processing, at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070306.pdf (https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070306.pdf).

Conclusion

Violations cited in this letter are not intended as an all-inclusive list. You are responsible for investigating these violations for determining the causes, for preventing their recurrence, and for preventing other violations in all your facilities.

If you are considering an action that is likely to lead to a disruption in the supply of drugs produced at your facility, FDA requests that you contact CDER's Drug Shortages Staff immediately, at drugshortages@fda.hhs.gov, so that FDA can work with you on the most effective way to bring your operations into compliance with the law. Contacting the Drug Shortages Staff also allows you to meet any obligations you may have to report discontinuances or interruptions in your drug manufacture under 21 U.S.C. 356C(b) and allows FDA to consider, as soon as possible, what actions, if any, may be needed to avoid shortages and protect the health of patients who depend on your products.

Correct the violations cited in this letter promptly. Failure to promptly correct these violations may result in legal action without further notice including, without limitation, seizure and injunction. Unresolved violations in this warning letter may also prevent other Federal agencies from awarding contracts.

Until these violations are corrected, we may withhold approval of pending drug applications listing your facility. We may re-inspect to verify that you have completed your corrective actions. We may also refuse your requests for export certificates.

After you receive this letter, respond to this office in writing within 15 working days. Please specify what you have done since our inspection to correct your violations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Please send your electronic response to orapharm1_responses@fda.hhs.gov. Please reach out to Compliance Officer, Yvette Johnson, at yvette.johnson@fda.hhs.gov with any questions.

Sincerely,
/S/

Diana Amador-Toro
Program Division Director/District Director
OPQO Division I
New Jersey District Office

CC: N-Molecular Inc. d.b.a. SOFIE
Philip Nielson, R.Ph.
Pharmacist-in-Charge
11 Rogers Rd, Ste 6
Haverhill, MA 01835

Was this helpful? Yes No

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

Commonwealth of Virginia

State Corporation Commission

CERTIFICATE OF GOOD STANDING

I Certify the Following from the Records of the Commission:

That SOFIE Co. is duly incorporated under the law of the Commonwealth of Virginia;

That the corporation was incorporated on December 8, 1995;

That the corporation's period of duration is perpetual; and

That the corporation is in existence and in good standing in the Commonwealth of Virginia as of the date set forth below.

Nothing more is hereby certified.

Signed and Sealed at Richmond on this Date:

January 31, 2024 .

Bernard J. Logan, Clerk of the Commission

CERTIFICATE NUMBER : 202402019785097

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 59446

NAME: SOFIE CO.

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

5900-B OBATA WAY
GILROY CA 95020
SANTA CLARA COUNTY

ISSUANCE DATE

MAY 31, 2024

EXPIRATION DATE

OCTOBER 15, 2024

CURRENT DATE / TIME

JUNE 3, 2024
7:57:20 AM

LICENSE RELATIONSHIPS

NAME: MCGUIRE, ZACHARY RYAN **ADDRESS NOT DISCLOSED**

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 88259 **PRIMARY STATUS:** CLEAR

BOARD OF PHARMACY

LICENSING DETAILS FOR: LSC 101112

NAME: SOFIE CO

LICENSE TYPE: STERILE COMPOUNDING PHARMACY

LICENSE STATUS: CLEAR

ADDRESS

5900 B OBATA WAY
GILROY CA 95020-7065
SANTA CLARA COUNTY

ISSUANCE DATE

SEPTEMBER 28, 2017

EXPIRATION DATE

SEPTEMBER 1, 2024

CURRENT DATE / TIME

JUNE 3, 2024
7:57:30 AM

LICENSE RELATIONSHIPS

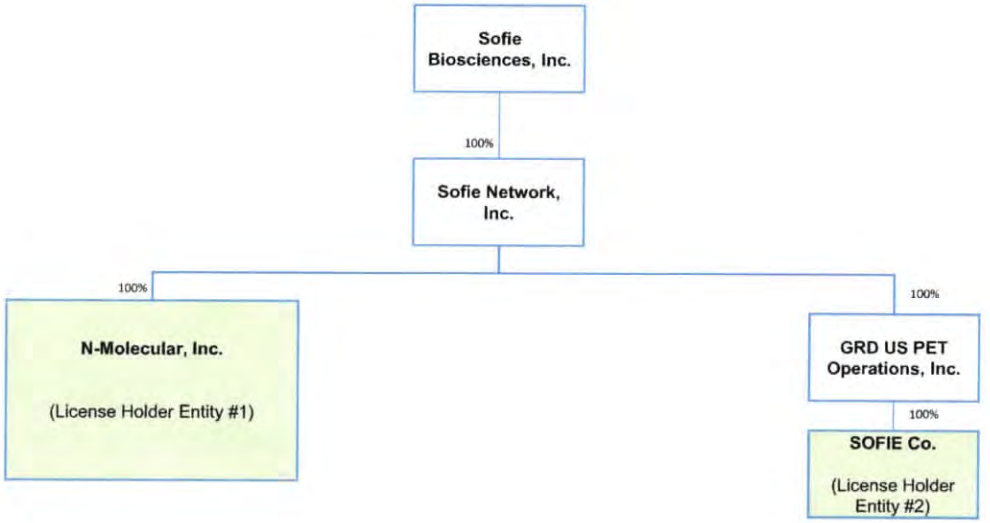
NAME: SOFIE CO

LICENSE/REGISTRATION TYPE: PHARMACY (COMMUNITY)

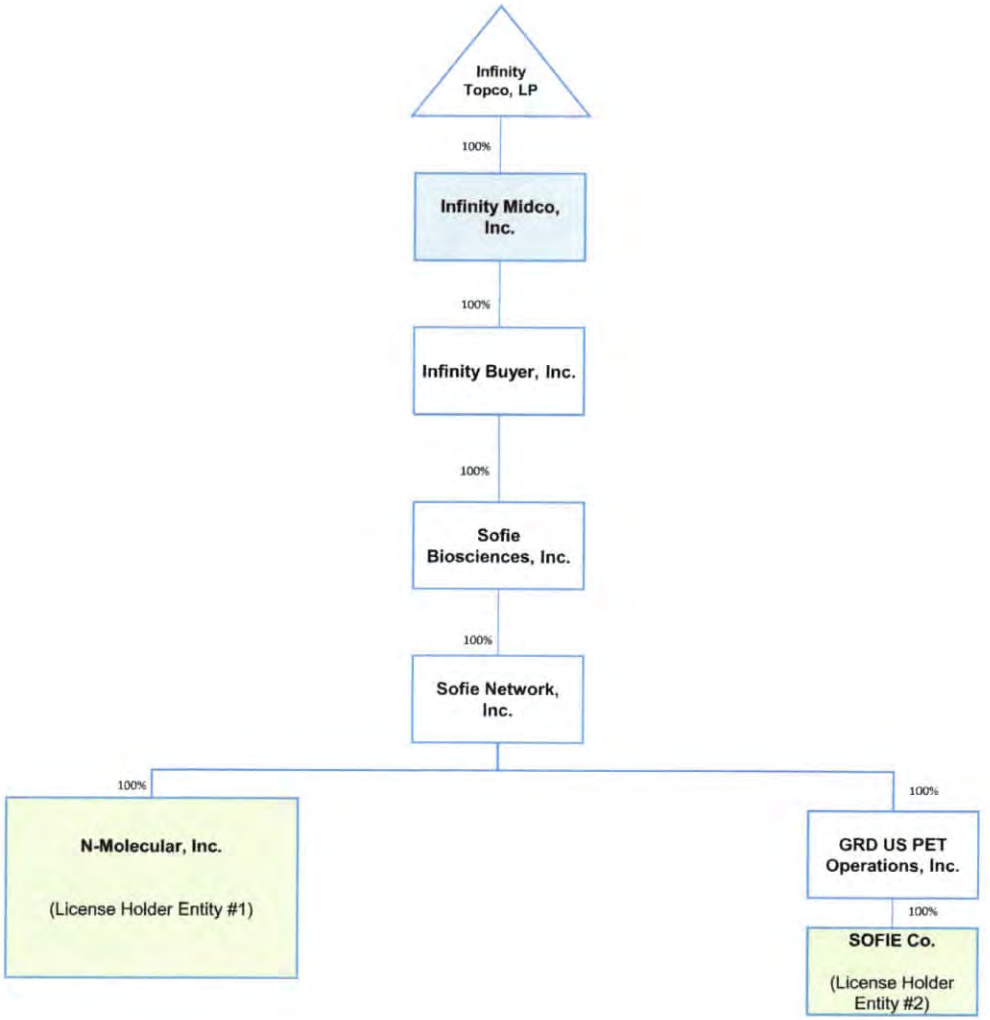
LICENSE NUMBER: 55786 **PRIMARY STATUS:** CANCELLED

ADDRESS :
5900-B OBATA WAY
GILROY CA 95020
SANTA CLARA COUNTY

Pre-Closing Structure



Post-Closing Structure



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler SOFIE Co.

Pharmacy/Wholesaler License # (if applicable) PH04414

Physical Address 5900-B Obata Way

City Gilroy State CA Zip 95020

Mailing Address (if different from physical address) same

City _____ State _____ Zip _____

Telephone 408-842-0520 Website https://sofie.com

Licensing Company Email regulatory.affairs@sofie.com

Section 2: Personal Information

First Austin Merritt Middle Thierry Last Merritt

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Addr[redacted] Vintage Lane, Unit 320

City Morgan Hill State CA Zip 95037

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Medical University of South Carolina		06/16 - 05/20	
Address	**City**	**State**	**Zip**
173 Ashley Ave MSC 141	Charleston	SC	29425
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
The Citadel		01/18 - 06/19	
Address	**City**	**State**	**Zip**
171 Moultrie St	Charleston	SC	29409
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
Coastal Carolina University		08/11 - 12/15	
Address	**City**	**State**	**Zip**
100 Chanticleer Dr E	Conway	SC	29528
Diploma/Degree obtained, if any			
B.S. Biology			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/22 -	[redacted]Vintage Lane, Apt. 320	Morgan Hill	CA	95037
08/21 - 08/22	[redacted] McCandless Drive, Apt. 411	Milpitas	CA1	95035
06/20 - 08/21	[redacted] Village Drive, Unit 401	King of Prussia	PA	19406
06/16 - 6/20	[redacted]Greenridge Road	North Charleston	SC	29406
06/13 - 06/16	[redacted]nnisbrook Ct	Myrtle Beach	SC	29579

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
SOFIE			09/22 -	
Business Address		**City**	**State**	**Zip**
5900B Obata Way		Gilroy	CA	95020
Phone	**Title**		**Number of Employed Hours**	
408-842-0520	Facility Manager		3000	
Description of Duties				
Manage the operations of production, QC, and distribution of radiopharmaceuticals. Maintain the cleanliness and upkeep of the facility.				

Business Name			From - To (MM/YY – MM/YY)	
PETNET Solutions			07/20 - 05/22	
Business Address		**City**	**State**	**Zip**
398 Industrial Drive		North Wales	PA	19454
Phone	**Title**		**Number of Employed Hours**	
(215) 699-9042	Production Manager		3000	
Description of Duties				
Manage the operations of production				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Austin T. Merritt, **certify that as the designated representative for**

SOFIE,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. Yes I am at least 21 years of age;
3. Yes I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. Yes I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. Yes I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. Yes I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. Yes I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Austin, Merritt

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

21FEB24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Austin, Merritt

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

21FEB24

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Santa Clara

I, Austin T. Merritt, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

23FEB24

Date

Subscribed and Sworn to before me this 23rd day of Feb, 2024

B. Sandhu

Notary Public Signature

B. SANDHU
COMM. # 2427961
NOTARY PUBLIC-CALIFORNIA
SANTA CLARA COUNTY
MY COMM. EXP. DEC. 20, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: SOFIE Co.

NV Pharmacy or Outsourcing facility license # (if applicable): PH04414

Physical Address: 5900-B Obata Way

City: Gilroy State: CA Zip: 95020

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 408-842-0520 Toll Free # (NAC 639.708, NRS 639.23286): 866-607-6645

Fax: 408-842-0220 Contact Email: regulatory.affairs@sofie.com

Website: https://sofie.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Austin Merritt

Supervising/Managing Pharmacist NV Pharmacist Registration #: N/A

Name of Person with direct knowledge of compounding procedures: Kunj Patel

Email of Person with direct knowledge of compounding procedures: kunj.patel@sofie.com

Telephone of Person with direct knowledge of compounding procedures: [redacted]

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☒ Low ☐ Medium ☐ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ☒ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Pylarify (Piflufolastat F-18 Injection) - radioactive diagnostic agent indicated for Positron Emission Tomography (PET) of prostate - specific membrane antigen (PSMA) positive lesions in men with prostate cancer.

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☒ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
N/A

6. What laboratory performs this additional testing?
Name: N/A
Address: N/A
City: N/A State: N/A Zip: N/A
Telephone: N/A

7. What is your procedure for visual inspection of compounded sterile products?
The pharmacy inspects compounded sterile products against a black / white background.

8. How often do you perform glove fingertip and medial fill testing?
Initially and then annually.

9. What is your policy if an employee fails a glove fingertip or media-fill test?
A deviation is opened to investigate the failure and the operator is removed from aseptic processing until a root cause of failure can be determined.

10. Describe your initial and annual training program for all personnel performing sterile compounding:
The training program encompasses didactic training, aseptic technique with exam, garbing and hand hygiene, cleaning and disinfecting, and media fill testing. All operators must prove competency in the areas described above and all observations are performed by the PIC or a qualified pharmacist.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
Daily cleaning of the ISO 5 enclosures must be performed prior to use, moving from "cleaner area" to "dirty" during cleaning. All agents used have a five (5) minute contact time. Daily cleaning consists of Steri-perox and Vesta-cyde, followed by IPA.
Weekly / Remediation cleaning consists of Decon Clean, a sporicidal agent (Spor-Klenz or Hypo-chlor), followed by IPA.

Cleaning of the ISO 7/8 area consist of daily and monthly cleaning, moving from the "cleaner area" to "dirty." Daily cleaning consists of cleaning and disinfecting countertops, carts, or other room furniture, pass through boxes, door handles, items that are used daily, floors, and waste removal. Steri-perox and IPA is used.
Monthly cleaning encompasses all items listed above as well as the ceiling and walls. Decon Clean or Decon Quat is used initially, followed by a sporocidal agent (Spor-Klenz or Hypo-chlor 0.52%). IPA is then used on all surfaces and sterile water is used on the floors.

12. Who performs the sterile compounding process at your facility?
Unit doses are dispensed by the pharmacy staff (pharmacists and pharmacy technicians).

13. Who is responsible and accountable for the sterile compounding process at your facility?
The pharmacist in charge / facility manager and the pharmacist on duty during dispensing (who is releasing the product).

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
The pharmacy does not ship / mail any radiopharmaceuticals.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)

1. What type of primary engineering controls will you be using in your facility?
N/A

2. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No

7. If yes, list the name of the device:
N/A

8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?
N/A

9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?
N/A

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:
N/A

2. What sterilization methods are utilized at your facility?
N/A

3. Does your facility utilize biological indicators? ☐ Yes ■ No

4. If yes, describe how they are utilized:
N/A

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kunj Patel
Name of Person who Completed the Form

Director, Pharmacy Compliance
Title

Kunj Patel
Signature (copies or stamps not accepted)

3/7/24
Date

Board Use Only	Date Received: 3/7/24 Date Approved: _____ Approved By: _____

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 7/27/2023 Inspector: Alyce Petrutiu

Firm: SOFIE Phone: (408) 842-0520

Address: 5900 B OBATA WAY City: GILROY Zip: 95020

Ownership: CORPORATION

Permit #: LSC101112 PHY55786 Permit Exp: 9/1/2023 DEA#: N/A DEA Exp: ___

Date of Self Assessment Form: 5/18/2023 Other Permit #: N/A Date of DEA Inventory: ___

Hours M-F: 10:00PM-2:00PM Hours Saturday 10:00PM-6:00AM Hours Sunday: CLOSED

PIC HAI M VU RPH55234 Administrator MARTIN MUNOZ

RPH Consultant ___

Staff	RPH Name:	License #:	Staff Name:	License #:
	CHARLIE LIN	RPH86217	DARREN E GLASSMAN	TCH187657
	AKRAM S KILDANI	RPH57842	ERIKA J CORRAL	TCH103415
	AUSTIN MERRITT	RPH88137	EXEQUIEL B LOPEZ JR	TCH158642
			MATEO D TAYAMEN	TCH191718
			SAMUEL GIL	TCH151701

Inspector Remarks:

Licensed Sterile Compounding Renewal Inspection

PIC: Hai Vu email: Hai.Vu@sofie.com cell: (650) 766-0830

In advance of the onsite inspection, the inspection documents were sent via e-mail by PIC Vu. An onsite inspection of the compounding area was performed on 7/27/23 with the assistance of PIC Vu, Facility Manager Austin Merritt, Quality Assurance Specialist Martin Munoz, and TCH Erika Corral. Inspector Rachel Powell also present.

Description of pharmacy: closed door PET nuclear pharmacy and FDA manufacturer
Service area: entire state of CA; commercial and IND drugs to WA, OR, NV, AZ, CO
Sterile to sterile, low risk, non-HD compounding of radiopharmaceuticals only; maximum 12-hour BUD, all patient specific
Average number of kits/doses dispensed daily: 11 batches/225 doses

- 18F-FDG, 18F-NaF, 18F-FBB (Neuraceq), 18F-PyL (Pylarify), 18F-FPP, 18F-GTP1

Waste: Stericycle, ACTenviro
RAM license #7131-43 expiration 6/16/2028
No controlled substances, no DEA license

According to statements and documents provided by PIC:

No physical layout changes to the sterile compounding facility in the past 12 months
Changes to the sterile compounding equipment in the past 12 months:

- Three Synthera synthesizers were replaced by two GE FASTlab 2 units (FDG production)
- A third Trasis AllinOne unit added (Pylarify production)
- Removal of Pinestar dosing hood (August 2022)

No changes in types of sterile products compounded in the past 12 months
No adverse events related to pharmacy's CSPs from the past 12 months

- One prescriber complaint due to incorrect dose (wrong syringe placed in container, two doses swapped); documentation reviewed, no patient harm

No FDA or accreditation inspections in last 12 months
No changes to list of sterile medications compounded in the past 12 months
No waivers in use

Posted:

Original license with renewal (PHY/LSC)
Out of state licenses

Compounding Area:

Unclassified handwashing room containing a sink, leading into ISO 8 anteroom containing garbing supplies, leading into positive pressure ISO 7 buffer room containing ISO 5 Germfree BSC, ISO 5 DHC, six TEMA synthesis modules (manufacturing), and three pass-thrus to unclassified pharmacy area

Certification: performed every 6 months. Last done by ENV Services on 1/31 and 2/1/23 under dynamic conditions.

- BSC and DHC certified
- Non-viable air sampling performed
- HEPA filters leak test passed
- ACPH
- Video of smoke studies reviewed onsite

Items Reviewed:

- Previous inspection
- Change of PIC documents (effective 4/26/23)
- Compounding and Pharmacy self-assessments
- Master formulas, batch records, labels, dispensing records
  - FBB, 6/8/23
  - FDG, 6/8/23
  - FPP, 6/5/23
  - PyL 6/8/23
- QC performed on every manufactured batch: ID/purity, sterility, radioactive potency, endotoxin, half-life
- Reference materials readily available
- Environmental Monitoring Trending Report, quarter one 2023, comprised of viable air and surface sampling and non-viable air sampling (bi-weekly for ISO 7 and ISO 8 areas, daily for ISO 5 DHC)
- Dose calibrator linearity

- Dose calibrator constancy
- Two months of the following reviewed:
  - Room, refrigerator, freezer, incubator temperature logs
  - Differential pressure logs
  - Humidity logs
  - Cleaning logs, daily/monthly, rooms/hoods
    - Agents used in addition to sterile water: Decon-Clean, Spor-Klenz, sIPA, Steri-Perox
- Pest inspection report, Orkin last inspection 6/29/23
- Certification of dosimeters

Items Observed:

- Visual inspection of compounding areas and hoods
- Staff garbing and gowning/handwashing, performed by QA Specialist Martin Munoz
- Pressure differentials between rooms
- Room, refrigerator, freezer, incubator temperatures, constantly monitored by MadgeTech
- Hot/cold running water, see correction
- Eye wash area
- Dedicated cleaning supplies
- Radiation dosimeters

Policies and Procedures Reviewed

- Annual review of Policies & Procedures by PIC, proof of completion
- Hand hygiene and garbing
- Facility & Equipment cleaning & sanitizing
- Beyond Use Dating
- Patient Dose Recall
- Action level for CFUs detected during viable surface, viable air, and gloved fingertip sampling
- Action to be taken when viable air, viable surface, and gloved fingertip sampling CFUs exceeded

Training: Viewed for RPH Charlie Lin and TCH Mateo Tayamen

- Gloved fingertip/media-fill
- Aseptic technique/compounding competencies
- Didactic and math skills assessment
- Radiation safety

Discussion/Education:

- PIC Vu assumed PIC role on 4/26/23. He previously held that position from 11/2017 through 5/2022. Newly licensed Facility Manager Austin Merritt will be assuming PIC role in the near future. Refer to BPC 4113 and BPC 4101, forms are available on the BOP website.
- Buffer room contained two clipboards of paper, a small area of separation at the floor-wall junction under the TEMA cell, and a cracked computer screen. Scheduled maintenance report viewed for August, the floor seal will be addressed per PIC. Ensure all items in the classified areas are easily cleanable.
- Discussed requirements of CCR 1714 and BPC 4116, possession of key (access) to pharmacy is restricted to pharmacist and a pharmacist is required to be onsite any time another person is present, and BPC 4059.5(a), dangerous drugs and devices shall be signed for and received by a pharmacist. RPH Merritt was unlicensed from 9/19/22 through 7/21/23 while obtaining CA RPH license via reciprocation and employed at the facility. All

discretionary tasks completed during this time were during FDA manufacturing process (non-pharmacy related activities) however he was in the pharmacy without a CA licensed pharmacist present and signing for deliveries.

- Notice to Consumer and Interpretive Services notices not observed in the pharmacy. Ensure posted as required, see CCR 1707.6(a) and CCR 1707.5(d).
- A PDF of the 2023 law book is available online at the Board's website: https://www.pharmacy.ca.gov/laws_regs/lawbook.pdf
- The January 2023 issue of The Script is available online. The newsletter includes information regarding new and amended regulations as well as links to information regard the revisions to USP chapters 795 and 797. Previous issues also are available in the newsletter archive.
- Send notification of all recalls, ADRs, and complaints to: compounding.report@dca.ca.gov
- Please keep a signed copy of this inspection report on file and readily retrievable for three years.

Alyce Petrutiu, RPh, Inspector
California State Board of Pharmacy
(831) 245-7618 | FAX (831) 242-8969
alyce.petrutiu@dca.ca.gov

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) Hai Vu

Inspector (sign) _____

Inspector (print) ALYCE PETRUTIU / Rachel Powell

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

ORDER OF CORRECTION

Date: 7/27/2023 Permit #: LSC101112

Time of Day: 2:45 PM

Name as shown on permit: **SOFIE**

Address: 5900 B OBATA WAY City: GILROY

Please be advised it appears there is a failure to comply with the following laws governing the practice of pharmacy, and/or the rules and regulations of the Board of Pharmacy:

1. CCR 1714(c)	Operational Standards and Security. The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes. In that at the time of inspection, the size and configuration of the sink was inadequate for handwashing and did not provide hot water. (as related to sterile compounding) ac

I have reviewed, discussed, understand and received a copy of this form.

Inspector (sign) /Rachel Powell/ Signed hv

Inspector (print) ALYCE PETRUCCI /Rachel Powell/ Print Name Hai Vu

Date 7/27/23 Title PIC

Pursuant to Business and Professions Code §4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of correction, for an office conference with the board's executive officer to contest the order of correction.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 7/7/2022 Inspector: Alyce Petrutiu

Firm: SOFIE CO Phone: (408) 842-0520

Address: 5900 B OBATA WAY City: GILROY Zip: 950207065

Ownership: CORPORATION

Permit #: LSC101112 PHY55786 Permit Exp: 9/1/2022 DEA#: N/A DEA Exp: ___

Date of Self Assessment Form: 6/14/2022 Other Permit #: N/A Date of DEA Inventory: ___

Hours M-F: 10PM-2PM Hours Saturday 10PM-6AM Hours Sunday: CLOSED

PIC HAI M VU RPH55234 Administrator JERROD BROWN, REGIONAL DI

RPH Consultant ___

Staff RPH Name:	License #:	Staff Name:	License #:
JONATHAN H KATAOKA	RPH80413	CYNDI COVARRUBIAS	TCH139386
NGOC ANH H NGUYEN	RPH76301	DAVID R OCTAVI	TCH160430
CHINH N NGUYEN	RPH72447	EXEQUIEL B LOPEZ JR	TCH158642
		MARTIN MUNOZ, QA SPECI	MANAGER
		SAMUEL GIL	TCH151701
		THEODORE A ARAGON	TCH14440

Inspector Remarks:

Licensed Sterile Compounding Renewal Inspection

PIC: HAI VU Email: Hai.Vu@sofie.com **Phone:** (650) 766-0830

In advance of the onsite inspection, the inspection documents were sent via e-mail by PIC Vu. An onsite inspection of the compounding area was performed on 7/6/2022 with the assistance of PIC Vu and QA Specialist Martin Munoz. Simultaneous routine inspection conducted, see PHY 55786.

Description of pharmacy: closed door PET nuclear pharmacy and FDA manufacturer
Low risk, radiopharmaceutical compounding: 18F-FDG, 18F-NaF, Neuraceq, 18F-DCFPyl, 18F-GTP1, 18F-PI-2620, 68Ga-PSMA
Average number of products compounded daily: 6 to 9 batches, 250 to 300 doses
Shipping area includes Northern CA, Central Coast, Los Angeles, Orange County, Inland Empire, NV, WA, OR, AZ, CO, ID

Wholesaler: Curium, Advanced Accelerator Applications (Netspot)
Waste: Steri-Cycle

Shredding: Iron Mountain
Pest control: Orkin, monthly visits; last visit: 6/21/2022
RAM license #7131-43; exp: 6/16/2028
No waivers in use

According to documents provided by PIC:
Physical layout changes to the sterile compounding facility in the past 12 months:

- Three new rooms built out (walls added only), floor plan provided, pharmacy footprint and cleanroom unaffected
  - Ancillary room in front of entry to gowning room
  - Pharmacist room
  - Material storage room

Changes to the sterile compounding equipment in the past 12 months:

- Two Synthera+ units installed

No changes in types of sterile products compounded in the past 12 months
No adverse events related to pharmacy's CSPs from the past 12 months

- One facility complaint regarding abnormal distribution of Pylarify, documentation reviewed, reported to FDA

No FDA, DEA, or accreditation inspections in last 12 months
Changes to list of sterile medications compounded in the past 12 months:

- Deletion of 68Ga-DOTATATE (Netspot)

Posted:
Original license with renewal
Compounding Area:
Handwashing room leading into an ISO 8 anteroom with garbing supplies, leading into ISO 7 buffer room containing one ISO 5 Pinestar 797 MT dosing hood, one ISO 5 Germfree BBF 4SSRX BSC, one TEMA hot cell, and three pass throughs to unclassified pharmacy area
Certification: performed every 6 months. Last done by ENV Services on 2/9 and 2/10/2022 under dynamic conditions.

- Non-viable air sampling performed
- HEPA filters leak test passed
- ACPH
- Video of smoke studies reviewed onsite

Items Reviewed:

- Previous inspection
- Compounding and Pharmacy self-assessments
- References materials readily available
- Synthera + daily check and maintenance logs, Apr/May 2022
- Room, refrigerator, freezer, incubator temperature logs, Apr/May 2022
- Differential pressure logs, Apr/May 2022
- Cleaning logs, daily/monthly, rooms/hoods, Apr/May 2022
- Agents used in addition to sterile water: Decon-Clean, Decon-Quat, sIPA, Hypo-Chlor, Spor-Klenz, Steri-Perox
- In house viable air and surface sampling

- ISO 8 monthly, ISO 7 bi-weekly, ISO 5 daily
- In house non-viable air sampling
  - ISO 5 daily, ISO 7 bi-weekly
- Master formula, batch records, labels, ITLC/HPLC, sterility, reviewed for:
  - 18F-FDG lot # 5CA12261301, 18F-PI-2620 (FPP) lot # CA122061301, 18F-DCFPyl lot # CA 122061301
- Instant thin layer or high-performance liquid chromatography performed on all preparations

Items Observed:

- Visual inspection of compounding area and hoods
- Drug/device storage
- Quarantine area for expired/rejected
- Staff garbing and gowning/handwashing
- Pressure differentials between rooms
- Room, refrigerator, freezer, incubator temperatures
- Hot/cold running water
- Eye wash area
- Dedicated cleaning supplies

Policies and Procedures Reviewed:

- Annual review of Policies & Procedures by PIC, proof of completion
- Hand hygiene and garbing
- Facility & Equipment cleaning & sanitizing
- Labeling Efficiency and Radiochemical Purity of Compounded Final Drug Product by Thin Layer Chromatography
- Beyond Use Dating
- Action level for CFUs detected during viable surface, viable air, and gloved fingertip sampling
- Action to be taken when viable air, viable surface, and gloved fingertip sampling CFUs exceeded
- CSP recall

Training: Viewed for RPH Chinh Nguyen and TCH Samuel Gil

- Gloved fingertip/media fill
- Aseptic technique/compounding competencies
- Didactic and math skills assessment
- Radiation safety training

Discussion/Education:

- PIC Vu completed the latest versions of the compounding and pharmacy self-assessments in June 2022. Prior self-assessments were completed in June 2021, fully compliant.
- Computer workstations in the buffer room have keyboards which are not easily cleaned and disinfected – see correction.
- Documentation of cleaning logs showed significant improvement since previous inspection. Discussed SOP requirement of weekly review of logs with PIC Vu and new QA Specialist Martin Munoz. May documents showed late review however June logs were reviewed within required timeline.
- Per CCR 1751.6(e)(1)(B), pharmaceutical calculations are required as part of ongoing training and performance evaluation. Per PIC Vu, compounding personnel use apps for calculation of pharmaceutical half-

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

life. Facility will design training to comply with law - see action item.

- For the most updated BOP COVID-19 waivers:
https://pharmacy.ca.gov/licensees/emergency_declaration.shtml
- Please keep a copy of this inspection report readily available for three years.

Action Items:
Please provide pharmaceutical calculations training for RPH Chinh Nguyen and TCH Samuel Gil by end of business, 7/21/2022.

Alyce Petrutiu, RPh, Inspector
California State Board of Pharmacy
(831) 245-7618 | FAX (831) 242-8969
alyce.petrutiu@dca.ca.gov

"Pursuant to Business and Professions Code 4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of corrections, for an office conference with the board's executive officer to contest the order of correction."

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) Hai Vu

Inspector (sign) _____

Inspector (print) ALYCE PETRUTIU

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

ORDER OF CORRECTION

Date: 7/7/2022 Permit #: LSC101112

Time of Day: 12:30 PM

Name as shown on permit: **SOFIE CO**

Address: 5900 B OBATA WAY City: GILROY

Please be advised it appears there is a failure to comply with the following laws governing the practice of pharmacy, and/or the rules and regulations of the Board of Pharmacy:

1. CCR 1751.4(c)	Facility and Equipment Standards for Sterile Compounding. All equipment used in the areas designated for compounding must be made of a material that can be easily cleaned and disinfected. In that at the time of inspection, keyboards in the buffer room had spaces around and below each key where particles could accumulate, increasing the risk for microbial contamination and were not made of material that can be easily cleaned.

I have reviewed, discussed, understand and received a copy of this form.

Inspector (sign) Petrutiu Signed Hai Vu

Inspector (print) ALYCE PETRUTIU Print Name Hai Vu

Date 7/7/2022 Title PIC

Pursuant to Business and Professions Code §4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of correction, for an office conference with the board's executive officer to contest the order of correction.

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

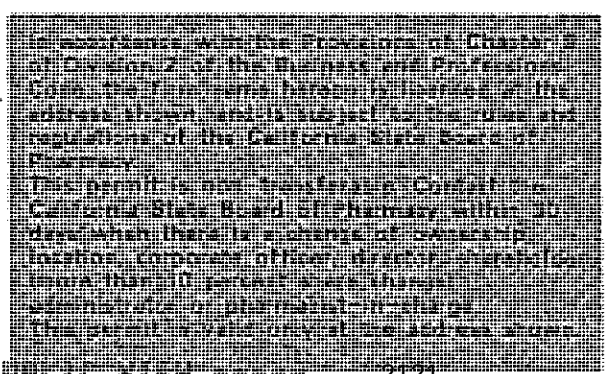
Renewal Certificate

Retail Pharmacy Permit

LICENSE NO. PHY 55786 VALID UNTIL SEPTEMBER 01, 2024
RECEIPT NO. 00186840

SOFIE CO
5900-B OBATA WAY
GILROY CA 95020

7/21/23
7/21/23



The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW

BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Renewal Certificate

Sterile Compounding License

LICENSE NO. LSC 101112
RECEIPT NO. 00186864

VALID UNTIL SEPTEMBER 01, 2024

SOFIE CO
5900 B OBATA WAY
GILROY CA 95020-7065

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.
This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.
This permit is valid only at the address shown.

8/22/23
8/22/23

The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

WPHLSC 09/30/19

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 55786

NAME: SOFIE CO

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

5900-B OBATA WAY
GILROY CA 95020
SANTA CLARA COUNTY

ISSUANCE DATE

SEPTEMBER 28, 2017

EXPIRATION DATE

SEPTEMBER 1, 2024

CURRENT DATE / TIME

FEBRUARY 19, 2024
11:40:19 AM

LICENSE RELATIONSHIPS

NAME: SOFIE CO

LICENSE/REGISTRATION TYPE: STERILE COMPOUNDING PHARMACY

LICENSE NUMBER: 101112 **PRIMARY STATUS:** CLEAR

ADDRESS :
5900 B OBATA WAY
GILROY CA 95020-7085
SANTA CLARA COUNTY

NAME: MERRITT, AUSTIN THIERRY

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 88137 **PRIMARY STATUS:** CLEAR

ADDRESS NOT DISCLOSED

BOARD OF PHARMACY

LICENSING DETAILS FOR: LSC 101112

NAME: SOFIE CO

LICENSE TYPE: STERILE COMPOUNDING PHARMACY

LICENSE STATUS: CLEAR

ADDRESS

5900 B OBATA WAY
GILROY CA 95020-7065
SANTA CLARA COUNTY

ISSUANCE DATE

SEPTEMBER 28, 2017

EXPIRATION DATE

SEPTEMBER 1, 2024

CURRENT DATE / TIME

FEBRUARY 19, 2024
11:39:15 AM

LICENSE RELATIONSHIPS

NAME: SOFIE CO

LICENSE/REGISTRATION TYPE: PHARMACY (COMMUNITY)

LICENSE NUMBER: 55786 **PRIMARY STATUS:** CLEAR

ADDRESS :
5900-B OBATA WAY
GILROY CA 95020
SANTA CLARA COUNTY

4UU

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: ASAP PHARMACY

Physical Address: 16612 107TH COURT

City: ORLAND PARK State: IL Zip: 60467

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 7086711200 Toll Free # (NAC 639.708, NRS 639.23286): 8772852727

Fax: 7084488598 Contact Email: asappharmacy@wecareasap.com

Website: WWW.WECAREASAP.COM

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): PRITI SHAH

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): _____

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: CHRISTOPHER J SIMPSON	NV Pharmacist Registration #: 18826
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NO/NOT APPLICABLE	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: ILLINOIS

Parent Company (if any): WECARE ASAP ACQUISITION, INC

Corporation/Organization Name: AMERICAN SERVICE AND PRODUCT, INC

Mailing Address: 16612 107TH COURT

City: ORLAND PARK State: IL Zip: 60467

Telephone: 7086711200 Email: asappharmacy@wecareasap.com

Contact Person Name: SHARDHA CHENNA

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the SECRETARY (title) for ASAP PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

SHARDHA CHENNA

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

10/8/2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, SHARDHA CHENNA hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the SECRETARY (title) for ASAP PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 11th day of OCTOBER, 2024

Notary Public

MERI SURIC
Notary Public, State of New Jersey
My Commission Expires Sep 11, 2027

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SHARDHA CHENNA

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Ch. Shradha

Original signature of Authorized Person (copies or stamps not accepted)

10/08/2024

Date

Board Use Only	Date Received: 10/14/24	Amount: $500 ck 97471879-7

File Number 6167-606-6

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

I, **Alexi Giannoulias,** *Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that*

AMERICAN SERVICE AND PRODUCT INC., A DOMESTIC CORPORATION, INCORPORATED UNDER THE LAWS OF THIS STATE ON MAY 31, 2001, ADOPTED THE ASSUMED NAME ASAP PHARMACY ON APRIL 21, 2024, APPEARS TO HAVE COMPLIED WITH ALL THE PROVISIONS OF THE BUSINESS CORPORATION ACT OF THIS STATE, AND AS OF THIS DATE, IS IN GOOD STANDING AS A DOMESTIC CORPORATION IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 12TH *day of* SEPTEMBER ***A.D.*** 2024 .

Authentication #: 2425604092 verifiable until 09/12/2025
Authenticate at: https://www.ilsos.gov

Alexi Giannoulias
SECRETARY OF STATE

Date of Inspection 06/27/2024 License No. 054.022874 CS License No. 320.014264	**Initial Community Pharmacy Inspection** Illinois Division of Professional Regulation 320 W Washington St. Springfield IL 62786 9511 West Harrison Suite 300 St. Des Plaines IL 60016	IDFPR

Pharmacy Name	Type(s) of Operation
AMERICAN SERVICE AND PRODUCT INC dba ASAP Pharmacy	Community
Responsible Person / PIC	**RPh Lic # and Exp Date**
Priti Mayur Shah	051.286418 3/31/26
Address	
16612 107th Court	

City	Zip Code	Phone Number
Orland Park	60467	708-671-1200

Purpose for the Inspection

☐ New Pharmacy ☐ Change in Address ☒ Ownership Change ☐ Operations Change

Observations

Compliant	Deficient	N/A	
☒	☐	☐	Name Adequately Reflected on Signage
☒	☐	☐	Hours of Operation Posted
☒	☐	☐	Patient Counseling Sign Properly Displayed
☒	☐	☐	Storage location for Bags, Coats, Etc.
☒	☐	☐	Sufficient Lighting
☒	☐	☐	Pharmacy Temperature Controlled
☒	☐	☐	Proper References Available
☐	☐	☒	Proper Compounding Supplies
☒	☐	☐	Scale or Balance
☒	☐	☐	Adequate Storage for Cold Chain Product
☒	☐	☐	Temperature Monitoring Devices in Refrigerator Freezer
☒	☐	☐	Sink Within the Pharmacy
☒	☐	☐	Hot and Cold Water form Sink
☒	☐	☐	Proper Drainage from Sink
☒	☐	☐	License Prescription Area Contiguous
☒	☐	☐	Pharmacy can Produce a Complete RX Label

☒	☐	☐	Alarm Communicates via Cellular
☐	☐	☒	Adequate Door Contacts
☒	☐	☐	Adequate Motion Sensors
☐	☐	☒	Glass Break Sensors
☐	☐	☒	Video Surveillance
☒	☐	☐	Perimeter of the Pharmacy Secure
☒	☐	☐	Adequate CII Storage Security

COMMENTS

This is a change of ownership inspection conducted by DCI Elizabeth Bhogapurapu. Present for the inspection is PIC Priti Shah.

The license will be activated effective today, 6/27/24.

Signatures

Elizabeth Bhogapurapu

Digitally signed by Elizabeth Bhogapurapu
Date: 2024.06.27 13:01:08 -05'00'

Drug Compliance Investigator

Date

Pharmacy Representative

06/27/2024

Date

State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

*LICENSE NO.
054.022874
051.286418

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below:

EXPIRES:
03/31/2026

LICENSED PHARMACY

COMMUNITY

AMERICAN SERVICE AND PRODUCT INC
DBA ASAP PHARMACY
PRITI MAYUR SHAH
16612 107TH COURT
ORLAND PARK, IL 60467-8898

MARIO TRETO, JR.
SECRETARY

CAMILE LINDSAY
ACTING DIRECTOR

The official status of this license can be verified at IDFPR.illinois.gov

19495430

Cut on Dotted Line

For future reference, IDFPR is now providing each person/business a unique identification number, 'Access ID', which may be used in lieu of a social security number, date of birth or FEIN number when contacting the IDFPR. Your Access ID is: 4539490

American Service and Product, Inc.
16612 107th Court
Orland Park, IL 60467
Phone: 708-671-1200
Fax: 708-448-8598
www.wecareasap.com

Owner(s)/Stockholder(s)/Officer(s)/Principals of Co. (for ASAP Pharmacy)

1. Name: **BERNARD FISCHMAN**

   Title: PRESIDENT

   Address: [redacted] Penn St, Brooklyn, NY 11211.

   [redacted]

2. Name: **SHARDHA CHENNA**

   Title: SECRETARY

   Address: [redacted] Lafayette Dr, Livingston, NJ 07039.

   [redacted]

At ASAP Pharmacy, we value our call to be servants. We recognize the value of every person and promise to give them excellent and personalized care: to educate, empower, and each one to experience a fuller quality of life beyond the prescription.

Illinois Department of Financial and Professional Regulation

Division of Professional Regulation

JB Pritzker
Governor

Mario Treto, Jr.
Secretary

Camile Lindsay
Acting Director
Division of
Professional
Regulation

CERTIFICATION OF LICENSURE

dba ASAP Pharmacy
Priti Mayur Shah
16612 107th Court
Orland Park, IL 60467-8898

Licensee:	AMERICAN SERVICE AND PRODUCT INC
Number:	054.022874
Profession:	LICENSED PHARMACY
Date of Issuance:	06/27/2024
Expiration Date:	03/31/2026
License Status:	ACTIVE
License Method:	NON-EXAM
Disciplinary History:	Has not been disciplined

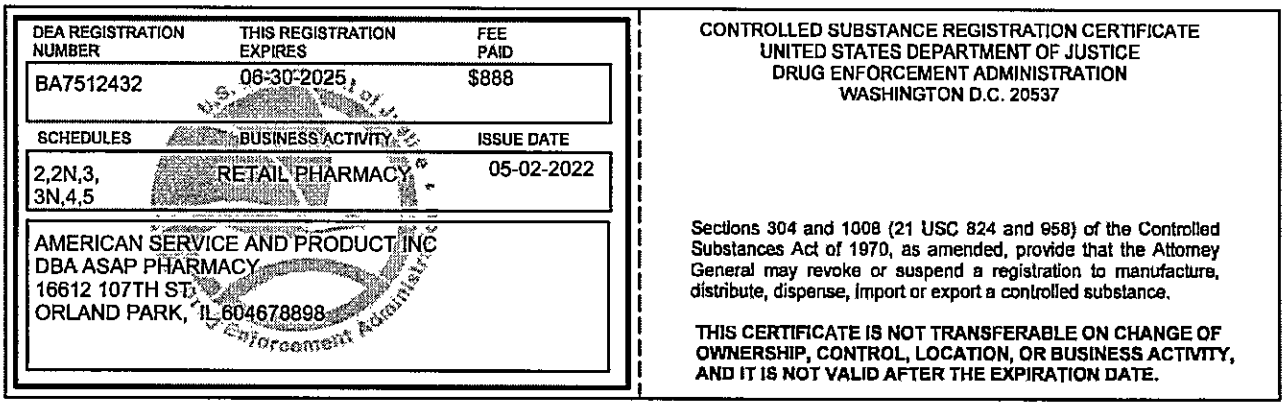
This document is a certified copy of the records maintained and kept by this department in the regular course of business as of 09/16/2024

Camile Lindsay

Camile Lindsay
Acting Director
Division of Professional Regulation

09/16/2024
Date

Refer to the Department's Web Site at IDFPR.Illinois.gov to verify professional licenses via License Look-Up.



DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BA7512432	06-30-2025	$888

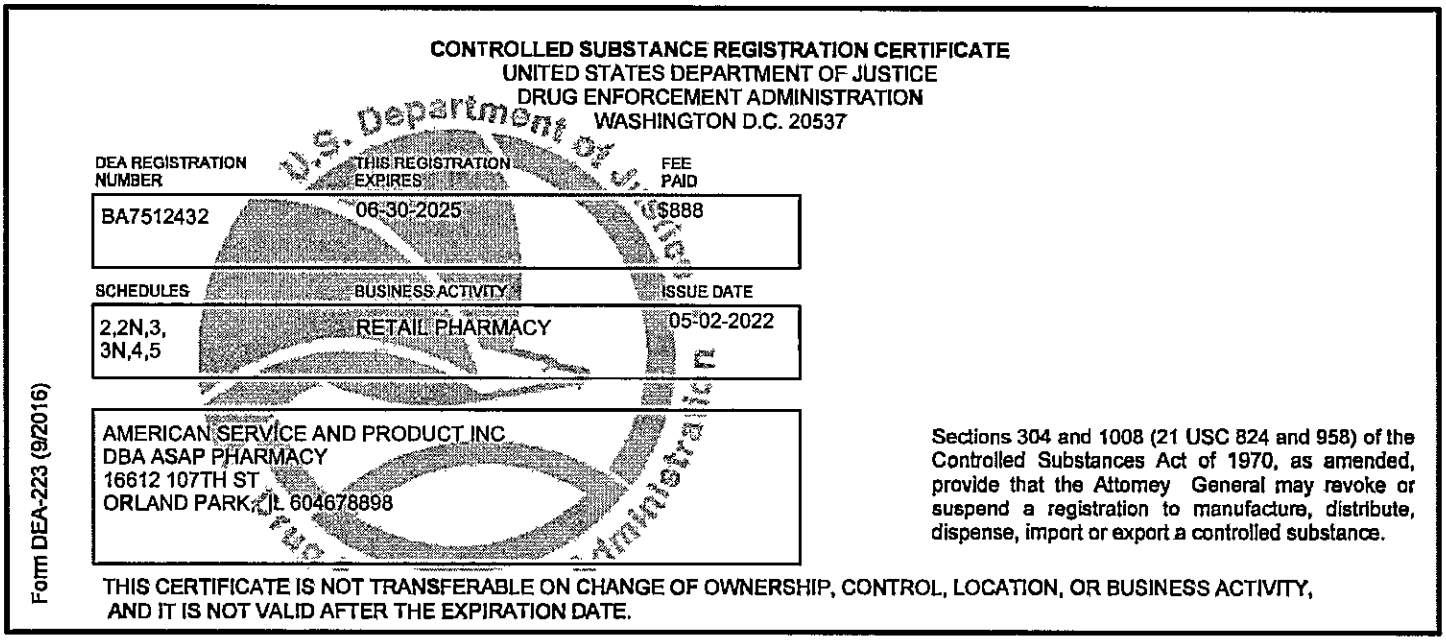
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-02-2022

AMERICAN SERVICE AND PRODUCT INC
DBA ASAP PHARMACY
16612 107TH ST
ORLAND PARK, IL 604678898

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.



CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BA7512432	06-30-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-02-2022

AMERICAN SERVICE AND PRODUCT INC
DBA ASAP PHARMACY
16612 107TH ST
ORLAND PARK, IL 604678898

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler ASAP PHARMACY

Pharmacy/Wholesaler License # (if applicable) 054.022874

Physical Address 16612 107TH COURT

City ORLAND PARK State ILLINOIS Zip 60467

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 7086711200 Website WWW.WECAREASAP.COM

Licensing Company Email fpr.drugcomplianceunit@illinois.gov

Section 2: Personal Information

First PRITI Middle MAYUR Last SHAH

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] ARMINGDALE DR #202

City DARIEN State ILLINOIS Zip 60561

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
MIDWESTERN UNIVERSITY CHICAGO COLLEGE OF PHARMACY		05/1997-8/1998	
Address	**City**	**State**	**Zip**
555 31ST STREET	DOWNERS GROVE	IL	60515
Diploma/Degree obtained, if any			
DOCTOR OF PHARMACY			
School Name		From - To (MM/YY – MM/YY)	
MASSACHUSETTS COLLEGE OF PHARMACY AND AHS		08/1994-01/1997	
Address	**City**	**State**	**Zip**
179 LONGWOOD AVE	BOSTON	MA	02115
Diploma/Degree obtained, if any			
BS IN PHARMACY			
School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF ILLINOIS AT CHICAGO		08/1992-05/1994	
Address	**City**	**State**	**Zip**
1200 West Harrison St.	CHICAGO	IL	60607
Diploma/Degree obtained, if any			
N/A			
School Name		From - To (MM/YY – MM/YY)	
WAUBONSIE VALLEY HIGH SCHOOL		08/1988-05/1992	
Address	**City**	**State**	**Zip**
2590 Ogden Avenue	AURORA	IL	60504
Diploma/Degree obtained, if any			
HS DIPOLMA			
School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/18 TO DATE	[redacted]FARMINGDALE DR # 202	DARIEN	IL	60561
01/08 TO 12/17	[redacted]JAMES PETER CT	DARIEN	IL	60561
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
ASAP PHARMACY			04/2020-CURRENT	
Business Address		City	State	Zip
16612 107TH COURT		ORLAND PARK	IL	60467
Phone	Title		Number of Employed Hours	
7086711200	PHARMACIST IN CHARGE		9000	
Description of Duties				
Pharmacist in charge and responsible for operations inside the pharmacy, dispensing medications, counseling, etc.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, PRITI SHAH, **certify that as the designated representative for**

AMERICAN SERVICE AND PRODUCT, INC (DBA ASAP PHARMACY),

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. PS I am at least 21 years of age;
3. PS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. PS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. PS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. PS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. PS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

PRITI SHAH

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/07/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

PRITI SHAH

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/8/2024

Date

Please have this section completed in the presence of a Notary Public.

State of NEW YORK, ss. County of BRONX

I, PRITI SHAH, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/8/2024

Date

Subscribed and Sworn to before me this 8th day of OCT 2024.

ch. Ravi Kumar

Notary Public Signature

RAVI K CHENNA
Notary Public - State of New York
No. 01CH6266914
Qualified in Bronx County
My Comm. Expires Aug. 6, 2028

2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site ASAP PHARMACY

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) 054.022874

Physical Address 16612 107TH COURT

City ORLAND PARK State ILLINOIS Zip 60467

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 7086711200 Website WWW.WECAREASAP.COM

Licensing Company Email fpr.drugcomplianceunit@illinois.gov

Section 2: Personal Information

First SHARDHA Middle _____ Last CHENNA

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City LIVINGSTON State NJ Zip 07039

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
SCREC			06/01 TO 05/05	
Address		City	State	Zip
NH-05, GANAPAVARAM		CHILAKALURIPET	AP	522619
Diploma/Degree obtained, if any				
EEE				

School Name			From - To (MM/YY – MM/YY)	
ABHYUDHAYA COLLEGE			06/99 TO 04/01	
Address		City	State	Zip
LAKSHMI PURAM		GUNTUR	AP	522007
Diploma/Degree obtained, if any				
INTERMEDIATE				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/15--TILL DATE	[redacted]LAFAYETTE DR	LIVINGSTON	NJ	07039
12/06--11/15	[redacted]STAATS COURT	SOUTH PLAINFIELD	NJ	07080
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
LINDEN PHARMACY			01/18 TO TILL DATE
Business Address	**City**	**State**	**Zip**
1368 LINDEN BLVD	BROOKLYN	NY	11212
Phone	**Title**		
7183423131	COMPLIANCE ANALYST		
Description of Duties			
LOOKING AFTER COMPANIES' OPERATIONS AND BUSINESS PRACTICES TO FOLLOW ALL GOVERNMENT/STATE BOARD/FEDERAL REQUIREMENTS.			

Business Name			From - To (MM/YY – MM/YY)
SWAY ALLIANCE LLC (DBA WEST SIDE RX AND VACCINES)			05/24 TILL DATE
Business Address	**City**	**State**	**Zip**
2949 BINGLE ROAD	HOUSTON	TX	77055
Phone	**Title**		
2818887322	SECRETARY		
Description of Duties			
OWNER			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SHARDHA CHENNA

Print Name (First, Last)

Ch Shradha

Original Signature (electronic, copies or stamps not accepted)

10/08/2024

Date

Please have this section completed in the presence of a Notary Public.

State of NEW JERSEY, ss. County of ESSEX.

I, SHARDHA CHENNA, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Ch Shradha

Original Signature

10/11/2024

Date

Subscribed and Sworn to before me this 11th day of OCTOBER 2024

Notary Public Signature

MERI SURIC
Notary Public, State of New Jersey
My Commission Expires Sep 11, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site ASAP PHARMACY

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) 054.022874

Physical Address 16612 107TH COURT

City ORLAND PARK State ILLINOIS Zip 60467

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 7086711200 Website WWW.WECAREASAP.COM

Licensing Company Email fpr.drugcomplianceunit@illinois.gov

Section 2: Personal Information

First BERNARD Middle _____ Last FISCHMAN

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] PENN ST

City BROOKLYN State NY Zip 11211

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
YESHIVA BETH HILLEL OF KRASNA		09/77--06/80	
Address	**City**	**State**	**Zip**
1613 44TH ST	BROOKLYN	NY	11204
Diploma/Degree obtained, if any			
BS DEGREE			

School Name		From - To (MM/YY – MM/YY)	
YESHIVA BETH HILLEL OF KRASNA		09/74--06/77	
Address	**City**	**State**	**Zip**
1613 44TH ST	BROOKLYN	NY	11204
Diploma/Degree obtained, if any			
HS DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2000 TILL DATE	[redacted]PENN ST	BROOKLYN	NY	11211
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
BNF CONSULTING AGENCY			01/16 --TILL DATE	
Business Address		**City**	**State**	**Zip**
238 PENN ST		BROOKLYN	NY	11211
Phone	**Title**			
718-223-7008	PRESIDENT			
Description of Duties				
OWNER				

Business Name			From - To (MM/YY – MM/YY)	
MEDPACK PHARMACY			01/09-- TILL DATE	
Business Address		**City**	**State**	**Zip**
5923 STRICKLAND AVE		BROOKLYN	NY	11234
Phone	**Title**			
3475061000	OWNER			
Description of Duties				
OWNER				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

BERNARD FISCHMAN

Print Name (First, Last)

Bernard Fischman

Original Signature (electronic, copies or stamps not accepted)

10/8/2024

Date

Please have this section completed in the presence of a Notary Public.

State of NEW YORK, ss. County of BRONX.

I, BERNARD FISCHMAN, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Bernard Fischman

Original Signature

10/8/2024

Date

Subscribed and Sworn to before me this 8th day of OCT 2024.

Ch. Ravi Kumar.

Notary Public Signature

RAVI K CHENNA
Notary Public - State of New York
No. 01CH6266914
Qualified in Bronx County
My Comm. Expires Aug. 6, 2024
2028

(Seal)

4VV

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-Nevada	☒ Ownership Change*	☐ Hospital (# beds _____)	☒ Dangerous drugs
	☐ Location Change *	☐ Internet	☒ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FC3611236
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☒ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH 03491		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Cascade Specialty Pharmacy LLC

Physical Address: 19062 State Highway 305 NE

City: Poulsbo State: WA Zip: 98370

Mailing Address (if different from physical address): N/A

City: _____ State: _____ Zip: _____

Telephone: 360 779 2737 Toll Free # (NAC 639.708, NRS 639.23286): 866-341-8370

Fax: 360 779 4905 Contact Email: CascadeLicensing@revelationpharma.com

Website: cascaderx.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Angela Williams

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24351

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Angela Williams	NV Pharmacist Registration #: 24351
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): _____

Corporation/Organization Name: Revelation Pharma, LLC

Mailing Address: 9777 Pyramid Ct. Ste 230

City: Englewood State: CO Zip: 80112

Telephone: 224-715-2685 Email: CascadeLicensing@revelationpharma.com

Contact Person Name: Savannah Mansour

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Authorized Officer (title) for Cascade Specialty Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Angela Williams

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

10/2/2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Angela Williams hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Authorized Officer (title) for Cascade Specialty Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SAVANNAH MANSOUR
OFFICIAL SEAL
Notary Public, State of Illinois
My Commission Expires
August 25, 2026

SUBSCRIBED AND SWORN TO
Before me, a notary public this 8 day of October, 2024

Notary Public

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Angela Williams, Authorized Officer

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

10/2/2024

Date

Board Use Only	Date Received: _____	Amount: 500.00 / cc.

State Of Delaware

Entity Details

10/8/2024 1:58:42PM

File Number:	3999917	Incorporation Date / Formation Date:	6/20/2024
Entity Name:	CASCADE SPECIALTY PHARMACY, LLC		
Entity Kind:	Limited Liability Company	Entity Type:	General
Residency:	Domestic	State:	DELAWARE
Status:	Good Standing	Status Date:	6/20/2024

Registered Agent Information

Name:	CORPORATION SERVICE COMPANY		
Address:	251 LITTLE FALLS DRIVE		
City:	WILMINGTON	Country:	
State:	DE	Postal Code:	19808
Phone:	302-636-5401		

Washington State Department of Health

This organization

Cascade Specialty Pharmacy

is authorized by RCW 18.64 to have a

Pharmacy License

To Provide

Controlled Substance

Ancillary Utilization

Operated by: **Poulsbo Compounding Pharmacy, LLC**

Pharmacy Type: **Community/Retail**

Located at: **19062 State Highway 305 NE**
Poulsbo, WA 98370-7507

Secretary

Status
ACTIVE

Credential Number
PHAR.CF.61499243

Effective Date
06/01/2024

Expiration Date
05/31/2025

Washington State Department of HEALTH

Facility Search

Search

Search

Facility Information

NEW SEARCH | RESULTS

Facility Name: Cascade Specialty Pharmacy
Address: 19062 State Highway 305 NE, Poulsbo, WA, 98370-7507
Owner's Name: Poulsbo Compounding Pharmacy, LLC
License #: PHAR.CF.61499243
Facility Status: ACTIVE
Facility Type: Pharmacy License
License Expires On: 05/31/2025

If you find any errors in this description, please complete the Feedback form and send it to us.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC3611236	08-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	11-20-2023

CASCADE SPECIALTY PHARMACY
19062 STATE HIGHWAY 305 NE
POULSBO, WA 983707507

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC3611236	08-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	11-20-2023

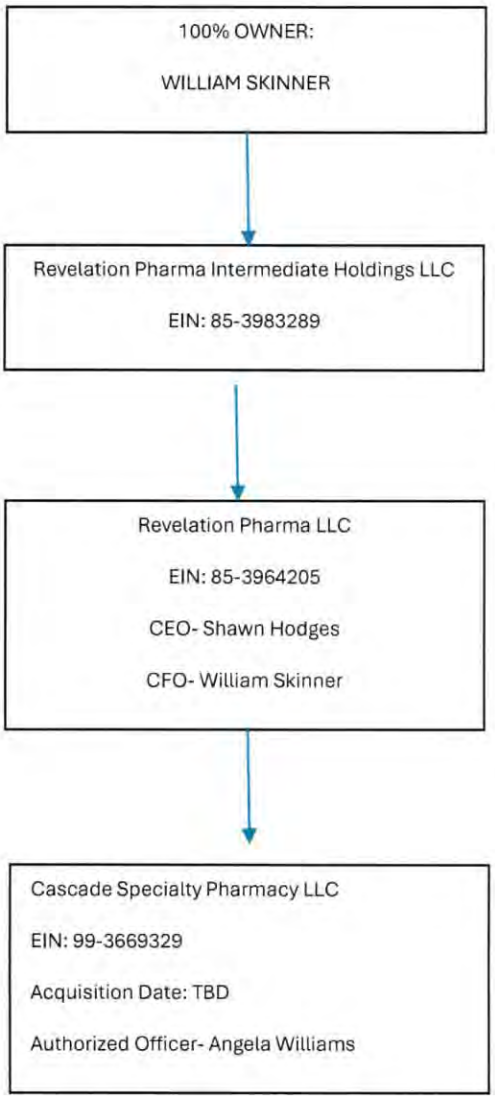
CASCADE SPECIALTY PHARMACY
19062 STATE HIGHWAY 305 NE
POULSBO, WA 983707507

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

OWNERSHIP TRACE



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler CASCADE SPECIALTY PHARMACY, LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 19062 STATE HIGHWAY 305 NE, PO

City POULSBO State WA Zip 98370

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 360-779-2737 Website Cascaderx.com

Licensing Company Email Cascadelicensing@Revelationpharma.com

Section 2: Personal Information

First Angela Middle Christine Last Williams

Alias(es, nicknames, name changes, etc.) Angela Christine Thomas

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] Killeen Pl SW

City Port Orchard State WA Zip 98367

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Western University of Health Sciences		08/03-05/07	
Address	**City**	**State**	**Zip**
309 E Second St	Pomona	CA	91766
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Azusa Pacific University		08/94-12/97	
Address	**City**	**State**	**Zip**
901 E Alosta Ave	Azusa	CA	91702
Diploma/Degree obtained, if any			
Bachelor's of Psychology			

School Name		From - To (MM/YY – MM/YY)	
University of Puget Sound		08/93-05/94	
Address	**City**	**State**	**Zip**
1500 N Warner St	Tacoma	WA	98416
Diploma/Degree obtained, if any			
none			

School Name		From - To (MM/YY – MM/YY)	
Charter Oak High School		09/89-6/93	
Address	**City**	**State**	**Zip**
1430 E Covina Blvd	Covina	CA	91724
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/20-Present	[redacted]illeen Pl SW	Port Orchard	WA	98367
04/18-10/20	[redacted]merican Pl SE	Port Orchard	WA	98367
09/17-04/18	[redacted]learwater Ln SE	Port Orchard	WA	98367
05/07-09/17	[redacted]N Mangrove Ave	Covina	CA	91724

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Cascade Specialty Pharmacy			12/23-Present
Business Address	**City**	**State**	**Zip**
19062 State Highway 305	Poulsbo	WA	98370
Phone	**Title**		**Number of Employed Hours**
360-779-2737	Lead Operations Pharmacist		1900

Description of Duties
Manage compounding pharmacy. Process prescriptions, fill prescriptions, verify prescriptions, and counsel patients. Quality assurance reporting and ensure regulatory compliance.

Business Name			From - To (MM/YY – MM/YY)
Walmart Pharmacy #2325			10/21-12/23
Business Address	**City**	**State**	**Zip**
3497 Bethel Rd SE	Port Orchard	WA	98366
Phone	**Title**		**Number of Employed Hours**
360-874-9063	Pharmacy Manager		5100

Description of Duties
Managed daily activities of outpatient retail pharmacy. Process prescriptions, fill prescriptions, verify prescriptions, and counsel patients. Quality assurance reporting and ensure regulatory compliance.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Angela Williams, **certify that as the designated representative for**

Cascade Specialty Pharmacy LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ACW I am at least 21 years of age;
3. ACW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ACW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ACW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ACW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ACW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Angela Williams

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/02/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Angela Williams

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/08/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Illinois, ss. County of Cook

I, Angela Williams, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/8/24

Date

Subscribed and Sworn to before me this 8 day of October.

Notary Public Signature

SAVANNAH MANSOUR
OFFICIAL SEAL
Notary Public, State of Illinois
My Commission Expires
August 25, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Cascade Specialty Pharmacy, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable) _____

Physical Address 19062 State Hwy 305 NE

City Poulsbo State WA Zip 98370

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 360-779-2737 Website CascadeRx.com

Licensing Company Email CascadeLicensing@RevolutionPharma.com

Section 2: Personal Information

First ANGELA Middle CHRISTINE Last WILLIAMS

Alias(es, nicknames, name changes, etc.) ANGELA CHRISTINE THOMAS

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted] KILLEEN PL SW

City PORT ORCHARD State WA Zip 98367

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
WESTERN UNIVERSITY OF HEALTH SCIENCES		08/03 - 05/07	
Address	**City**	**State**	**Zip**
309 E. SECOND ST	POMONA	CA	917606
Diploma/Degree obtained, if any			
DOCTOR OF PHARMACY			

School Name		From - To (MM/YY – MM/YY)	
AZUSA PACIFIC UNIVERSITY		08/94 - 12/97	
Address	**City**	**State**	**Zip**
901 E ALOSTA	AZUSA	CA	91702
Diploma/Degree obtained, if any			
BACHELORS OF PSYCHOLOGY			

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF PUGET SOUND		08/93 - 05/94	
Address	**City**	**State**	**Zip**
1500 N WARNER ST	TACOMA	WA	98416
Diploma/Degree obtained, if any			
NONE			

School Name		From - To (MM/YY – MM/YY)	
CHARTER OAK HIGH SCHOOL		09/89 - 06/93	
Address	**City**	**State**	**Zip**
1430 E COVINA BLVD	COVINA	CA	91724
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/20 - PRESENT	[redacted] KILLEEN PL SW	PORT ORCHARD	WA	98367
04/18 - 10/20	[redacted] AMERICAN PL SE	PORT ORCHARD	WA	98367
09/17 - 04/18	[redacted] CLEARWATER LNSE	PORT ORCHARD	WA	98367
05/07 - 09/17	[redacted] N MANGROVE AVE	COVINA	CA	91724
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
CASCADE SPECIALTY PHARMACY	12/23 - PRESENT

Business Address	City	State	Zip
19062 STATE HIGHWAY 305	POULSBO	WA	98370

Phone	Title
360-779-2737	LEAD OPERATIONS PHARMACIST

Description of Duties: Manage Compounding pharmacy. Process prescriptions, fill prescriptions verify prescriptions, and Counsel patients. Quality assurance reporting and ensure regulatory compliance.

Business Name	From - To (MM/YY – MM/YY)
WALMART PHARMACY #2325	10/21 - 12/23

Business Address	City	State	Zip
3497 BETHEL RD SE	PORT ORCHARD	WA	983606

Phone	Title
360-874-9063	PHARMACY MANAGER

Description of Duties: Managed daily activities of outpatient retail pharmacy. Process, fill, verify perscriptions and Counsel patients. Quality assurance and ensure regulatory compliance.

Business Name	From - To (MM/YY – MM/YY)
WALGREENS PHARMACY	01/21 - 10/21

Business Address	City	State	Zip
3099 BETHEL RD SE	PORT ORCHARD	WA	983606

Phone	Title
360-876-5212	PHARMACY MANAGER

Description of Duties: Manage daily activities of outpatient retail pharmacy. Process, fill, and verify prescription. Counsel patients.

Business Name	From - To (MM/YY – MM/YY)
WALMART PHARMACY #2325	10/18 - 12/20

Business Address	City	State	Zip
3497 BETHEL RD SE	PORT ORCHARD	WA	983606

Phone	Title
360-874-9063	PHARMACIST / PHARMACY MANAGER

Description of Duties: Managed daily activities of outpatient retail pharmacy. Process, fill, verify prescriptions and Counsel patients Supervise ancillary staff.

Business Name	From - To (MM/YY – MM/YY)
CVS PHARMACY	10/17 - 09/18

Business Address	City	State	Zip
3201 NW RANDALL WAY	SILVERDALE	WA	98383

Phone	Title
360-536-6010	PHARMACY MANAGER

Description of Duties: Managed daily activities of outpatient retail pharmacy. Process, fill, verify prescriptions and Counsel patients. Supervise ancillary staff.

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
FOOTHILL MEDICAL PLAZA PHARMACY			07/07 - 09/17	
Business Address	**City**		**State**	**Zip**
415 W. ROUTE 66	GLENDORA		CA	91740
Phone	**Title**			
OUT OF BUSINESS	PHARMACY MANAGER			
Description of Duties				
Managed daily outpatient retail pharmacy activities. Process, fill, verify prescriptions, counsel patients, manage inventory. Supervise ancillary staff				

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ANGELA WILLIAMS
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/2/2024
Date

Please have this section completed in the presence of a Notary Public.

State of Illinois, ss. County of Cook County IL

I, Angela Williams, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/2/24
Date

Subscribed and Sworn to before me this 2 day of October.

Notary Public Signature

SAVANNAH MANSOUR
OFFICIAL SEAL
Notary Public, State of Illinois
My Commission Expires
August 25, 2026

(Seal)

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Business e-Profile ID:	1810127		**Inspection Information**
Legal Business Name:	Poulsbo Compounding Pharmacy, LLC	**Conference Call Date:**	6/10/2024
Doing Business As (DBA):	Cascade Specialty Pharmacy	**Start Time: 24-hour format (13:00)**	10:00
Address:	19062 State Highway 305 NE	**End Time: 24-hour format (13:00)**	11:00
City:	Poulsbo	**Onsite Inspection Date(s):**	6/12/2024 and 6/13/2024
State:	Washington	**Start Time(s): 24-hour format (13:00)**	9:00 and 9:00
Zip Code:	98370	**End Time(s): 24-hour format (13:00)**	17:00 and 14:45
Telephone number:	360-779-2737	**Inspector Name(s):**	Paul N. Limberis, RPh
Toll free number:	866-341-8370	**Inspection performed by (NABP, State, etc):**	NABP
Fax number:	360-779-4905	**Observer Name/Affiliation (if applicable):**	N/A
Website:	www.cascaderx.com	**Observer Name/Affiliation (if applicable):**	N/A

Focused Information

The following, if any, are specific Section(s) and/or Question(s) to which the facility may want to consider further response. The facility is encouraged to read the inspection report in its entirety and carefully. As this Focused Information section is not all inclusive, there may be Section(s) and/or Question(s) not noted below to which the facility may want to consider further response.

General Pharmacy- 88.03 and 91.00
Nonsterile - 29.0, 29.8, and 29.12
Hazardous- 13.14.03, 73.01 and 73.03

Additional information on NABP's Inspection website.

NABP Disclaimer: NABP can only verify the authenticity of an Inspection Report if it is transmitted directly from NABP to an intended recipient. NABP cannot verify the authenticity of an Inspection Report transmitted from any other party.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	(X)
Sunday			X
Monday	9:00	17:30	
Tuesday	9:00	17:30	
Wednesday	9:00	17:30	
Thursday	9:00	17:30	
Friday	9:00	17:30	
Saturday			X

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	Brandon Knott	bknott@cascaderx.com	200560
Nonsterile Designated person(s)	Angela Williams	angela@cascaderx.com	253455
Sterile Designated person(s)	N/A	N/A	N/A
Hazardous Designated person(s)	Demi Swetzof	demi@cascaderx.com	1416987

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Brandon Knott	Owner, PIC	Y
2	Emily Miller	Pharmacist	Y
3	Angela Williams	Pharmacist - DP Nonsterile	Y
4	Demi Swetzof	Technician - DP Hazardous	Y
5	Heather Kuss	Technician	Y
6	Zachary Sleigh	Technician	Y
7	John White	Tech-in-Training	Y
8	Andi Ellis	Technician	Y
9	Jessica Griffin	Technician	Y
10	Lauren Meyer	Admin	Y

If more than 10, list the first 10 below, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present.
In addition to the staff listed above there were an additional 5 Pharmacy Assistants, and 1 Production Supervisor/Technician-In-Training.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Business Licensure Information for State of Residence and Federal

(board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
Washington State Board of Pharmacy	Cascade Specialty Pharmacy	Pharmacy	PHAR.CF.61499243 - Exp: 5/31/2026
Drug Enforcement Administration	Cascade Specialty Pharmacy	Controlled Substance - Pharmacy	FC3611236 - Exp: 8/31/2024

Inspector Notes: List states in which Non-Resident licenses are held: Non Resident licenses are held in AK, AZ, CA, CO, ID, IL, IN, MO, MT, NM, OR, PA, SD, WI, WY. This Cascade Specialty Pharmacy opened in 2022. The pharmacy specializes in Nonsterile compounding (hazardous and nonhazardous). They perform very little commercial product dispensing. The pharmacy predominantly compounds products for ENT use (powder packets which are then used in nasal rinses) consisting of different steroid, antibiotic and antifungal products. They do not stock ReliOn Insulin, do not use any platforms that are a marketplace for pharmacies to buy, sell or bid on overstock/short dated products. They do not compound with semaglutide and they do not dispense any biological products.

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description
Doc01_Gen10.00	White Bag - RX Patient Label for administration at physician office.
Doc02_Gen16.00, Doc03_Gen24.00	State Board of Pharmacy letters for new Pharmacy and Change in Ownership Inspections. FDA 325-Close-Out Letter.
Doc04_Gen37.04	P.S Industries- reverse distributor DEA License
Doc05_NS 20.0	COA's from API sources
Doc06_HAZ 3.00	Hazardous drug list, by category

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail	X	Central Fill/Processing/Shared Services	X
Open to the Public	X	Nuclear Pharmacy	
Closed Door		Specialty Pharmacy	
Drive-through window		White bagging/ clear bagging	X
Mail- in state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	Outsourcing Facility	
Mail- out of state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	FDA Registered Drug Establishment (eg Manufacturer, repackager, relabeler)	
Local Delivery (if out of state describe in note)		Wholesale Distributor	
Veterinary Pharmacy (occasionally dispenses prescriptions for animals)	X	Provide prescription drugs for "Office Use" (eg distributes)	
Institutional (hospital or correctional facility)		Handles Medical Marijuana	
Long-Term Care (nursing home, residential care)		Nonsterile Compounding	X
Investigational Drugs, Clinical Trials/Research		Nonsterile Hazardous Drug Compounding	X
Telepharmacy		Sterile Compounding	
Internet Pharmacy		Sterile Hazardous Drug Compounding	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply		Compounded Sterile Preparations (CSPs) Type "X" for all that apply	
CNSPs with controlled substance(s)	X	CSPs with controlled substance(s)	
CNSPs with vitamins or nutritional supplements		CSPs with vitamins or nutritional supplements (includes total parenteral nutrition)	
CNSPs sold to other pharmacies - If so, list to whom – instate, out of state, under common ownership/shared services – central fill agreement; and state if patient specific or distributed		CSPs sold to other pharmacies - If so, list to whom - in state, out of state, under common ownership/shared services - central fill agreement; and state if patient specific or distributed	
Patient specific (compounded preparation labeled for an individually identified patient):		**Patient specific** (compounded preparation labeled for an individually identified patient):	
CNSPs for animals	X	CSPs for animals	
CNSPs for human patients	X	CSPs for human patients	
Distributed (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):		**Distributed** (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
CNSPs to practitioners for office use		CSPs to practitioners for office use	
CNSPs to hospitals, clinics, or surgery centers		CSPs to hospitals, clinics, or surgery centers	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Types of CNSPs:		Categories of CSPs:	
Aqueous	X	Category 1 CSPs	
Nonaqueous	X	Category 2 CSPs	
Specific types:		Category 3 CSPs	
Solid oral preparations	X	Types of CSPs:	
Liquid oral preparations	X	Allergenic extracts	
Otic preparations	X	Allergenic extracts in addition to prescription patient sets	
Rectal preparations	X	Immediate Use	
Vaginal preparations	X	Proprietary bag and vial systems	
Topical preparations:	X	Blood-derived or other biological material (eg autologous serum)	
Nasal and sinus preparations:	X	Sterile injections/ sterile infusions	
Other (please list):		Ophthalmic dosage forms	
		Baths and soaks for live organs and tissues	
		Implants/ Pellets	
		Other (please list):	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Facility Size in Square Feet *(can be approximated)* and Number of PECs		Personnel	
Total Pharmacy size:	3000	Total Pharmacists:	3
Nonsterile Compounding Room size:	100, 300, 700	Number of Compounding Pharmacists:	2
Nonsterile Compounding powder hoods number:	5 total	Total Student Interns:	0
Nonsterile Hazardous Drugs (HD) Compounding Room size:	200	Total Technicians:	8
Nonsterile HD Compounding CVE/BSC/CACI hoods number:	1- CVE- Double Filter	Number of Compounding Technicians:	3
Sterile Compounding Ante Room size:	N/A	Of technicians, how many are nationally certified?	6
Sterile Compounding Clean/Buffer Room size:	N/A	Of technicians, how many are techs-in-training?	2
Sterile Compounding Number LAFW hoods/areas:	0	Total Other Unlicensed Personnel:	14
Sterile Compounding Number BSC hoods:	0	Ratio #Technician(s) : #Pharmacist(s) present at time of inspection:	8 Tech:3 RPh
Sterile Compounding Number CAI/CACI hoods:	0	If multiple compounding suites are present under this licensed location (eg outsourcing facilities or hospital health systems), describe in notes other spaces where compounding occurs (eg location name, approximate size of space, and number and type of PECs:	N/A
Negative Pressure Sterile HD Room size:	N/A		
Sterile HD Compounding Number of BSC hoods:	0		
Sterile HD Compounding Number of CACI hoods:	0		

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample)	N/A
Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason.	N/A

	Volume Dispensed		**Volume Distributed**
Total Prescriptions Dispensed/day:	199	Total Orders Distributed/day:	0
% Veterinary Prescriptions	13%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	9%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	100%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	0%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	18%	% Hazardous Drugs (HD) Orders	0%

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)			
Alaska (AK)	16	0	May 2024
Arizona (AZ)	146	0	May 2024
Arkansas (AR)			
California (CA)	609	0	May 2024
Colorado (CO)	97	0	May 2024
Connecticut (CT)			
Delaware (DE)			
District of Columbia (DC)			
Florida (FL)			
Georgia (GA)			
Hawaii (HI)			
Idaho (ID)	20	0	May 2024
Illinois (IL)	0	0	May 2024
Indiana (IN)	1	0	May 2024
Iowa (IA)			
Kansas (KS)			
Kentucky (KY)			
Louisiana (LA)			
Maine (ME)			
Maryland (MD)			
Massachusetts (MA)			
Michigan (MI)			
Minnesota (MN)			
Mississippi (MS)			
Missouri (MO)	0	0	May 2024
Montana (MT)	0	0	May 2024

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):

Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)			
Nevada (NV)			
New Hampshire (NH)			
New Jersey (NJ)			
New Mexico (NM)	11	0	May 2024
New York (NY)			
North Carolina (NC)			
North Dakota (ND)			
Ohio (OH)			
Oklahoma (OK)			
Oregon (OR)	147	0	May 2024
Pennsylvania (PA)	0	0	May 2024
Rhode Island (RI)			
South Carolina (SC)			
South Dakota (SD)	1	0	May 2024
Tennessee (TN)			
Texas (TX)			
Utah (UT)			
Vermont (VT)			
Virginia (VA)			
Washington (WA)	2435	0	May 2024
West Virginia (WV)			
Wisconsin (WI)	12	0	May 2024
Wyoming (WY)	0	0	May 2024
Other:			

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy
e-Profile ID: 1810127
Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Notes
	General Pharmacy		
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	40 hours +
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	Yes	The pharmacy subleases an office in the basement to an accountant.
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	No	
4.01	Does the pharmacy hold .pharmacy verification?	No	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	No	
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	No	Patients are able to email the pharmacy to reorder refills, not through the website.
8.00	Are photographs allowed during the inspection (**no PHI**)?	Yes	
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**		Angela Williams - DP Nonsterile Compounding, Demi Swetzof - DP - Hazardous, Lauren Meyer - Admin. Emily Miller - Pharmacist

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy
e-Profile ID: 1810127
Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Notes
	Types of Practice Additional Questions **If any part of a question is no, enter "No" and explain the observation.**		
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	Yes	<1% in WA only. These are numbing preparations to be used prior to in-office nasal procedures. See Doc01_Gen10.00.
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy
e-Profile ID: 1810127
Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Notes
	General Operations and Licensure **If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	Yes	Facility and Pharmacist licenses are posted in front lobby area. Technician licenses are posted in pharmacy. Out-of-State licenses are maintained in a binder.
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	New pharmacy inspection, 4/11/2022 and change of ownership inspection 11/02/2023. See Doc.02_Gen16.00.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	No	No deficiencies were noted.
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	Yes	The pharmacy has waivers in states as required for zero reporting controlled substance dispensing.
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy
e-Profile ID: 1810127
Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Notes
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	The other pharmacy co-owned was inspected by the FDA in April, 2019. The FDA sent a close-out letter on 7/26/2021. See Doc03_Gen24.00.
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	No	
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	Records are maintained on site for two years, then scanned and maintained indefinitely.
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	Yes	Records are maintained on site for two years, then scanned and maintained indefinitely.
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	These are maintained electronically indefinitely.
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	These are maintained electronically indefinitely.
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	The Pioneer system will allow for an order to be deactivated, but not deleted.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy
e-Profile ID: 1810127
Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Notes
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	N/A	
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	This is detailed in the policies and procedures. The pharmacy follows the most stringent law/regulation. The pharmacy receives updates through state list-serves, these are reviewed and the P&P's are updated as needed.
	Personnel **If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	Staff licenses are verified with BOPs annually. This is documented by the Admin - Lauren Meyer.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	PSV checks are performed at hire and annually by the Admin - Lauren Meyer.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	No additional services requiring certification.
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	N/A	No ration requirement in WA. The pharmacy normally operates at 8 Tech:3 RPh ratio. Total number of staff working is 18-19.
	Facility and Security **If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	ADT system is in place. This includes door alarms, motion detectors, motion detectors by zone, and notification to the PIC of any activity.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	Yes	These are locked in a box in the dispensing area of the pharmacy.
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	A pharmacist will remain on site until the pharmacy can be properly secured.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy
e-Profile ID: 1810127
Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Notes
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	N/A	No destruction on site
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	The pharmacy uses P.S. Industries Inc. as their reverse distributor. See Doc04_Gen37.04. - Reverse Distributor - DEA License.
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	Yes	P.S. Industries also takes care of hazardous waste.
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	Yes	There is a consultation area in the front lobby area, and a private office can also be used.
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Yes	69F - dispensing pharmacy, 71F - Compound Room 1, 71F - Compound Room 2, 70F - Hazardous Compounding Room.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process.*	Yes	Accurite continuous monitoring system is used. Range is 68-77 degrees F. Records are maintained electronically indefinitely. Excursion notifications are emailed to the pharmacists.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	Product is evaluated, manufacturers are contacted for excursion data, if deemed to have had it's integrity compromised, the product is removed from inventory and set aside for destruction or return.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy
e-Profile ID: 1810127
Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Notes
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	Accurite continuous monitoring system is used. Range is 36-46 degrees F. Records are maintained electronically indefinitely. Excursion notifications are emailed to the pharmacists.
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	Yes	41.7F -Shipping, 42F - Bulk, 44.6F - Lab, 44.6F - Dispensing, 38.8F - Hazardous
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	Accurite continuous monitoring system is used. Range is -13 to 14 degrees F. Records are maintained electronically indefinitely. Excursion notifications are emailed to the pharmacists.
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	Yes	Freezer is -2F.
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	Product is moved to a working unit.
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	HVAC repair service on contract is contacted. The pharmacy also has a back-up generator.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	Product is evaluated, manufacturers are contacted for excursion data, if deemed to have had it's integrity compromised, the product is removed from inventory and set aside for destruction or return.
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	Yes	1 - Kirby Lester
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy
e-Profile ID: 1810127
Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Notes
	Product Receipt and Inventory **If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	Yes	Sources are vetted and must be licensed and have FDA registration.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	No	
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase*	No	
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	Yes	Anda and McKesson. API sources include Darmerica, PCCA, Letco, Medisca, and Spectrum
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	Yes	
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	No	
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	Yes	License verification with the BOPs
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	Yes	Verification on the FDA website
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy
e-Profile ID: 1810127
Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Notes
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	None to date
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	Yes	The pharmacy reviews the transaction data electronically provided by McKesson and Anda. These are electronically maintained.
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	Yes	PIC and two Pharmacists have POA.
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	Yes	PIC and two Pharmacists have POA.
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	Yes	A copy of the CSOS is also attached to the signed invoice.
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	Yes	
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy
e-Profile ID: 1810127
Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Notes
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	Yes	The pharmacy has a CF agreement with the other commonly owned pharmacy in Poulsbo, WA for providing sterile patient specific compounded prescriptions. The CF pharmacy compounds the prescription, dispenses it, and then transports it to the pharmacy for patient pick-up.
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	All commercial and compounded product inventory is maintained in the Pioneer system. API product inventory is maintained in PK software. Inventory is reconciled with each dispense and quarterly.
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	Reports would be made to the DEA, BOP, and law enforcement.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	Yes	
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	Yes	Inventory is reconciled with each dispense.
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	Yes	11/4/2023. Inventory is performed every two years per regulation, and quarterly.
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	Yes	
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy
e-Profile ID: 1810127
Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Notes
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	The pharmacy performs monthly checks for outdates for all products.
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	
60.02	How often is active-stock examined for drugs past the expiration date?		Product is removed from inventory at 2 months prior to exp/BUD dates.
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	Yes	
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy
e-Profile ID: 1810127
Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Notes
	Prescription Processing **If any part of a question is no, enter "No" and explain the observation.**		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	Primarily, pharmacy technicians will enter new patient data, which is reviewed by the pharmacist at PVI. Patient profile data is updated with each patient contact.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	Yes	The species of the patient is indicated in the patient profile, along with the owner's name. The species also prints on the prescription label.
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	New providers are contacted and verified. Faxes and phones are checked along with provider NPI and license verifications.
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Yes	After verification with the provider, if there are suspected problems, the local authorities are consulted, DEA and the applicable Board.
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	Addresses are compared. Provider/patient record notes may be requested.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	Both
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	Yes	
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	A pharmacist will verify all the order entry at the PVI step.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy
e-Profile ID: 1810127
Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Notes
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	DUR occurs at the pre-check PVI step.
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	Yes	Animal species limitations and precautions.
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	Yes	Patients that receive nasal rinse products are also check against other nasal spray use. Weight checks for pediatric and animal prescriptions.
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	Plumbs, Trissels, USP, PCCA
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	Electronically reported
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Yes	
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	The system will document the pharmacist credentials with each override.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy
e-Profile ID: 1810127
Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Notes
67.07	Is the DUR process performed electronically by the computer system? *Identify integrated drug database used.*	Yes	First Data Bank, updated weekly, and Medispan, also updated weekly
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	Yes	These are documented in the patient notes and/or specific prescription notes section of the patient profile.
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	No	The pharmacy uses Plumbs Veterinary Handbook.
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	Pharmacists conduct final checks using bar code scanning to review the prescription and bar code scanning to verify the correct product has been dispensed.
69.00	Are filled prescriptions appropriately labeled? *Describe*	Yes	Labels meet all state requirements.
70.00	**Confidentiality**: Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	Pioneer Rx for dispensing and PK system for compounding.
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	Shred IT bins located throughout the pharmacy. They provide weekly pick-ups.
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	Products are shipped using UPS and USPS. The pharmacy conducts quarterly shipping validation tests and reports are provided through the QMC.
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	Yes	For the few sterile injectable compounded medications, these are compounded at the co-owned pharmacy location in Poulsbo, WA. They are filled there, then transported to this pharmacy for dispensing to the patient. This is for walk-in patients only.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy
e-Profile ID: 1810127
Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Notes
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	Yes	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	No	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	Yes	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
	Patient Counseling and Communication **If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all <u>new</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	Yes	Proactively
75.01	Is an "offer" to counsel made for all <u>new</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	N/A	
76.00	Does the pharmacist provide counseling for all <u>refilled</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	No	An offer is made.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy
e-Profile ID: 1810127
Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Notes
76.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy? *Indicate who makes the "offer"*	Yes	Technician will make the offer and a pharmacist will counsel.
77.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	Yes	Proactively
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer"*	N/A	
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how*	N/A	No deliveries
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how*	Yes	A pharmacist speaks with the patient for counseling prior to the shipment.
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how*	Yes	Pre-printed PPI's are used.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how*	N/A	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NAEP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy
e-Profile ID: 1810127
Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Notes
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn)*	N/A	
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	Yes	Patient counseling is documented in the patient and prescription notes sections in the patient profile.
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).*	No	Patients are able to leave a voicemail message after hours and the pharmacist will contact them the next business day.
85.00	Are processes in place to handle a drug recall?	Yes	The pharmacy is able to track to the lot number level for drug recalls.
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy
e-Profile ID: 1810127
Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Notes
	Quality Assurance/Quality Improvement Program **If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program*	Yes	Pharmacist - Angela Williams and the PIC - Brandon Knott oversee the QI program for the pharmacy.
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both*	Yes	These are maintained electronically and in hard copy.
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy
e-Profile ID: 1810127
Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Notes
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	No	Contributing factors are not currently included in the QRE form.
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	Yes	Analyzed with each event and then summarized monthly.
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	N/A	
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	Quality meetings are held monthly and quarterly.
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy
e-Profile ID: 1810127
Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Notes
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	QIP to address "other medication additions" to patient profiles has been implemented, measured and improved.
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	No	
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	N/A	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	Quarterly self audits are performed.
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	Yes	
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures for Compounded Nonsterile Preparations (CNSPs)		**Please note NABP did not review each SOP for alignment on USP <795>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**	
1.0	Does the pharmacy have standard operating procedures (SOPs) on all aspects of the compounding operation that cover the minimum topic requirements in USP <795> standards? ***If no, document "missing" in Inspector Notes*** ***If yes, document the name, number, and version of each SOP in the Inspector Notes.***	Yes		11
1.1	**Buildings and Facilities:** The pharmacy has an SOP for the compounding facility. ***Inspector note: Per USP <795>, there is a written SOP for "the method of designation" for the area designated specifically for nonsterile compounding and processes for maintaining, cleaning, and sanitizing the compounding area and equipment.***	[redacted]	1.25, version 1, 1.30 version 1, 1.35 version 1	4.1, 5, 11
1.2	**Personnel Training and Evaluation:** The pharmacy has an SOP describing the training program, the frequency of training, and the process for evaluating the competency of personnel. ***Inspector note: Per USP <795>, "Facility SOPs must describe procedures for monitoring and observing of compounding activities and personnel."***		1.60 version 2, 1.65 version 1	2, 11

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
1.3	**Personal Hygiene and Garbing:** The pharmacy has an SOP regarding personal hygiene, glove, and garbing requirements consistent with compounding activities. ***Inspector note: Per USP <795>, "Garbing requirements and frequency of changing garb must be determined by the facility and documented in the facility's SOPs."***		1.60 version 2, 1.65 version 1, 1.35 version 1	3.3, 11
1.4	**Components:** The pharmacy has an SOP describing selection, handling, storage, and inventory control of all components used in compounding. ***Inspector note: Per USP <795>, "The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP."***		3.10 version 1, 3.12 version 1, 3.20 version 1	6.2, 11
1.5	**Temperature Monitoring:** The pharmacy has an SOP regarding temperature monitoring and handling of excursions. ***Inspector note: Per USP <795>, "The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s)."***		1.21 version 1	4.2, 11
1.6	**Equipment**: The pharmacy has an SOP for assessment of need for closed system processing devices (based on the types of CNSPs prepared). ***Inspector note: Per USP <795>, "Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples of closed-system processing devices include containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags. The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented."***		1.30 version 1, 2.00 version includes 2.00-2.30, version 1	6.1, 11

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
1.7	**Safety Data Sheet (SDS)/Spill Management:** The pharmacy has an SOP describing spill management and disposal. ***Inspector note: Per USP <795>, "The management and documentation of nonhazardous component spills and disposal must be described in the facility's SOPs."***		3.40 version 1	6.2.5, 11
1.8	**Master Formulation Records (MFR):** The pharmacy has an SOP on the process for MFR creation and content. ***Inspector note: Per USP <795>, "Any changes or alterations to a Master Formulation Record are approved and documented in accordance with the facility's written SOP."***		4.10 version 1	7.1, 11
1.9	**Labeling:** The pharmacy has an SOP on the processes for labeling, label verification (confirming against the prescription or medication order, the MFR, and the compounding record (CR)) in order to prevent errors and CNSP mix-ups and required displayed information. ***Inspector note: Per USP <795>, "Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups."***		5.20 version 1	9, 11
1.10	**Quality Assurance (QA)/Quality Control (QC) Program:** The pharmacy has an SOP regarding its QA and QC program, including roles of the designated person(s), trainers, compounding personnel; adherence to procedures; and prevention and detection of errors and quality issues. ***Inspector note: Per USP <795>, "QA and QC programs must be formally established and documented in SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with this chapter, and laws and regulations of the applicable regulatory jurisdiction."***		6.10 version 1, 6.20 version 1, 4.5 version 1	11, 12 USP <1163>

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
1.11	**QA/QC Program Complaint Handling and Adverse Event Reporting:** The pharmacy has an SOP for evaluation of complaints and adverse events, including investigations and corrective actions. ***Inspector note: Per USP <795>, the pharmacy, "must develop and implement SOPs for complaint handling." SOPs are to include any state or federal requirements for reporting to government agencies (example adverse event reporting). Further, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease compounding until problems have been identified and corrected."***		6.10 version 1, 6.20 version 1	1.1.3, 11, 12.1, 12.2, 12.3
1.12	**Packaging:** The pharmacy has an SOP describing packaging CNSPs. ***Inspector note: Per USP <795>, "SOPs must describe packaging of CNSPs."***		5.40 version 1	11, 13.1
1.13	**Transporting:** The pharmacy has an SOP describing transporting CNSPs. ***Inspector note: Per USP <795>, there must be "written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed."*** ***If the pharmacy does not transport CNSPs, inspector should answer statement as N/A.***		5.40 version 1	11, 13.2

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
1.14	**Recalls:** The pharmacy has an SOP describing minimum requirements for recalls. ***Inspector note: Per USP, "The facility must have procedures in place to:*** ***- Determine when recalls must be initiated, which should include procedures to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, strength, purity, or other quality attributes)*** ***- Recall any unused dispensed CNSPs and quarantine any stock remaining in the pharmacy*** ***- Investigate if other lots are affected and recall if necessary*** ***An SOP for recall of dispensed CNSPs must contain:*** ***- Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall*** ***- Procedures to determine the distribution of any affected CNSP, including the data and quantity of distribution*** ***- Procedures to identify patients who have received the CNSP*** ***- Procedures for disposal and documentation of the recalled CNSP (and)*** ***- Procedures to investigate and document the reason for recall."***		5.50 version 1	12.1
	Designated Person(s) and Personnel Training Program **Inspector must complete the <795> Records Review module to complete this section.**			
2.0	Does the pharmacy have a designated person(s) who meets the requirements in USP <795> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CNSPs."*** ***If no, go to compliance statements.***	Yes		1.1.4

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NAEP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
2.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		1.1.4, 12
2.2	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented. ***Inspector note: Per USP, "The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program... The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed."***	Yes		1.1.4, 12
2.3	The designated person(s) is responsible for overseeing a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs.	Yes		1.1.4, 2
2.4	The designated person(s) is responsible for selecting components used by the pharmacy.	Yes		1.1.4, 6.2.1
2.5	The designated person(s) is responsible for monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed.	Yes		1.1.4
2.6	The designated person(s) is responsible for ensuring SOPs are fully implemented and following up if problems, deviations, or errors are identified.	Yes		1.1.4, 11

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
2.7	The designated person(s) is responsible for establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs.	Yes		1.1.4
3.0	Has the pharmacy created and implemented a training program that is in compliance with USP <795> standards? ***Inspector note: Per USP, "Training and competency of personnel must be documented."*** ***Inspector is to review a minimum of five personnel records and document their observations (see <795> Records Review module).*** ***If no, go to compliance statements.***	Yes		2, 14
3.1	All personnel who compound CNSPs have been initially trained and qualified before being allowed to independently compound (eg, perform their job functions). ***Inspector note: Per USP, compounding personnel are defined as "Personnel trained to compound or oversee compounding of preparations."*** ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	Yes		2, 14
3.2	All personnel who have direct oversight, perform in-process checks, final verification of a CNSP, and/or dispense a CNSP have been initially trained and qualified (according to SOPs) being allowed to independently perform their job functions. ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	Yes		2, 14

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
3.3	All compounding personnel, including those who have direct oversight of compounding personnel, have completed an initial training and at least every 12 months thereafter. ***Inspector note: Per USP, "Other personnel, who do not compound and only perform functions such as in-process checks, final verification, or dispensing of CNSPs must undergo training as required by the facility's SOPs."*** ***If questions 2.0-2.12 in the records review tab for compounding personnel or personnel who have direct oversight over compounding personnel are answered "no" or "missing," this statement should be answered no. For details, see the Records Review module.***	Yes	Two compounding employees have been employed less than one year, so they have initial training documentation.	2, 14
4.0	Does the designated person(s) have a documented (periodic) evaluation of their direct observations for compounding activities and documentation of any deficiencies in the record? ***Inspector note: Per USP, this is a recommendation, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*** ***Inspector should complete the <795> Records Review module question 3.0.***	Yes	Weekly observations are performed by the designated person.	2, 14
	Compounding Personal Hygiene and Garbing			
5.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3
5.1	Compounding personnel are required to report to the designated person(s)conditions that may contaminate the compounding preparation area. ***Inspector note: Per USP <795>, examples of conditions that have a higher risk of contaminating the CNSP include: rashes, recent tattoos, open sores, conjunctivitis, and active respiratory infection.***	Yes		

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
5.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in the compounding areas before their conditions have resolved.	Yes		3
5.3	Personnel removes any unnecessary items (outer garments, jewelry that could interfere with garbing, and earbuds/headphones) before entering the compounding area. ***Inspector note: Inspector should also observe compounding area to identify any items stored that do not belong (ie, dirty garments, jackets, or electronics).***	Yes		3.1
5.4	If personnel do not remove an item, the designated person has determined that the quality of the environment and CNSPs are not adversely affected by the accommodation.	Yes		3.1
6.0	Do personnel perform hand hygiene, wear required garb and gloves, and follow requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3
6.1	All personnel entering the compounding area complete hand hygiene procedures.	Yes		3.2 Box 1
6.2	Garb is used for all compounding activities. ***Inspector note: Per USP <795>, gloves are mandatory garb for all compounding activities.***	Yes		3.2, 3.3 Box 1
6.3	Pharmacy uses SDS to determine other garb requirements for the components and compounding activity.	Yes		3.3

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
6.4	Additional garb (shoe covers, hair and facial hair covers, face masks, gowns) is worn as needed for protection of the personnel/CNSPs. ***If no, please list the garb worn for the type of component and compounding activity.***	Yes		3.3
6.5	The garb purchased by the pharmacy is appropriate for the type of compounding being performed.	Yes		3.3
6.6	Garb is stored in manner that minimizes risk of contamination (away from sinks to avoid splashing, etc).	Yes		3.3
6.7	Gowns that are reused do not leave the compounding area.	Yes	Gowns are reused for one day only, then removed for laundering.	3.3
6.8	Visibly soiled garb or garb with tears or punctures are changed immediately (are not reused).	Yes		3.3
6.9	Soiled garb is disposed of or sent for laundering.	Yes		3.3
6.10	Shoe covers, hair and facial hair covers, face masks, and head covers are not reused once personnel have left the compounding area.	Yes		3.3
7.0	Are non-disposable garb such as goggles cleaned then sanitized with 70% isopropyl alcohol before re-use?	Yes		3.3
	Buildings and Facilities			
8.0	Does the compounding area meet the facility requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.1
8.1	The pharmacy has a designated compounding space for nonsterile compounding.	Yes		4.1

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
8.2	The compounding area is well lit.	Yes		4.1
8.3	The compounding area is clean and sanitary.	Yes		4.1
8.4	The compounding area is orderly (eg, clutter free, no tripping hazards).	Yes		4.1
8.5	The compounding area is in a good state of repair.	Yes		4.1
8.6	The compounding area is designed for orderly placement of equipment and materials to prevent mix- ups among components, containers, labels, in-process materials, and finished CNSPs.	Yes		4.1
8.7	The compounding area is not being used for other activities at the same time that it is used for compounding.	Yes		4.1
8.8	The compounding area is designed, arranged, and used in a manner that minimizes cross contamination from non-compounding areas.	Yes		4.1

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
9.0	Is the compounding area free of carpet?	Yes		4.1
10.0	Does the pharmacy's storage area (for CNSPs, components, equipment, and containers) meet requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.2
10.1	The pharmacy records the temperature of the compounding storage area on days when the pharmacy is open. ***Inspector note: Per USP, "Compounding personnel must monitor temperatures in the storage area(s) either manually at least once daily on days that the facility is open, or continuously with a temperature recording device to ensure the temperature remains within the appropriate range for the CNSPs and components."*** ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes	Accu Rite continuous electronic monitoring system.	4.2
10.2	The pharmacy's temperature monitoring records are readily retrievable. ***Inspector note: Per USP, "The results of the temperature readings must be documented on a temperature log or stored in the continuous temperature recording device and must be retrievable."***	Yes	Electronically maintained, and printed monthly.	4.2
10.3	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Per USP, "All temperature monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer." USP reports that these devices may be verified against a calibrated device.*** ***Monitoring devices are typically calibrated or replaced.***	Yes	Monitors are calibrated annually.	4.2

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
10.4	Pharmacy has a process to evaluate temperature excursions. ***Inspector note: Per USP, "When it is known that a CNSP or component has been exposed to temperatures either below or above the storage temperature limits for the CNSP or component, personnel must determine whether the CNSP or component integrity or quality has been compromised and if so, the CNSP or component must be discarded."***	Yes		4.2
10.5	CNSPs, components, equipment, and containers are stored off the floor.	Yes		4.2
10.6	CNSPs, components, equipment, and containers are stored in a manner that permits inspection and cleaning of the storage area(s).	Yes		4.2
10.7	CNSPs, components, equipment, and containers are stored in a clean environment (free of dirt, dust, and debris, and rodent/pest/insect free) to prevent contamination.	Yes		4.2
11.0	What is the current temperature of the nonsterile compounding storage area? ***Record in the Inspector Notes.***	[redacted]	Hazardous - 72.8 degrees F, Large Lab 73,5 degrees F, Small lab 73.9 degrees F, Packet Room 72.1 degrees F.	4.2
12.0	Are plumbing fixtures, water sources, and cleanliness of sink in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.3
12.1	The pharmacy staff can easily access a sink within or nearby the nonsterile compounding area.	Yes		4.3
12.2	There is hot and cold running water available at the sink within or nearby the nonsterile compounding area.	Yes		4.3

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
12.3	The sink is emptied of all items unrelated to compounding and before being used to clean any equipment used in nonsterile compounding.	Yes		4.3
12.4	The sink is cleaned when visibly soiled (before being used to clean equipment used in nonsterile compounding).	Yes		4.3
12.5	The plumbing system is free of any defects that may contribute to contamination of CNSPs.	Yes		4.3
13.0	Is purified water, distilled water, or reverse osmosis water used for rinsing equipment and utensils used in nonsterile compounding? ***Inspector note: This is a USP recommendation.***	Yes	Reverse osmosis	4.3 USP <1231>
	Cleaning and Sanitizing			
14.0	What agent(s) are used for cleaning and sanitizing the nonsterile compounding area? ***Inspector note: Per USP <795>, "agents must be selected and used with consideration of compatibilities, effectiveness, and minimal potential to leave residues."*** ***List the agents in the Inspector Notes.***	[redacted]	For Hazardous compounding room, Clorox Bleach Germicidal wipes, and Peridox RTU, followed by 70% Isopropyl Alcohol. For the small and large labs Hydrogen Peroxide wipes followed by Isopropyl alcohol, Detonox for dishwashing, Swiffer Antibacterial clean daily for floors	5
15.0	Does the pharmacy perform cleaning and sanitizing activities on all surfaces at the minimum frequency per Table 1 and documented in a log or other record in compliance with USP <795> standards? ***Review compounding cleaning logs.*** ***If no, go to compliance statements.***	Yes		5 Table 1
15.1	All work surfaces are cleaned and sanitized at the **beginning of each shift** on days when compounding occurs.	Yes		5 Table 1
15.2	All work surfaces are cleaned and sanitized at the **end of each shift** on days when compounding occurs.	Yes		5 Table 1

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
15.3	All work surfaces are cleaned and sanitized **between compounding CNSPs with different components**.	Yes		5 Table 1
15.4	Floors are cleaned and sanitized daily on days when compounding occurs.	Yes		5 Table 1
15.5	Walls and ceilings are cleaned and sanitized when visibly soiled. ***Inspector note: No specific frequency is specified by USP. View compounding area walls and ceilings. If inspector observes soiled walls or ceilings, inspector should answer statement as no.***	Yes		5 Table 1
15.6	All work surfaces, floors, walls, ceilings and storage shelving are cleaned and sanitized when surface contamination (eg, splashes) or spills are known or suspected.	Yes		5 Table 1
15.7	Storage shelving is cleaned and sanitized at least every three months.	Yes		5 Table 1
16.0	Are floors in the compounding area easily cleanable, non-porous, and non-particle generating? ***Inspector note: This is a USP recommendation. Per USP, "Surfaces should be resistant to damage by cleaning and sanitizing agents."***	Yes		5

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
	Equipment and Components			
17.0	Does the pharmacy use a closed-system processing device (eg, CVE, BSC, and single-use containment glove bags)? ***Inspector note: Per USP, examples of closed-system processing devices include: containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags.*** ***If yes, list the type(s) in the Inspector Notes.***	Yes	5 - CVE,s and 1 - CVE with double filter for HD compounding.	6.1
18.0	Does the pharmacy select, store, clean, and maintain equipment in compliance with USP <795> standards? ***Inspector note: Per USP <795>, "Equipment surfaces that contact components are not reactive, additive, or sorptive, and must not alter the quality of CNSPs."*** ***Review certification reports, calibration records, and cleaning logs.*** ***If no, go to compliance statements.***	Yes	The hoods are certified annually, last performed on 2/8/2024.	6.1
18.1	Equipment and supplies are readily available at the pharmacy for the types of CNSPs prepared. ***Inspector note: For example, if the pharmacy compounds with API as a component, which must be weighed, a scale or balance would be expected.***	Yes	Nine balances are used, annually certified, last performed on 2/8/2024.	6.1

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
18.2	Pharmacy has evaluated and documented the nonsterile compounding pharmacy activities for weighing, measuring, and otherwise manipulating for an assessment of risk. ***Inspector note: Per USP, "components that could generate airborne chemical particles (eg, active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs."*** ***If no, inspector should describe observations.***	Yes		6.1
18.3	The equipment and devices used for compounding CNSPs are clean and stored in a manner and frequency that minimizes the risk of contamination. ***Inspector note: Per USP <795>, "After compounding, the equipment must be cleaned to prevent cross contamination of the next preparation." Additionally, per Table 2:*** ***- CVE/BSC are cleaned and sanitized at the beginning and end of each shift when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected;*** ***- CVE/BSC horizontal surfaces are cleaned and sanitized between compounding of different components;*** ***- Under the work surface of a BSC is cleaned and sanitized at least monthly; and*** ***- Other devices and equipment used in compounding are cleaned before initial use, in between compounding CNSPs with different components, and following manufacturer recommendations.*** ***If no, inspector should describe observations.***	Yes		6.1 Table 2
18.4	Equipment and devices used in compounding or testing of CNSPs are inspected prior to use (to ensure they are in good working order). ***Inspector note: For example, the pharmacy may need to tare a scale and/or balance prior to use.***	Yes		6.1

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
18.5	Equipment and devices are verified for accuracy as recommended by the manufacturer (at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent). ***If the pharmacy does not compound CNSPs that require equipment or devices that must be calibrated for accuracy (such as ones needed for weighing or measuring), the inspector should answer this statement as N/A.***	Yes	Hoods and balances are inspected and certified annually, last performed on 2/8/2024.	6.1
18.6	If a CVE or BSC is used by the pharmacy, it is certified at least every 12 months, according to the manufacturer specifications or regulations of the applicable regulatory jurisdiction. ***If the pharmacy does not have the record or documentation of the certification and maintenance of the CVE/BSC, the inspector should answer this statement as no. If the pharmacy does not have a CVE or BSC, the inspector should answer this statement as N/A.***	Yes	Hoods and balances are inspected and certified annually, last performed on 2/8/2024.	6.1
19.0	Does the pharmacy compounding CNSPs use APIs?	Yes		6.2
20.0	Does the pharmacy select APIs that comply with the requirements in USP <795> standards? ***Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.*** ***If no, go to compliance statements.***	Yes	See Doc 05_NS20.0 - COA's - PCCA, Medisca, Letco, Spectrum, and Darmerica.	6.2.1
20.1	APIs comply with criteria in the USP-NF monograph, if one exists. ***If the pharmacy does not compound any CSPs that have an available USP monograph, the inspector should answer this statement as N/A.***	Yes		6.2.1

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
20.2	All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that the test results for the component show the API meets expected quality. ***Inspector note: Per USP, the API should be checked to ensure it is pharmaceutical grade and meets the requirements in the chemical monograph. COA will report an assay has been performed and will include water content (so any corrections/calculations can be performed).***	Yes		6.2.1
20.3	All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Food, Drug, and Cosmetic Act, Section 503A, requirement as well. If the API comes from a repackager, the pharmacy must be able to confirm the manufacturer of the API was registered as an Establishment with FDA.***	Yes		6.2.1
21.0	When formulations indicate the inclusion of water, is purified water or better quality (eg, sterile water for irrigation) used in compliance with USP <795> standards?	Yes		6.2.1
22.0	What type(s) of water is used for compounding CNSP? ***List the type(s) in the Inspector Notes.***	[redacted]	Sterile Water for Irrigation and Sterile Water for Injection are used.	6.2.1
23.0	Do the pharmacy's component receipt processes comply with the requirements in USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.2

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
23.1	For non-conventionally manufactured components, the COA is reviewed upon receipt. ***Inspector note: Per USP, "the COA must be reviewed to ensure that the component has met the acceptance criteria in an appropriate USP–NF monograph, if one exists." Pharmacy's review should be documented. Alternatively, the pharmacy can demonstrate how it's been reviewed (for example, there are notes to show a water content calculation back to 100% based on the specific COA). Inspector can verify the COA is retrievable.***	Yes		6.2.2
23.2	The pharmacy documents specific information according to the facility's SOP, including: receipt date, quantity received, supplier name, lot number, expiration date, and the results of any testing performed (whether performed in-house or through a third-party).	Yes		6.2.2, 14
23.3	For all components that lack a vendor expiration date, the pharmacy clearly and indelibly marks on each packaging system received the date the component must no longer be used by the pharmacy. ***Inspector note: Per USP, "Packaging systems of components (i.e., API and added substances) that lack a vendor's expiration date must not be used by the compounding facility after 3 years from the date of receipt. A shorter expiration date must be assigned according to Pharmaceutical Compounding—Sterile Preparations 797 , 9.3.2 Component receipt if the same component container is also used in sterile compounding or if the ingredient is known to be susceptible to degradation."***	Yes		6.2.2
23.4	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		6.2.2

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
23.5	Any other lots of that (rejected) component from that vendor are examined to determine whether other lots have the same defect.	Yes		6.2.2
24.0	Does the pharmacy re-inspect all components before use and handle them in compliance with USP <795> standards? *If no, go to compliance statements.*	Yes		6.2.3, 6.2.4
24.1	Compounding personnel visually re-inspect each component, including packaging system (any evidence of container breakage, looseness of cap or closure) and deviation from the expected appearance or texture of the contents (that might have changed during storage).	Yes		6.2.3
24.2	Compounding personnel ascertain before use that components are the correct identity based on labeling, that they have been stored under required conditions, and there is no evidence of deterioration or other aspects of unacceptable quality before use of component.	Yes	Bar code verification	6.2.3
24.3	Components where correct identity, strength, purity, and quality cannot be confirmed (eg, containers with damaged or incomplete labeling), are immediately rejected and if not immediately discarded, labeled as rejected and segregated from active stock.	Yes		6.2.3
24.4	Compounding personnel handle all components following facility SOPs, manufacturer's instructions/labeling, and laws/regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.4
24.5	All components are handled in a manner that minimizes the risk of contamination, mix-ups, and deterioration.	Yes		6.2.4

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
25.0	When components are removed from the original container and not used in compounding (eg, excess after weighing), are they discarded and not returned to the original container (to minimize risk of contamination of the original component container)? ***Inspector note: This is a USP recommendation.***	Yes		6.2.4
26.0	Does the pharmacy maintain a chemical hazard, spill management, and disposal information program in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.5
26.1	Pharmacy staff have access to safety data sheets (SDS).	Yes	Electronically available to all staff, as well as maintained in a binder.	6.2.5
26.2	Pharmacy staff have documented, annual training for those who might have to clean up a spill.	Yes		6.2.5, 14
26.3	The pharmacy has a readily accessible spill kit in the compounding area.	Yes		6.2.5
26.4	The pharmacy has a process to manage and document any nonhazardous spills and disposal.	Yes		6.2.5
26.5	Waste of any component is disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.5

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
	Master Formulation Records (MFR) and Compounding Records (CR) **Inspector should review a minimum of five (5) MFRs and five (5) CRs.**			
27.0	Is an MFR created for each unique formulation of a CNSP in compliance with USP <795> standards? ***Inspector note: Per USP, an MFR is a detailed record of procedures that describes how the CNSP is to be prepared.*** ***If no, go to compliance statements.***	Yes		7.1
27.1	An MFR is created for each unique formulation.	Yes		7.1 Box2
27.2	Any changes or alterations to the MFR are approved and documented.	Yes		7.1
27.3	Does the designated person(s) or designee evaluate CNSP's characteristics when considering the assigned BUD for an MFR? ***Inspector note: Per USP, "When establishing a BUD for a CNSP, compounders must consider parameters that may affect quality, including but not limited to the following:*** ***- Chemical and physical stability properties of the API and any added substances in the preparation (e.g., if the API and added substances in the preparation are known to rapidly degrade over time and/or under certain storage conditions, reduce the strength of the preparation, or produce harmful impurities)*** ***- Compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, adsorption, and storage conditions)*** ***- Degradation of the container closure system, which can lead to a reduction in integrity of the CNSP*** ***- Potential for microbial proliferation in the CNSP (and)*** ***- Significant deviations from essential compounding steps and procedures; changes to essential compounding steps may have an impact on the stability of the formulation."***	Yes		7.1, 10.2 Table 4

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
28.0	Does the pharmacy's MFRs contain all requirements in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and include as an attachment.***	Yes		7.1
28.1	MFR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.1
28.2	MFR identifies the identities and amounts of all components and, if applicable, relevant characteristics of components (eg, particle size, salt form, purity grade, solubility).	Yes		7.1
28.3	MFR includes the type of container–closure system(s).	Yes		7.1
28.4	MFR has complete instructions for preparing the CNSP, including equipment, supplies, and a description of the compounding steps. ***Inspector note: Per USP, the MFR will also include, "Other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature)." MFRs will include the detailed instructions necessary for an experienced compounder. Some examples of other details to ensure repeatability include, but are not limited to: speed duration, settings on equipment, and specific order of mixing (if applicable).*** ***Inspector should review several MFRs for completeness of instructions.***	Yes		7.1
28.5	MFR has a physical description of the final CNSP.	Yes		7.1
28.6	MFR includes the assigned beyond-use date (BUD) and storage requirements.	Yes		7.1

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
28.7	MFR contains the reference source to support the assigned BUD.	Yes		7.1
28.8	Labeling requirements (eg, shake well) are described on the MFR.	Yes		7.1
28.9	If applicable, the MFR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of APIs.	Yes		7.1
28.10	An MFR has QC procedures (eg, pH testing, visual inspection) and expected results.	Yes		7.1
29.0	Does the pharmacy complete a Compounding Record (CR) for all CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and the CR (no PHI or PII is to be collected).***	No		7.2, 14
29.1	A CR is completed for each CNSP prepared.	Yes		7.2, 14
29.2	The CR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.2, 14
29.3	The CR includes the date (or date and time) the CNSP was prepared.	Yes		7.2, 14
29.4	The CR includes the assigned internal identification number (eg, prescription, order, or lot number).	Yes		7.2, 14
29.5	The CR has a method to identify the individuals involved in the compounding process of the CNSP.	Yes		7.2, 14
29.6	The CR has a method to identify the individual who completed the review and verified the final CNSP.	Yes		7.2, 14

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
29.7	The CR includes: name, vendor or manufacturer, lot number, and expiration date of each component.	Yes		7.2, 14
29.8	The CR includes the weight or measurement of each component.	No	CR did not reference flavor and quantity in notes.	7.2, 14
29.9	The CR identifies the total quantity compounded.	Yes		7.2, 14
29.10	The CR lists the assigned BUD and storage requirements.	Yes		7.2, 14
29.11	If applicable, the CR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of API.	Yes		7.2, 14
29.12	The CR has a physical description of the final CNSP.	No	Final description does not match flavor/color of MFR.	7.2, 14
29.13	The CR includes the results of quality control procedures (eg, pH testing, visual inspection).	Yes		7.2, 14
29.14	The CR contains a MFR reference for the CNSP.	Yes		7.2, 14
29.15	Each CR is reviewed for completeness before the CNSP is released.	Yes		7.2, 8
29.16	The CR shows traceability of all components in the case of a recall or known quality issue.	Yes		7.2, 12.1, 14

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
30.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes. These checks indicate that appropriate procedures for measuring/mixing are followed for each step, including pharmacist verification of steps performed by non-pharmacists and visual inspection of preparation.*** ***Inspector should describe their observations in the Inspector Notes.***	Yes	In-process physical checks for hormone cream consistency.	2, 7.2, 8
	Labeling			
31.0	Are the pharmacy's labels for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		9
31.1	Information on the label is prominently and legibly displayed. ***Inspector note: Per USP, labeling includes other accompanying materials along with the CSP, which is defined as "All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container."***	Yes		9
31.2	The labeling meets any state or federal regulatory requirements.	Yes		1.1.3, 9
31.3	The label on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		9
31.4	The label on the immediate container includes the active ingredients and their amount(s), activity(ies), or concentration(s).	Yes		9
31.5	The label on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		9

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
31.6	The label on the immediate container includes the BUD. ***If no, please describe whether the pharmacy instead used the term "expiration date" or similar language or if this information was not included on the label.***	Yes		9
31.7	The label on the immediate container includes the dosage form.	Yes		9
31.8	The label on the immediate container includes the total amount or volume, if it is not obvious from the container.	Yes		9
32.0	Does the labeling on the dispensed CNSP include the route of administration? ***Inspector note: This is a USP recommendation.***	Yes		9
33.0	Does the labeling contain information identifying the CNSP as a compounded preparation? ***Inspector note: Per USP, this is a recommendation.***	Yes		9 USP <7>
34.0	Does the labeling on the dispensed CNSP display any applicable special handling instructions or warning statements? ***Inspector note: This is a USP recommendation.***	Yes		9
35.0	Does the labeling on the dispensed CNSP display the name of the compounding facility and contact information if the CNSP was to be sent outside of the facility or health care system? ***Inspector note: This is a USP recommendation.*** ***If the pharmacy only compounds CNSPs for patient use onsite (eg, a health care facility), inspector should answer this question as N/A .***	Yes		9

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
	Establishing Beyond Use Dating (BUDs)			
36.0	Is each CNSP assigned and labeled with a BUD in compliance with USP <795> standards? ***Inspector note: Per USP, the BUD is defined as, "The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded." This is not the same term as "expiration date." If no, go to compliance statements.***	Yes		10 USP <7>
36.1	CNSP label has a BUD that specifies the date, or the hour and date, beyond which the preparation cannot be used and must be discarded.	Yes		10.1
36.2	CNSP labels do not list an "expiration date" or equivalent language.	Yes		10.1
36.3	BUDs are assigned from the date (and time) of preparation.	Yes		10.1
36.4	BUDs are assigned based on dispensing in tight, light resistant containers/overpacks. ***Inspector note: Per USP, the Table 4 maximum limits for BUD are, "based on the ability of the CNSP to maintain chemical and physical stability and to suppress microbial growth. These BUDs represent the limit for CNSPs that are packaged in tight, light-resistant containers unless conditions in 10.4 CNSPs Requiring Shorter BUDs or 10.5 Extending BUDs for CNSPs apply."***	Yes		10.3
36.5	The BUD assigned to the CNSP does not exceed the shortest remaining expiration date of any of the commercially available starting components.	Yes		10.4

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
37.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest BUD of any individual compounded components? ***Inspector note: Per USP, "For CNSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CNSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CNSP must not be negatively impacted." Another example of these "acceptable instances" (similar to pH-altering components mentioned above) inspectors may see are stock solutions (and other formulas within a formula) such as methocel 1%.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		10.4
38.0	Does the designated person(s) evaluate a CNSP formulation to establish the maximum BUD? ***If no, who establishes the maximum BUD for a MFR?***	Yes		7.1, 10.2, 10.3
39.0	Does the pharmacy compound CNSPs with a USP monograph?	No		10.5
40.0	Does the pharmacy compound CNSPs following the USP monograph precisely? ***If no, go to compliance statements.***	N/A		10.5
40.1	Pharmacy staff have access to the USP monograph for reference.	N/A		10.5
40.2	CNSPs are prepared in accordance with the USP monographs. ***If no, inspector to collect a copy of the compounding record, label; and describe what specific steps of the monograph were not followed.***	N/A		10.5

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
40.3	Components used by the compounder match those listed in the monograph. ***If no, describe the source of the component in monograph and the source that the pharmacy used.***	N/A		10.5
40.4	The maximum BUD specified in the USP monograph is not exceeded. ***If no, identify the drug, monograph-stated BUD, and the BUD used by the pharmacy.***	N/A		10.5
41.0	Does the pharmacy compound CNSPs that are not available from a USP monograph?	Yes		10.4
42.0	Does the pharmacy adhere to the BUD (maximum) limits established in Table 4 for CNSPs in compliance with USP <795> standards? ***Inspector note: This question is for the CNSPs compounded that are <u>not</u> following a USP monograph or those CNSPs where extending BUD requirements were applied (where pharmacy has completed or has access to CNSP-Specific Stability Information). Per USP, the pharmacy is not required to measure water activity (A_w) for a CNSP.*** ***If no, go to compliance statements.*** ***If <u>all</u> CNSPs compounded at the pharmacy are following a USP monograph or the pharmacy is following a stability study that used a stability-indicating assay analytical method for the API, CNSP formulation, and material of composition of the container closure system, then the inspector should answer this question as N/A.***	Yes		10.4

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
42.1	**Non-preserved, Aqueous Dosage Forms**: The non-preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 14 days with refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound non-preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>
42.2	**Preserved, Aqueous Dosage Forms:** The preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 35 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
42.3	**Nonaqueous, Oral Liquid Dosage Forms:** The nonaqueous, oral liquid dosage form CNSP is labeled with a BUD that does not exceed 90 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous oral liquid dosage forms are ones that have a A_w < 0.6. Some examples of oral liquids that are nonaqueous include: oil-based oral solution or suspension.*** ***If pharmacy does not compound nonaqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>
42.4	**Nonaqueous Dosage Forms:** The nonaqueous dosage form CNSP is labeled with a BUD that does not exceed 180 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous (Solid) dosage forms are ones that have a A_w < 0.6. Some examples include capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.*** ***If pharmacy does not compound other nonaqueous solid dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
43.0	Does the pharmacy label any CNSPs with BUDs that extend beyond the maximum limits in Table 4 USP <795>?	Yes		10.5 Table 4
44.0	Does the pharmacy follow the requirements for labeling a CNSP with a BUD that exceeds Table 4 in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		10.5
44.1	The labeled BUD for an aqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	Yes		10.5
44.2	The labeled BUD for a nonaqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	Yes		10.5
44.3	Pharmacy is following the results of their own stability study. ***If the pharmacy only follows cited stability studies (does not conduct their own stability studies) for extending BUDs, answer this question as N/A.*** ***If pharmacy is following a bracketed study, inspector may mark this statement as yes if concentrations of CNSPs are at or within the concentrations specified within the study.*** ***If pharmacy is following a bracketed study and is using a concentration outside the study, answer this question as a no and describe observations.***	N/A		10.5

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
44.4	The pharmacy has a copy of the cited stability study, which used a stability-indicating analytical method, for extending BUDs. ***Per USP, any stability study that meets the requirements of a stability-indicating assay method can be used (whether it is published or unpublished, such as a study provided by a chemical supplier) to extend BUDs up to 180 days for a CNSP.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	Yes	PCCA references - Formula Plus	10.5
44.5	The cited stability study (which uses a stability-indicating analytical method for extending BUDs) describes the API(s), CNSP formulation, and material composition of the container closure used. ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	Yes		10.5
44.6	If the cited stability study (which uses a stability-indicating analytical method for extending BUDs) is bracketed, the pharmacy's CNSP formulation is at or within the low and high concentration of each active ingredient within the stability study. ***If no, describe the concentrations cited in the stability study and the concentration of the CNSP compounded by the pharmacy.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.***	Yes		10.5

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
44.7	Aqueous CNSPs whose labeled BUDs are extended beyond Table 4, have: - been tested for antimicrobial effectiveness at least once for each formulation in the type of (with the same material composition of the) container closure system that will be used; - received study results from an FDA-registered facility (for the same CNSP formulation using the same material composition of the container closure system); or - a study published from peer-reviewed literature (for the same CNSP formulation using the same material composition of the container closure system). ***Inspector note: Pharmacy may rely on a bracketed study from the above options as long as the bracketed study information includes the low and high concentration of each active ingredient in the formulation. Per USP, this is "to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must fall within the bracketed range.***	Yes		10.5
	Quality Assurance (QA), Quality Control (QC), and Quality Management (QM) Inspector to review at least one complaint, one adverse event, and one recall (if applicable).			
45.0	Does the pharmacy have a QA/QC program to ensure that CNSPs are prepared per the requirements in USP <795> standards and any applicable regulatory requirements? ***If no, go to compliance statements.***	Yes		1.1.3, 12
45.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (<795>) and the laws and regulations of the applicable regulatory jurisdiction."***	Yes		12
45.2	The QA/QC programs address adherence to procedures.	Yes		12

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
45.3	The QA/QC programs address prevention and detection of errors and other quality problems.	Yes		12
45.4	The QA/QC programs address evaluation of complaints and adverse events. ***Review at least one complaint and one adverse event. If there are no complaints or adverse events, review the process that the pharmacy would follow in the event of a complaint or adverse event.***	Yes		12
45.5	The QA/QC programs address appropriate investigations and corrective actions.	Yes		12
46.0	Has the pharmacy received any complaints related to CNSPs within the past year?	Yes	Patient stated cream felt as though it were thicker and grittier. One gel was "runny".	12
47.0	Does the pharmacy follow complaint handling requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.2
47.1	The pharmacy has a complete written or electronic record of each complaint made. ***Inspector note: Per USP, "The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint. In addition, to the extent that the information is known, the following should be recorded: the name and strength of the CNSP and the assigned internal identification number (e.g., prescription, order, or lot number). The record must also include the findings of any investigation and any follow-up. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained."***	Yes		12.2
47.2	Complaints are reviewed in accordance with SOPs by the designated person for the QA program.	Yes		12.2

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
47.3	Complaints are reviewed to determine whether it indicates a potential quality problem with the CNSP.	Yes		12.2
47.4	Complaints are fully investigated.	Yes		12.2
47.5	Complaint investigations consider whether the quality problem extends to other CNSPs.	Yes		12.2
47.6	Corrective action, if necessary, is implemented for all potentially affected CNSPs. ***Inspector note: Per USP, the pharmacy is to, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected."***	Yes		12, 14
47.7	A CNSP that is returned in connection with a complaint is quarantined until it is destroyed after the completion of the investigation and in accordance with the laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 12.2
48.0	Has the pharmacy initiated any recalls of CNSPs within the past two years? ***Inspector note: Per USP <795> requires all records to be readily retrievable for two years, including recalls; However, the state/jurisdictional regulator may require records to be kept for a longer period of time.*** ***Review most recent recall and describe in the Inspector Notes.*** ***If the pharmacy has not had any recalls within the past two years, inspector should answer the question as No.***	No		12.1, 14
49.0	Does the pharmacy follow recall and adverse event procedures for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.1, 12.2, 12.3

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
49.1	The pharmacy has procedures to determine when recalls must be initiated.	Yes		12.1
49.2	The pharmacy documented the implementation of the recall.	Yes		12.1
49.3	Pharmacy reports recalled CNSPs to the appropriate regulatory bodies (as required by laws and regulations of the applicable regulatory jurisdiction).	Yes		1.1.3, 12.1
49.4	Investigations into an adverse event that reveals a quality problem with a CNSP that is likely to affect other patients are reported to both patients and their prescribers.	Yes		12.3
50.0	Does the pharmacy procedures include a step to immediately notify the prescriber of a failure of specifications with potential to cause harm (eg, strength, purity, or other quality attributes)? ***Inspector note: This is a USP recommendation.***	Yes		12.1
	CNSP Packaging			
51.0	Does the pharmacy's packaging processes and materials meet the requirements in USP <795>? ***If no, go to compliance statements.***	Yes		13.1
51.1	The packaging materials protect CNSPs from damage, leakage, contamination, and degradation.	Yes		13.1
51.2	The packaging materials used protects personnel from exposure (from the packaged CNSP).	Yes		13.1
52.0	The packaging materials selected by the pharmacy maintain the physical and chemical integrity and stability needed for CNSPs (eg, protect from light).	Yes		13.1

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
	Compounding Personnel Observations - *Inspector must observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. It is acceptable for pharmacy staff to perform mock compounding activities (with two creams or other drugs) as long as all observations can be viewed.*			
53.0	**Personal Preparation Observation:** Before entering the compounding area, do personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		
53.1	Personnel removed all outer garments (eg, hats, scarves, bandanas, vests, coats, and jackets).	Yes		3.1
53.2	Personnel removed all items that are not easily cleanable and that might interfere with garbing.	Yes		3.1
53.3	Personnel removed all hand, wrist, and other exposed jewelry, including piercings, that could interfere with the effectiveness of garbing and hand hygiene (eg, watches, rings that may tear gloves).	Yes		3.1
53.4	Personnel removed earbuds or headphones.	Yes		3.1
53.5	Any accommodations permitted by the designated person(s) should be documented. ***Inspector note: Per USP <795>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	N/A	No accommodations at this time.	3.1
54.0	**Hand Hygiene Observation:** Were personnel who enter the compounding area to compound observed performing the appropriate hand washing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.2, Box 1

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
54.1	All personnel who enter the compounding area to compound performed hand hygiene.	Yes		3.2 Box 1
54.2	Personnel wash hands with soap and water for at least 30 seconds.	Yes		3.2
54.3	Personnel dry their hands completely with disposable towels or wipers.	Yes		3.2
54.4	Personnel do not solely rely on the use of alcohol hand sanitizers.	Yes		3.2
55.0	***Garbing Observation:*** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3 Box 1
55.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3 Box 1
55.2	All personnel who perform compounding activities don gloves. ***Inspector note: Per USP, "Gloves must be worn for all compounding activities."***	Yes		3.2, 3.3 Box 1
55.3	Gloves are inspected periodically for holes, punctures, or tears and replaced immediately if a defect is detected.	Yes		3.3 Box 1
56.0	Are gloves wiped or replaced before beginning compounding a CNSP with a different component or when other objects were touched (eg, pens, keyboards) to minimize risk of cross contamination with other CNSPs? ***Inspector note: This is a USP recommendation.***	Yes		3.3
57.0	List the name(s) of the CNSPs observed by the inspector as part of live compounding demonstration.			

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
58.0	**Compounding Observation:** Are compounding personnel using appropriate nonsterile compounding techniques for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		2 Box 3
58.1	The compounding personnel enter the nonsterile compounding area in accordance with the SOPs.	Yes		3.1, 4.1
58.2	The compounding personnel started with a clean compounding area for CNSPs.	Yes		4.1, 4.3, 5 Table 1
58.3	The compounding personnel selected the correct MFR for the CNSP to be prepared.	Yes		7, 7.1 Box 2
58.4	The compounding personnel performed hand hygiene. ***Inspector note: Per USP <795>, Box 1, personnel are to: wash hands with soap and water for at least 30 seconds, dry hands completely with disposable towels or wipers, and then don gloves.***	Yes		3.2 Box 1
58.5	The compounding personnel are appropriately garbed for the type of CNSP prepared.	Yes		3.3
58.6	The compounding personnel obtained the proper ingredients (APIs and/or components). ***Inspector note: All ingredients must be within date and match what is listed in the MFR. If the ingredient is an API, the COA must have already been reviewed and approved for use.***	Yes		6.2 (6.2.1 - 6.2.5)
58.7	The compounding personnel gathered all necessary materials, equipment, and supplies necessary and/or specified in the MFR and is in good working order prior to use for the CNSP. ***Inspector note: All items must be clean prior to use. If equipment requires calibration and/or certification, compounder must ensure the equipment or device is within proper specifications (eg, tare scales and/or balances).***	Yes		6.1 Table 2

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
58.8	The compounding personnel have knowledge of and access to any SDS.	Yes		6.2
58.9	The compounding personnel only compound one CNSP at a time (to proactively prevent mix-ups, errors, and cross contamination).	Yes		1.1.3
58.10	The compounding personnel compound the CNSP according to the MFR. ***If no, inspector needs to describe in detail their observations in the Inspector Notes and collect a copy of the MFR and CR (no PHI or PII to be collected).***	Yes		7.1, 7.2 Box 2
58.11	The compounding personnel document any required steps listed in the MFR on the CR. ***Inspector note: This would include any weights, volume, and any in-process checks needed.***	Yes		7.2, 14 Box 3
58.12	Documentation in the CR is legible. ***If no, collect copy of record that is illegible. Redact any PHI on record.***	Yes		14
58.13	The compounding personnel verify the correct BUD in accordance with the MFR requirements in USP <795>.	Yes		10 Table 3, Table 4
58.14	The compounding personnel performed any quality control steps specified in the MFR. ***Inspector note: Examples of this include, but are not limited to: testing of pH for a suspension, weighing of capsules, and visual inspection against product description specifications.*** ***If no, describe observations in Inspector Notes.***	Yes		7.2, 8, 8.1, 12 Box 3
58.15	The compounding personnel placed the CNSP into the proper container closure system.	Yes		8.1 Box 2

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
58.16	The compounding personnel labeled the CNSP. ***Inspector note: Storage requirements must be included on the label if refrigerated or frozen (so patient can identify the storage temperature requirements).***	Yes		9
58.17	The compounding personnel completed any documentation on the CR. ***If no, describe observations of what was missing or omitted in Inspector Notes.***	Yes		7.2, 8, 14 Box 3
58.18	The compounding personnel cleaned and sanitized the compounding area before the next CNSP (with differing ingredients) is prepared.	Yes		5
59.0	**Final CNSP check observation**: Does the visual inspection of the CNSP by the pharmacist confirm all USP <795> requirements? ***Observe a pharmacist check several CNSP prescriptions. List the name of CNSPs release inspection observed in the Inspector Notes.*** ***If no, go to compliance statements.***	Yes	Progesterone Versa 10mg/0.1 ml X 9. Methimazole Lipo 5 mg/0.1ml Lipo 150ml. Estradiol Paraben Free Cream 0.01% Versa 1015 gm.	8, 8.1, 9
59.1	CNSP was visually inspected to determine the physical appearance of the CNSP is as expected (eg, color, texture, physical uniformity), including any special characteristics listed in the MFR (eg, emulsions must be checked for phase separation).	Yes		8, 8.1
59.2	Visual inspection included checking for container closure integrity (eg, leakage, cracks, improper seals).	Yes		8, 8.1
59.3	CNSP label was verified against the prescription or medication order.	Yes		8, 8.1, 9
59.4	CNSP label was verified against the MFR.	Yes		8, 8.1, 9
59.5	CNSP label was verified against the CR.	Yes		8, 8.1, 9

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
59.6	If a CNSP will not be released or dispensed on the day the preparation was made, a visual inspection was conducted immediately before it is released or dispensed to make sure the CNSP did not develop any defects during storage.	Yes		8, 8.1
59.7	All checks and inspection that are performed are properly documented.	Yes		8.1, 14
59.8	CNSP that do not meet requirements, are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before disposal	Yes		8.1
60.0	Inspect several different finished compounded nonsterile preparations. Are all the finished compounded preparations free from any evidence of signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately.*** ***Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, particulates, dirt/debris/(suspected) mold within container closure); number of preparations affected (eg, two of the five containers on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes	Progesterone Versa 10mg/0.1 ml X 9.	12

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observation	Inspector Notes	USP Reference(s)
61.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and sanitizing activities in the compounding area in compliance with USP <795> standards? ***Document observations while pharmacy staff are performing live compounding activities in Inspector Notes.*** ***If no, go to compliance statements.***	Yes		5
61.1	Pharmacy staff starts with a clean and sanitized work surface prior to compounding a CNSP.	Yes		5 Table 1
61.2	Pharmacy staff perform cleaning and sanitizing between compounding CNSPs with different components. ***Inspector note: Per USP, "If cleaning and sanitizing are performed as separate steps, cleaning must be performed first."***	Yes		5 Table 1
61.3	Pharmacy staff ensure equipment and devices used in compounding activities are clean and sanitized after use (to prevent cross contamination of the next preparation).	Yes		6.1 Table 2
61.4	Pharmacy staff perform cleaning and sanitizing on work surfaces when visibly soiled, after spills, and/or when surface contamination is known or suspected.	Yes		5 Table 1

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Nonsterile <795> Employee File Records Review

Select the PIC, designated person, a staff pharmacist that checks compounded preparations, and two to three compounding pharmacy technicians. *Do not record the employee name, list only their title or position.
From the drop-down List:
*Mark as "Yes" if the document is present in the records and the competency evaluation was conducted in compliance with USP <795> requirements.
*Mark as "No" if the document is present in the records but is not in compliance with USP <795> requirements.
*Mark as "Missing" if any part of the record is missing and explain in Notes column.
*Mark as "N/A" if the training does not apply (eg, long-term employee may not have initial training available). Document further in the Notes column.

		Employee Records #1	Employee Records #2	Employee Records #3	Employee Records #4	Employee Records #5	
	Employee Title	**Pharmacist - DP**	**Pharmacist - PIC**	**Technician**	**Technician**	**Technician**	**Notes**
1.0	The training program provides initial training, evaluation, and documentation on the core competencies listed below:						Initial training began 1/18/2024
1.1	Compounding personnel are trained on facility SOPs.	Yes	Yes	Yes	Yes	Yes	Initial training began 1/18/2024
1.2	Compounding personnel are trained on USP <795> standards.	Yes	Yes	Yes	Yes	Yes	
1.3	The training record for hand hygiene is complete.	Yes	Yes	Yes	Yes	Yes	
1.4	The training record for garbing is complete.	Yes	Yes	Yes	Yes	Yes	
1.5	The training record for cleaning and sanitizing is complete.	Yes	Yes	Yes	Yes	Yes	
1.6	The training record for handling and transporting components and CNSPs is complete.	Yes	Yes	Yes	Yes	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

	Employee Title	Pharmacist - DP	Pharmacist - PIC	Technician	Technician	Technician	Notes
1.7	The training record for measuring and mixing is complete.	Yes	Yes	Yes	Yes	Yes	
1.8	The training record for proper use of equipment is complete.	Yes	Yes	Yes	Yes	Yes	
1.9	The training record for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Yes	Yes	Yes	Yes	Yes	
1.10	The training record for interpreting a Certification of Analysis (COA) is complete.	Yes	Yes	Yes	Yes	Yes	
1.11	The training record for how to read/interpret a Safety Data Sheet (SDS) is complete.	Yes	Yes	Yes	Yes	Yes	
1.12	The training record for spill management is complete.	Yes	Yes	Yes	Yes	Yes	
2.0	The annual competency assessment was evaluated and documented on the following topics:						Annual competencies will be performed starting January 2025.
2.1	Compounding personnel are re-trained on facility SOPs.	N/A	N/A	N/A	N/A	N/A	Annual competencies will be performed starting January 2025.
2.2	Compounding personnel are re-trained on USP <795> standards.	N/A	N/A	N/A	N/A	N/A	
2.3	The annual competency assessment for hand hygiene is complete.	N/A	N/A	N/A	N/A	N/A	
2.4	The annual competency assessment for garbing is complete.	N/A	N/A	N/A	N/A	N/A	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

	Employee Title	Pharmacist - DP	Pharmacist - PIC	Technician	Technician	Technician	Notes
2.5	The annual competency assessment for cleaning and sanitizing is complete.	N/A	N/A	N/A	N/A	N/A	
2.6	The annual competency assessment for handling and transporting components and CNSPs is complete.	N/A	N/A	N/A	N/A	N/A	
2.7	The annual competency assessment for measuring and mixing is complete.	N/A	N/A	N/A	N/A	N/A	
2.8	The annual competency assessment for proper use of equipment is complete.	N/A	N/A	N/A	N/A	N/A	
2.9	The annual competency assessment for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	N/A	N/A	N/A	N/A	N/A	
2.10	The annual competency assessment for interpreting a COA is complete.	N/A	N/A	N/A	N/A	N/A	
2.11	The annual competency assessment for how to read/interpret a SDS is complete.	N/A	N/A	N/A	N/A	N/A	
2.12	The annual competency assessment for spill management is complete.	N/A	N/A	N/A	N/A	N/A	
3.0	The designated person(s) has documented a (periodic) evaluation of their direct observations for compounding activities and documented any deficiencies in the record. *Inspector note: if there are not observations documented, the inspector should answer this question as N/A. Per USP, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*	Yes	Yes	Yes	Yes	Yes	Documented in quarterly QI Review Program.

Copyright © December 2023 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Glossary & References	USP <795>
Active Pharmaceutical Ingredient (API)	Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body. Also referred to as a bulk drug substance. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added Substance	An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with inactive ingredient, excipient, and pharmaceutical ingredient.
Administration	The preparation of a nonsterile pharmacologic or other therapeutic agent for ingesting, inserting, applying, or otherwise providing a nonsterile medication in its final form to a single patient. This includes crushing a tablet(s) or opening a capsule(s) to mix with food or liquids to facilitate patient dosing.
Alcohol-based hand rub	An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Assigned trainer	One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CNSPs.
Beyond-use date (BUD)	The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded.
Biological Safety Cabinet (BSC)	A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
Bulk drug substance	See the entry for Active Pharmaceutical Ingredient.
Certificate of analysis (COA)	A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
Cleaning	The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleaning agent	An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Closed-system processing device	A device designed to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples include CVEs, BSCs, or single-use containment glove bags.

Copyright © December 2023 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Glossary & References	USP <795>
Component	Any ingredient used in the compounding of a preparation, including any API, added substance, or conventionally manufactured product.
Compounded nonsterile preparation (CNSP)	A preparation not intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance.
Compounding	The process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.
Compounding area	An area that is specifically designated for nonsterile compounding.
Compounding personnel	Personnel trained to compound or oversee compounding of preparations.
Compounding record (CR)	Documents the compounding of each CNSP.
Container closure system	Packaging system components that together contain and protect the dosage form. This includes primary packaging system components and secondary packaging system components if the latter are intended to provide additional protection.
Containment glove bag	A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE)	A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.
Conventionally manufactured product	A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Designated person(s)	One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CNSPs.
FDA	US Food and Drug Administration
Formulation	The specific qualitative and quantitative composition of the final CNSP.
Hazardous Drug (HD)	Any drug identified by at least one of the following criteria: carcinogenicity, teratogenicity or developmental toxicity; reproductive toxicity in humans; organ toxicity at low dose in humans or animals; genotoxicity or new drugs that mimic existing HDs in structure or toxicity. See <800>.
Label	The part of the labeling on the immediate container.
Labeling	All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container.

Copyright © December 2023 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Glossary & References	USP <795>
Master formulation record (MFR)	A detailed record of procedures that describes how the CNSP is to be prepared.
Monograph	A quality documentary standard within USP–NF that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Oversight	The review, monitoring, and supervision of actions taken by personnel; bearing responsibility for those actions; and being available if and when needed for consultation, even if not physically present.
Preservative	A substance added to inhibit microbial growth.
Purified water	The minimal quality of source water for the production of Purified Water is drinking water whose attributes are prescribed by the US Environmental Protection Agency (EPA), the European Union, Japan, or the World Health Organization (WHO). This source water may be purified using unit operations that include deionization, distillation, ion exchange, reverse osmosis, filtration, or other suitable purification procedures. (See <1231>, 3.1.1 Purified Water.)
Quality Assurance (QA)	A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.
Quality Control (QC)	The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met for the CNSP.
Reconstitution	The process of adding a diluent to a conventionally manufactured product to prepare a solution or suspension.
Release inspection and testing	Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
Sanitizing agent	An agent for reducing, on inanimate surfaces, the number of microorganisms (eg, 70% isopropyl alcohol).
SDS	Safety data sheet.
SOP	Standard operating procedure.
Specification	The tests, analytical methods, and acceptance criteria to which any components, CNSP, container closure system, equipment, or other material used in the compounding of CNSPs must conform to be considered acceptable for its intended use.
Stability	The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
Verify	To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Water activity (a_w)	A measure of the fraction of total water that is unbound and freely available to participate in chemical, biochemical, or physicochemical reactions or provide an environment that can support microbial growth. Note that a_w is not water content.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
	General Information and Scope:		
1.00	Does the pharmacy handle any drugs on the National Institute for Occupational Safety and Health (NIOSH) list that **require** all the containment requirements of USP <800>?	Yes	Anastrozole, Chlorambucil, Fluorouracil
1.01	Does the pharmacy handle any ***hazardous drug*** active pharmaceutical ingredients (HD API)? *If yes, please list.*	Yes	
1.02	Does the pharmacy handle any antineoplastic requiring manipulations (which can produce particles, aerosols, or gasses)? *If yes, please list.*	Yes	Anastrozole, Chlorambucil, Fluorouracil
2.00	Does the pharmacy handle any drugs on the NIOSH list that **do not** require all containment requirements of <800>?	Yes	
2.01	Does the pharmacy handle any final dosage forms of HDs (either compounded or manufactured unless required by the manufacturer) that do not require further manipulation other than counting and repackaging? *If yes, please list.*	Yes	Cyclosporine, Progesterone, Estrogen, Testosterone, Methimazole, Zonisamide, Piroxicam.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
2.02	Does the pharmacy handle any dosage forms of other HDs **that are handled in full compliance** with containment requirements of <800>? *If yes, please list.*	No	
2.03	Does the pharmacy handle any dosage forms of other HDs **that are not handled** using all containment requirements of <800>? *If yes, please list.*	Yes	All other medications not on NIOSH Group 1. See Doc06_Haz3.00
	List of Hazardous Drugs		
3.00	The pharmacy maintains a list of any items it handles that are included on the current NIOSH list of antineoplastic and other HDs. ***Review and attach list.*** *Verify that pharmacy has access to a copy of current NIOSH list.*	Yes	See Doc06_Haz3.00
4.00	The pharmacy reviews this list at least every 12 months for additions, deletions, or other changes and documents the review. *Verify documentation and* ***list date*** *of last change/review.*	Yes	3/21/2024 last review/update
5.00	The pharmacy reviews this list whenever the pharmacy adds a new agent or dosage form to the items it handles.	Yes	
6.00	The pharmacy has a system in place for the evaluation of new drugs (purchased, stored, handled, and/or dispensed) to determine whether they are considered HD.	Yes	
6.01	Pharmacy evaluates the drugs against the current version of the NIOSH list.	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
6.02	In the absence of information, the pharmacy treats any new drug as an HD.	Yes	
7.00	If the pharmacy handles any HDs not using all containment requirements of <800>, an assessment of risk was performed for each drug and dosage form individually to determine alternative containment strategies, if needed, and work practices for each. *Review documentation of assessment and SOPs related to work practices/alternative containment.*	Yes	
8.00	The assessment of risk evaluation performed by the pharmacy's organization includes all required information, for each drug and dosage form. *The first five (5) items below must be included in the evaluation in order to be compliant.*	Yes	
8.01	Type of HD (eg, antineoplastic, non-antineoplastic, reproductive risk only);	Yes	
8.02	Dosage form;	Yes	
8.03	Risk of exposure;	Yes	
8.04	Packaging;	Yes	
8.05	Manipulation; and	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
8.06	If applicable, Table II and III drugs have alternative containment strategies and/or work practices to minimize occupational exposure.	Yes	
8.07	The assessment of risk is reviewed at least every 12 months, and the review is documented. *Enter date of last review in the notes.*	Yes	11/1/2023
	Personnel Responsibilities		
9.00	The pharmacy has a designated person(s) to oversee the handling of HDs who is qualified and trained for development of standard operating procedures (SOPs); overseeing compliance with standards, laws, and rules; ensuring competency of personnel; and ensuring environmental control.	Yes	
9.01	The designated person oversees the monitoring of the facility, including testing/sampling programs, maintaining, and documentation, and acting on results.	Yes	
	Documentation and Standard Operating Procedures (SOPs)		
10.00	The assessment of risk and SOPs for handling HDs addresses all potential types of exposure, including all activities occurring within the operation that present an opportunity for exposure:		SOP 6.5, version 1.0
10.01	**Receiving**: Contacting HD residues on packaging, work surfaces, floors	Yes	SOP 3.12, version 1.0

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
10.02	**Dispensing**: Counting or packaging tablets and capsules	Yes	SOP 6.5, version 1.0
10.03	**Compounding/other manipulations**: Crushing/splitting tablets, opening capsules, pouring liquids, weighing or mixing, constituting/reconstituting powdered/lyophilized HDs, expelling air from HD syringes, HD residue on personal protective equipment (PPE), cleaning activities of HD areas, and HD equipment maintenance.	Yes	SOP 1.35, version 1.0 and 1.65, version 1
10.04	**Administration and other patient care activities** (if applicable).	N/A	
10.05	**Spills**: Spill generation, management, and disposal.	Yes	SOP 3.4, version 1.0
10.06	**Transport**	Yes	SOP 3.12, version 1.0
10.07	**Waste**: Collection and disposal of HD waste and trace contaminated waste	Yes	SOP 3.3, version 1.0
11.00	SOPs are reviewed at least every 12 months by the designated person, and the review is documented.	Yes	5/2/2024
12.00	SOPs are readily available to all who may need to handle HD or respond to a spill (pharmacy employees, housekeeping, nursing personnel, delivery personnel, etc). *Describe whether P&Ps are available electronically, by paper, or both.*	Yes	Electronically available as well as in a binder.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
13.00	SOPs address at a minimum: *If no, document "missing" in Inspector Notes for each SOP topic*		**Please note NABP did not review each SOP for alignment on USP <800>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**
13.01	Hazard communication program plan	Yes	SOP 6.4, version 2.0
13.02	Competent personnel	Yes	SOP 1.5 version 1.0, 1.6 version 2.0, 1.65 version 1.0
13.03	Occupational safety program	Yes	SOP 6.4, version 2.0
13.04	Designation of HD areas	Yes	SOP 1.35 version 1.0
13.05	Receiving HDs, including handling of damaged shipping containers/breakages	Yes	SOP 3.10 version 1.0
13.06	A list of HDs	Yes	
13.07	Storage of HDs	Yes	SOP 3.10 version 1.0
13.08	Compounding of HDs	Yes	SOP 1.35 version 1.0

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
13.09	Use and maintenance of proper engineering controls (eg, containment primary engineering control [C PECs], containment secondary engineering control [C SECs], and closed system drug transfer device [CSTDs]) to include SOPs for repairs, loss of power, moving, etc.	Yes	SOP 1.35 version 1.0
13.10	Hand hygiene and proper use of appropriate PPE based on activity (eg, receipt, transport, compounding, administration, spill, disposal).	Yes	SOP 6.4, version 2.0
13.11	Deactivation, decontamination, cleaning, disinfection SOPs include all of the following:		SOP 1.25 version 1.0
13.11.01	Agents used	Yes	Peridox, Clorox bleach wipes, Alcohol 70%
13.11.02	Dilutions, if used	N/A	All RTU
13.11.03	Frequency	Yes	

Copyright ® March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
13.11.04	PPE to be worn (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted--addressed in SOPs)	Yes	
13.11.05	Documentation requirements	Yes	
13.12	Receiving SOPs to include communications with suppliers about packaging and visual/other inspection of shipping containers for signs of damage and how to handle damaged containers.	Yes	
13.13	If a shipping container appears damaged and **does not need to be opened**:		
13.13.01	It is sealed without opening and wrapped in impervious plastic;	Yes	
13.13.02	Labeled as "hazardous"; and	Yes	
13.13.03	Returned to the supplier after contacting the supplier or disposed of as hazardous waste if supplier declines return.	Yes	
13.14	If a damaged shipping container **must be opened**:		
13.14.01	Container is sealed in plastic or an impervious container;	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
13.14.02	It is transported to the C-PEC before opening, preferably nonsterile compounding C-PEC, if available;	Yes	
13.14.03	container is placed on a plastic-backed preparation mat;	No	
13.14.04	It is opened and undamaged items are removed and wiped down with a disposable wipe;	Yes	
13.14.05	Damaged item is enclosed in an impervious container and labeled "hazardous";	Yes	
13.14.06	Damaged item is returned to the supplier or disposed of as hazardous waste;	Yes	
13.14.07	Deactivate, decontaminate, and clean the C-PEC in accordance with SOPs; and	Yes	
13.14.08	If a sterile compounding C-PEC must be used, it is also disinfected after cleaning prior to resuming any sterile compounding activities.	N/A	No sterile compounding
13.15	Safe work Practices SOPs	Yes	
13.16	Dispensing SOPs	Yes	
13.17	Packaging and labeling SOPs	Yes	
13.18	Transport SOPs	Yes	

Copyright ® March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
13.19	Administering SOPs, if applicable	N/A	
13.20	***Recommendation: Environmental monitoring (eg, wipe sampling) SOPs***	No	
13.21	HD waste segregation and disposal (including reference to following local, state, and federal regulations) SOPs	Yes	
13.22	Spill prevention and direction of spill cleanup and control SOPs must address the following:		SOP 3.40 version 1
13.22.01	Size and scope of spill;	Yes	
13.22.02	Responsible person for handling spills;	Yes	
13.22.03	Location of spill kits and clean-up materials;	Yes	
13.22.04	Capacity of the spill kits;	Yes	
13.22.05	PPE to be worn during spills;	Yes	
13.22.06	Handling of worn PPE and any exposed clothing under PPE;	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
13.22.07	Use of appropriate full-face, chemical cartridge-type respirator or powered air-purifying respirators (PAPR) if capacity of spill kit is exceeded or known or suspected airborne exposure to vapors/gases; and	Yes	
13.22.08	Medical evaluation/incident reporting/documentation/other handling of persons potentially exposed or with direct skin/eye contact to the HD.	Yes	
13.23	***Recommendation:*** *Does the pharmacy have a medical surveillance program? (a comprehensive control program to monitor and identify potential worker health care issues from HD exposure.)*	No	
14.00	The **hazard communication program** SOP has policies and procedures that ensure worker safety in all aspects of HD handling relevant to the pharmacy and ensure effective personnel training in proper labeling, transport, storage, and disposal of HDs, use of Safety Data Sheets (SDSs), based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).	Yes	
15.00	The pharmacy's hazard communication program includes, at a minimum, all of the following:		
15.01	A written plan that describes how the standard will be implemented;	Yes	
15.02	How containers of HDs/hazardous chemicals will be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings;	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
15.03	SDSs are maintained for each hazardous chemical they use (29 CFR 1910.1200);	Yes	Available electronically and in hard copy
15.04	How SDSs are readily accessible to personnel during each work shift and when they are in their work areas;	Yes	
15.05	Information and training provided to personnel prior to initial assignment to work with a hazardous chemical and whenever the hazard changes; and	Yes	
15.06	Personnel of reproductive capability confirm in writing that they understand the risks of handling HDs.	Yes	
	Personnel Training --*Check four employee files for documentation*		
16.00	All personnel handling HDs are trained based on their job function prior to independently handling HDs.	Yes	
17.00	Personnel file contains the employee's acknowledgement of the risk of handling HD (as part of the hazardous communication program).	Yes	
18.00	For non sterile HD compounding, personnel competency is observed and assessed at least annually for proper compounding technique, with no concerns identified.	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
19.00	For sterile HD compounding, personnel competency is observed and assessed at least annually for proper sterile compounding aseptic technique, with no concerns identified.	N/A	
20.00	After initial HD training, personnel are trained prior to introduction of any new HD or new equipment, or prior to any significant change in process or SOP.	Yes	
21.00	All HD training and assessments are documented for each employee who transports, compounds, or administers HDs, and meets Occupational Safety and Health Administration Standard 1910.120 and any other requirements of law or regulation.	Yes	
22.00	All personnel who perform custodial HD waste removal and cleaning in HD handling areas are trained in appropriate procedures to protect themselves and the environment.	Yes	
23.00	HD training, based on employee file review, all of the following are present:		
23.01	Overview of pharmacy's HD list and their risks;	Yes	
23.02	Review of the SOPs related to HDs;	Yes	
23.03	Proper use of PPE;	Yes	
23.04	Proper use of equipment and devices (eg, engineering controls);	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
23.05	Appropriate procedures for deactivation, decontamination, cleaning, and disinfection (if applicable);	Yes	
23.06	Response to known or suspected HD exposure;	Yes	
23.07	Spill management;	Yes	
23.08	Proper disposal of HDs and trace-contaminated materials; and	Yes	
23.09	New HD drug/new equipment or prior to any significant change in process or SOP.	Yes	
24.00	If respiratory protection is needed for any HDs handled, personnel are fit tested and trained in the proper use of the respirator.	Yes	
	Personal Protective Equipment		
25.00	For sterile and nonsterile compounding with HDs, personnel wear gowns; head, hair, and shoe covers; and two pairs of chemotherapy gloves.	Yes	
26.00	Appropriate PPE is readily accessible where HD is handled, include all of the following:		
26.01	Receipt (PPE appropriate to HD as set forth in SOPs, and at a minimum, chemotherapy gloves worn);	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
26.02	Storage;	Yes	
26.03	Transport;	Yes	
26.04	Nonsterile Compounding (if performed by the pharmacy);	Yes	
26.05	Sterile Compounding (if performed by the pharmacy);	N/A	
26.06	Administration, if applicable;	N/A	
26.07	Deactivation/decontamination, cleaning, and disinfecting (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted/addressed in SOPs);	Yes	
26.08	Spill control;	Yes	
26.09	Waste disposal; and	Yes	
26.10	If administering injectable antineoplastics, two pairs of chemotherapy gloves and permeability resistant gowns are worn.	N/A	
27.00	Disposable PPE is not reused.	Yes	
28.00	Reusable PPE is decontaminated and cleaned after each use.	Yes	Goggles and Face Shields

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
29.00	**Gloves**: The pharmacy is using appropriate gloves for the activities conducted (chemotherapy gloves meet ASTM standard D6978 -- or its successor -- and are resistant to cleaning agents used) and are resistant to cleaning agents used.	Yes	
29.01	**Recommendation**: Are *chemotherapy gloves worn for handling all HDs including non antineoplastics and for reproductive risk only HDs?*	Yes	
29.02	Chemotherapy gloves are powder free.	Yes	
29.03	Chemotherapy gloves are inspected for physical defects before use and defective gloves (eg, pin holes, tears, weak spots) are discarded.	Yes	
29.04	For sterile compounding, the outer chemotherapy gloves are sterile.	N/A	
29.05	Chemotherapy gloves are changed when torn, punctured, or contaminated.	Yes	
29.06	**Recommendation**: Are *chemotherapy gloves changed every 30 minutes (unless otherwise recommended by the manufacturer)?*	Yes	
29.07	Hands are washed with soap and water after removing chemotherapy gloves.	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
30.00	**Gowns**: The pharmacy is using appropriate gowns for the activities conducted (if required for type of compounding based on standards or assessment of risk).	Yes	
30.01	Gowns are disposable.	Yes	
30.02	Gowns resist permeability of HDs and are not laboratory coats, surgical scrubs, or isolation gowns (selected based on HDs handled).	Yes	
30.03	Gowns close in the back, are long sleeved, and have closed cuffs that are elastic or knit.	Yes	
30.04	Gowns do not have seams or closures that will allow HDs to pass through.	Yes	
30.05	Gowns are changed in accordance with the manufacturer's instructions, or if no permeation information is available, they are changed every two to three hours or immediately after a spill or splash.	Yes	
30.06	Gowns worn in HD areas are not worn to other areas.	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
31.00	**Head, hair** (beard and moustache, if appropriate)**, and shoe and sleeve covers.** The pharmacy is using appropriate head, hair, and shoe and sleeve covers for the type of compounding based on standards or assessment of risk to provide protection from contact with HD residue, if required.	Yes	
31.01	When HD compounding, a second pair of shoe covers are donned before entering the C SEC and doffed when exiting the C SEC.	Yes	
31.02	Shoe covers worn in HD areas are not worn into other areas of the facility.	Yes	
32.00	**Eye and Face Protection**: The pharmacy is using appropriate eye and face PPE protection for the activities conducted (based on assessment of risk that HDs are irritating to the eyes and mucous membranes, where there is risk of spills or splashes when working outside of a C PEC), if required.	Yes	
32.01	If a risk to eyes, goggles (or a full face respirator) are worn. *Eyeglasses or safety glasses with side shields are not substituted for goggles.*	Yes	
32.02	If a risk to face and eyes, goggles plus a face shield (or a full face respirator) are worn.	Yes	

Copyright ©March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
33.00	**Respiratory Protection**: The pharmacy is using appropriate respiratory PPE protection for the activities conducted (receiving, transport, compounding, administration, and waste disposal) based on assessment of risk based on type of HD and type of activity, if required. *Indicate what type of PPE which is available to employees (and is fit tested, when required).*	Yes	
33.01	Fit-tested NIOSH-certified N95 respirator;	Yes	
33.02	Elastomeric half-mask with a multi-gas cartridge and P100-filter;	Yes	
33.03	Full-face piece, chemical cartridge-type respirator;	Yes	
33.04	PAPR; and/or	No	
33.05	Other (describe in notes).	No	
34.00	Surgical masks are **not** used as PPE when respiratory protection is needed.	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
35.00	The pharmacy uses an appropriate respiratory PPE for large HD spills; deactivating, decontaminating, and cleaning underneath the work surface of the C-PEC; and when there is known or suspected airborne exposure to powders or vapors. *Indicate what type of PPE which is available to employees (and is fit-tested, when required).*	Yes	
35.01	Fit-tested NIOSH-certified N95 respirator;	Yes	
35.02	Elastomeric half-mask with a multi-gas cartridge and P100-filter;	Yes	
35.03	Full-facepiece, chemical cartridge-type respirator;	Yes	
35.04	PAPR; and/or	No	
35.05	Other (describe in notes).	No	
36.00	Surgical masks are **not** used as PPE when respiratory protection is needed.	Yes	
37.00	**Disposal of Used PPE**: Is all PPE worn during handling of HDs considered contaminated with at least trace quantities?	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
37.01	Worn PPE is placed in an appropriate HD waste container.	Yes	
37.02	The HD waste container is located in reasonable proximity to HD PPE doffing activities.	Yes	
37.03	Chemotherapy gloves, and sleeve covers if worn, are carefully removed and discarded immediately into an approved HD trace waste container inside the C PEC or contained in a sealable bag for discarding outside the C PEC.	Yes	
	Facilities and Engineering Controls		
38.00	There are signs prominently displayed before the entrance to all HD handling areas designating the hazard.	Yes	
38.01	Access to these areas are restricted to authorized personnel who have been appropriately trained.	Yes	
38.02	HD areas are located away from breakrooms/refreshment areas for personnel, patients, and/or visitors.	Yes	
39.00	There are designated HD areas for any of the following:		
39.01	Receiving and unpacking of HDs	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
39.02	Storage of HDs	Yes	
39.03	Nonsterile HD compounding (if performed by the pharmacy)	Yes	
39.04	Sterile HD compounding (if performed by the pharmacy)	N/A	
40.00	***Recommendation***: *If there is a requirement for certain designated areas to have negative pressure from surrounding areas, is there an uninterrupted power source (UPS) to the ventilation systems in order to maintain negative pressure in the case of power loss?*	Yes	Negative pressure HD compounding room
41.00	**Receipt**: Are HDs received and unpacked (removed from external shipping containers) in an appropriate environment? *Describe.*	Yes	
41.01	Antineoplastics and HD APIs are unpacked in an area with air pressure relative to surrounding areas that is either neutral or negative pressure. *Indicate the type of environment. If the environment is positive pressure, it is non-compliant.*	Yes	
41.01.01	Neutral	Yes	
41.01.02	Negative	No	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
42.00	HDs are not unpacked in a sterile compounding area (eg, no external containers are brought into C SEC).	Yes	
43.00	**Storage**: Are HDs stored in a manner to minimize accidental exposure? *Describe.*	Yes	
43.01	HDs are not stored on the floor.	Yes	
43.02	HDs are stored in a manner to minimize breakage and spillage.	Yes	
43.03	If facility is in an area prone to specific types of natural disasters, appropriate precautions are taken (eg, raised front lips on shelving in earthquake prone areas).	N/A	
44.00	Antineoplastic HDs that require manipulation (other than counting and repackaging final dosage forms) and HD API are stored separately from non HDs.	Yes	
44.01	These HDs are stored in an externally ventilated, negative pressure room.	Yes	
44.02	The HD storage room has at least 12 air changes per hour (ACPH).	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
44.03	Refrigerated antineoplastic HDs are stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH (eg, storage room, buffer room, or containment segregated compounding area [C SCA]).	Yes	
44.04	**Recommendation**: *If the refrigerator is located in a buffer room, is an exhaust located adjacent to the refrigerator's compressor and behind the refrigerator?*	N/A	
45.00	If non antineoplastic, reproductive risk only, and final dosage forms of antineoplastics are stored with other non HD inventory, there is a written policy/SOP addressing it.	Yes	
46.00	**Compounding**: There are appropriate engineering controls to protect the HD preparation from cross contamination, and if sterile compounding, from microbial contamination, during all phases of the compounding process.	Yes	
47.00	All HD compounding are performed within a C PEC located in a C-SEC room.	Yes	
47.01	The C SEC for both sterile and nonsterile HD compounding has all of the following:		
47.01.01	Has fixed walls;	Yes	
47.01.02	Is externally vented;	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
47.01.03	Is able to meet (12) or exceed ACPH requirements;	Yes	
47.01.04	Is physically separated (ie, a different room) from other preparation areas; and	Yes	
47.01.05	Has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to all adjacent areas.	Yes	
48.00	The C PEC operates continuously if it supplies some or all of the negative pressure in the C SEC or if it is used for sterile compounding.	Yes	
49.00	There is a sink readily available for handwashing on the hazardous side.	Yes	
49.01	There is an eyewash station readily available.	Yes	
49.02	Water sources and drains are a minimum of 1 meter away from the C PEC.	Yes	
50.00	Does the pharmacy engage in **nonsterile HD compounding**? If yes, complete 50.01 54. If no, skip to 55:	Yes	
50.01	Select the location where **nonsterile HD compounding** is performed type(s):		
50.01.01	C-PECs used for sterile HD compounding are located in a different room than C-PECs used for nonsterile HD compounding	N/A	No sterile compounding
50.01.02	C-PECs used for sterile HD compounding are located in the same room as C-PECs used for nonsterile HD compounding.	N/A	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
50.02	Select the type(s) of containment primary engineering control(s) used for **nonsterile HD compounding**:		
50.02.01	Class I biological safety cabinet (BSC)	No	
50.02.02	Class II BSC	No	
50.02.03	Containment ventilated enclosure (CVE)	Yes	
50.02.04	Compounding aseptic containment isolator (CACI)	No	
50.02.05	Other, describe	No	
51.00	Indicate if the C-PEC used for **nonsterile HD compounding** (must be one of two below in order to be compliant):		
51.01	Is externally vented *(preferred)* ; **and/or**	No	
51.02	Has redundant High Efficiency Particulate Air (HEPA) filters in series	Yes	
52.00	Does the pharmacy use the same C PEC (Class II BSC or CACI) used for sterile HD compounding and nonsterile HD compounding?	N/A	
52.01	Is **nonsterile HD compounding** only "occasional"? / *If yes, please describe frequency and quantity.*	No	
52.02	Is the **nonsterile HD compounding** activity only occurring when sterile HD compounding is not being performed?	N/A	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
52.03	Is the C PEC decontaminated, cleaned, and disinfected prior to resuming sterile compounding?	N/A	
53.00	The C SEC has at least 12 ACPH. *Verify documentation and monitoring.*	Yes	
54.00	The ceilings, walls, floors, fixtures, shelving, counters, and cabinets are smooth, impervious, free from cracks and crevices, and non shedding. *If non-compliant describe*	Yes	
55.00	Does the pharmacy engage in **sterile HD compounding**? If yes, complete 55.01 61.02.03. If no, skip to 62.	No	
55.01	Select the type(s) of containment primary engineering control(s) used for **sterile HD compounding**:		
55.01.01	CACI	N/A	
55.01.02	Class II BSC, Type A1 (formerly Type A and not suitable for volatile toxic chemicals and volatile radionuclides)	N/A	
55.01.03	Class II BSC, Type A2 (formerly Type B3)	N/A	
55.01.04	Class II BSC, Type B1	N/A	
55.01.05	Class II BSC, Type B2 (total exhaust for volatile components)	N/A	
55.01.06	Class III BSC	N/A	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
55.01.07	LAFW (not for antineoplastics)	N/A	
55.01.08	CAI (not for antineoplastics)	N/A	
56.00	The C PEC maintains ISO Class 5 or better air quality and is under continuous operation, unless power loss or repair occurs.	N/A	
57.00	Is the C-PEC used for **sterile HD compounding** externally vented?	N/A	
58.00	If a BSC or CACI that is used for **sterile HD compounding** is also used for non HD preparations, is the non HD preparation placed into a protective outer wrapper during removal from the C PEC?	N/A	
58.01	If used for both, is the non HD preparation labeled to require PPE handling precautions?	N/A	
59.00	If the C SEC is an unclassified containment segregated HD compounding area (C SCA: enclosed separate room with fixed walls, but not ISO classified), beyond-use dates (BUDs) are limited in accordance with <797> as Category 1 compounded sterile preparations.	N/A	
59.01	The C SEC (C-SCA) has at least 12 ACPH. *Verify documentation and monitoring.*	N/A	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
59.02	A handwashing sink is at least one meter or more away from the C-PEC	N/A	
59.02.01	Describe whether the sink is inside the C-SCA or directly outside the C-SCA		
60.00	If BUDs are longer than the Category 1 BUDs specified in <797>, the PEC is located in a C SEC, which is an ISO Class 7 buffer room adjacent to an ISO Class 7 anteroom.	N/A	
60.01	The buffer room has fixed walls.	N/A	
60.02	The buffer room is externally vented.	N/A	
60.03	The buffer room has HEPA filtered supply air.	N/A	
60.04	The buffer room has at least 30 ACPH.	N/A	
60.05	The buffer room has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to the anteroom.	N/A	
60.06	The anteroom has fixed walls.	N/A	
60.07	The ante room has a minimum of 30 ACPH of HEPA filtered supply air.	N/A	
60.08	The ante room maintains positive pressure of at least 0.02 inches water column relative to any adjacent unclassified areas.	N/A	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
60.09	The handwashing sink is located in the anteroom at least 1 meter or more away from the door to the buffer room to prevent contamination into the negative pressure buffer room.	N/A	
61.00	If the negative pressure HD buffer room is entered through a positive pressure non HD buffer room, there is a line of demarcation within the buffer room for donning and doffing PPE.	N/A	
61.01	There is a design and method to contain and minimize HD contamination when **transporting** HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room:	N/A	
61.02	Indicate how HD contamination is minimized:		
61.02.01	Pass-through chamber between negative pressure buffer room and adjacent space included in the facility's certification not compromising air quality in the buffer room *(verified in the facility's semi-annual certification report that pass through has not compromised air quality in the buffer room)*	N/A	
61.02.02	Use of sealed containers	N/A	
61.02.03	Other, *describe*	N/A	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
	Environmental Quality and Control - Surface wipe sampling		
62.00	**Recommendation**: **Surface wipe sampling** is performed routinely (initially and at least every six months) to monitor HD containment processes and trends, which includes all of the following:	No	
62.01	Interior of C-PEC and equipment within the C-PEC	N/A	
62.02	Pass-through chambers	N/A	
62.03	Surfaces in staging or work areas near the C-PEC	N/A	
62.04	Areas adjacent to the C-PEC (eg,. floors directly under, staging, and dispensing areas)	N/A	
62.05	Areas immediately outside the HD buffer room or the C-SCA	N/A	
	Receiving		
63.00	**Recommendation**: HDs are packaged by the supplier in impervious plastic to segregate them from other drugs and decrease possibility of exposure during unpacking and internal transfer.	Yes	
64.00	HDs are delivered to the HD storage area immediately after unpacking.	Yes	
65.00	A spill kit is readily accessible in the receiving area.	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
66.00	Containers are visually examined for signs of damage or breakage prior to opening.	Yes	
67.00	If a shipping container appears damaged and does not need to be opened, it is sealed, enclosed in an impervious container, labeled "hazardous" on the outside, and returned to the supplier after contact or disposed of as hazardous waste.	Yes	
67.01	If a damaged shipping container must be opened, it is done so according to SOPs, to include sealing the container in plastic or an impervious container, transporting it to the C PEC for unpacking, removing, and wiping the outside of the undamaged items with disposable wipes, resealing the damaged items in an impervious container and marking it "hazardous," returning it to the supplier after contact or disposing as hazardous waste, and deactivating, decontaminating, and cleaning the C PEC.\	Yes	
68.00	Damaged packages are considered spills and reported to the designated person. ***List last date of damaged package receipt.***	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
	Labeling, Packaging, Transport, and Disposal		
69.00	HDs requiring special HD handling are always clearly labeled as hazardous during transport and in accordance with any laws related to labeling of HDs.	Yes	
70.00	Labeling processes do not introduce contamination into non HD handling areas.	Yes	
71.00	Packaging materials are chosen that protect the HD and healthcare worker against damage, leakage, contamination, and degradation during transport, but also maintains the physical integrity, stability, and sterility of the HD.	Yes	
72.00	Pneumatic tubes are not used for transporting any liquid HDs or antineoplastic HDs.	N/A	
73.00	Labeling on HDs shipped outside the pharmacy meets all of the following requirements:		
73.01	Labeling specified in SDS for transport;	No	
73.02	Storage and disposal instructions; and	Yes	
73.03	Labeled with HD category.	No	

Copyright ©March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
	Dispensing, Packaging, and Compounding Processes		
74.00	Counting of antineoplastics is done by hand (eg, not placed into automated counting devices).	Yes	
75.00	Clean, dedicated (not used for non HD purposes), or disposable equipment is used for counting, packaging, and compounding of HDs.	Yes	
75.01	**Recommendation**: Equipment is decontaminated after every use.	Yes	
75.02	**Recommendation**: When compounding, a plastic backed preparation mat is placed on the C PEC work surface and changed and discarded appropriately as HD waste. All of the following should apply in order to make this a Yes.	No	
75.02.01	Immediately if a spill occurs	Yes	
75.02.02	Regularly during use	Yes	
75.02.03	At the end of a shift	Yes	
76.00	APIs or other powdered HDs are handled in a C PEC during particle generating activities, such as crushing, opening capsules, and weighing powders.	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
	Deactivating and Decontaminating (Cleaning and Disinfecting are performed in accordance with Chapters <795> and <797>)		
77.00	The pharmacy has chosen appropriate oxidizing agent(s) for deactivation and decontamination and proven effective by testing.	Yes	
78.00	Wipes or other appropriate delivery mechanisms (eg, not a spray bottle) are used for deactivation and decontamination.	Yes	
79.00	The C-PEC must be decontaminated. *All of the following must be done to be compliant.*	Yes	
79.01	Between compounding of different HDs	Yes	
79.02	At least daily when used	Yes	
79.03	Any time a spill occurs	Yes	
79.04	Before and after certification	Yes	
79.05	Any time voluntary interruption occurs	Yes	
79.06	If the ventilation tool is moved	Yes	
80.00	HD containers are wiped down prior to placing them in the C PEC and the solution used does not alter the product label.	Yes	

Copyright ® March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Poulsbo Compounding Pharmacy, LLC dba Cascade Specialty Pharmacy

e-Profile ID: 1810127

Inspection Date: 06/10/2024, 6/12/2024 and 6/13/2024

		Observatio	Notes
81.00	Areas, other than the work surface of the C PEC, where contamination can build up (such as areas under the work tray), are deactivated, decontaminated, and cleaned at least monthly.	Yes	
82.00	Additional PPE (eg, respirator) is used in accordance with SOPs, to protect the worker if containment airflows are compromised by opening the cabinets to get to these areas.	Yes	
	Spill Control		
83.00	Spills are contained and cleaned immediately.	Yes	
84.00	Trained/qualified personnel are always available during operation with HDs to handle spills.	Yes	
85.00	Only trained/qualified personnel engage in spill containment and cleanup.	Yes	
86.00	There are signs available to restrict access to spill areas.	Yes	
87.00	Spill kits, containing all ingredients necessary to clean HD spills, are readily available in all areas where HDs are routinely handled.	Yes	
88.00	Spill materials are disposed of as hazardous waste.	Yes	
89.00	The circumstances and management of all spills are documented. ***Review documentation for spills for the last year and list the most recent date.***	Yes	No spills to date.

4WW

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	☒ Retail/Community	☐ Retail/Community
☒ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☒ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH_____		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☒ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Costco Wholesale Corporation dba Costco Pharmacy #1710

Physical Address: 310 Integrity Drive Suite 105

City: Madison State: WI Zip: 53717

Mailing Address (if different from physical address): P.O. Box 35005 Attn: Licensing

City: Seattle State: WA Zip: 98124-3405

Telephone: 855-213-0070 Toll Free # (NAC 639.708, NRS 639.23286): 855-213-0070

Fax: _____ Contact Email: pharmacylicenses@costco.com

Website: https://www.costco.com/pharmacy/

Nevada Business License # (if applicable) NV19871025196

Supervising/Managing Pharmacist Name (NRS 639.220): Nicholas Cox

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24017

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Nicholas Cox	NV Pharmacist Registration #: 24017
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: Washington

Parent Company (if any):

Corporation Name: Costco Wholesale Corporation

Mailing Address: Attn: Licensing, P.O. Box 35005

City: Seattle State: WA Zip: 98124-3405

Telephone: 425-313-8100 Email: pharmacylicenses@costco.com

Contact Person Name: Heather Cimuchowski

Date of SEC Registration: 12/05/1985	SEC Registration Number: 0-20355	Stock Exchange Symbol: COST

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☒ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the SVP - Pharmacy (title) for Costco Wholesle Corporation (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Richard Stephens

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

8-1-24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Richard Stephens hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the SVP- Pharmacy (title) for Costco Wholesale Corporation (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

HEATHER J CIMUCHOWSKI NOTARY PUBLIC STATE OF WASHINGTON COMMISSION EXPIRES 7-09-26 83217

SUBSCRIBED AND SWORN TO
Before me, a notary public this 1 day of August, 2024

Heather J Cimuchowski
Notary Public

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Richard Stephens

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

8-1-24

Date

Board Use Only	Date Received: 8/5/24	Amount: $500-ck 10816871

Pharmacy Disciplinary Actions

1. December 2009 – Case #09-065-RPH-N; 09-065-PH-N. Costco Pharmacy #646 in Nevada and the pharmacist Virginia Agha were both fined by the Nevada State Board of Pharmacy due to a mistake in giving a customer larger dose of a prescription than was requested on the prescription. The fine has been paid.

2. July 2010 – Case # 2010-4158; 2010-4159; 2010- 4160; 2010-4161; 2010-4162; 2010-4163; 2010-4165; 2010-4166; 2010-4167; 2010-4168; 2010-4169; 2010-4170; 2010-2900 (documents can be found on state website). The Colorado Board of Pharmacy issued a complaint and fined Costco Pharmacy # 439, 440, 443, 468, 480, 570, 581, 629, 637, 676, 1014, 1022 and 1027 for failing to timely submit a data report required by Colorado Electronic Prescription Drug Monitoring Program within the required reporting period of April 16-25. Costco Pharmacies filed the report two days late with respect to the submittal of four (4) days of data. The fine has been paid. Costco remedied the technical issue and files on time.

3. May 2010 – Case #2010-03541. The Illinois Department of Financial and Professional Regulation issued a complaint and fined Costco Pharmacy #1040 for dispensing prescriptions without a pharmacist present. Specifically, on or about May 1, 2010, a Costco Wholesale Manager opening the pharmacy when the substitute pharmacist was delayed. The fine has been paid.

4. November 2012. Costco entered into a settlement agreement with the DEA and the US Attorney for the Eastern District of Michigan to resolve allegations concerning filling prescriptions for a prescriber whose DEA registration was no longer valid. Costco paid a fine of $100,000.00. Costco undertook extensive technology updates and policy and procedure updates and auditing to ensure the problem was rectified (see 2017 settlement below).

5. May 2013 – Case #53-12-126441. The Michigan Department of Licensing and Regulatory Affairs issued a complaint and fined Costco Pharmacy #374 for dispensing the incorrect medication to a patient. The fine was paid and probation was served. This, along with all medication errors, was reviewed and addressed by Costco's quality assurance committee.

6. July 2014 - #8-1305A-13X. The NJ Board of Pharmacy issued a violation to Costco Pharmacy #315 for an inspection that occurred on March 7, 2013. The violation was for having outdated and overfilled drug stock. A fine in the amount of $625.00 was paid on August 18, 2014. This was out of Costco policy and is one of the elements on all Costco audits.

7. July 2014 – Complaint #92049. The NJ Board of Pharmacy issued a violation to Costco Pharmacy #739 for not performing an adequate Drug Utilization Review for Larry J. Butterfield, Sr. A fine in the amount of $1,000.00 was paid on July 9, 2014. This, along with all medication errors, was reviewed and addressed by Costco's quality assurance committee.

8. November 3, 2014 - #C-14-040-B. The Texas State Board of Pharmacy issued a violation and penalty for Costco Wholesale #689 for failing to provide verbal patient counseling on July 15, 2014. A fine of $1,500 was paid on March 23, 2015.

9. November 2014 – #8-5213-13-X. The NJ Board of Pharmacy Issued a violation for Costco Pharmacy #749 for having outdated and misbranded drugs in the drug stock inventory. A fine of $250 was paid on November 28, 2014. This was out of Costco policy and is one of the elements on all Costco audits.

10. January 2015 – The MA Board of Pharmacy issued a probation of one day for Costco Pharmacy #302 for failing to identify an error in a prescription. This, along with all medication errors, was reviewed and addressed by Costco's quality assurance committee.

11. February 2015 – Notice No. D101210. The DC Pharmaceutical Division issued a notice of infraction for Costco Pharmacy #1120 for failing to keep the pharmacy clean. A reduced fine of $1,000 was assessed and paid. This is contrary to Costco policy and an element of our audits.

12. September 2016 - OAH No. 2015081057. Pursuant to an agreed settlement, the California Board of Pharmacy placed Costco Pharmacy #454 on probation for 3 years for violations relating to dispensing controlled substances. Specifically the Board alleged the pharmacy staff filled certain prescriptions between 2005 and 2010 that should not have been filled. Costco denied the allegations. No fine was incurred, though Costco paid costs and community service. Costco has since 2010 upgraded policies, processes, technology and auditing to increase vigilance regarding controlled substance prescriptions.

13. January 18, 2017. Costco entered into a settlement agreement with the DEA and the Department of Justice to resolve allegations concerning filling prescriptions for prescribers whose DEA registration were no longer valid, using valid, but incorrect prescriber DEA registration numbers, and various recordkeeping violations at Costco's retail and central fill pharmacies. Costco paid a fine of $11,750,000.00. Beginning in 2012 Costco undertook extensive technology updates and policy and procedure updates and auditing to ensure DEA registration review was accurately conducted on

each controlled substance prescription and that all controlled substance recordkeeping was compliant.

14. February 14, 2017. Case No. 2016-3852. The Colorado Board of Pharmacy issued a violation to Costco #480 for violations discovered in a routine inspection. These included immunization records failing to include the site of administration, failing to review the central prescription processing policy, deficiencies in DEA form 222, recordkeeping on transfers, and proper labeling of anabolic steroid prescriptions. Costco has paid a fine of $2,000 plus a 15% surcharge. Costco has provided additional support and supervisor review to this location. On March 1, 2019, the Colorado Department of regulatory Agencies restored the pharmacy to unencumbered status.

15. September 18, 2017. Case No. 2017 IBP 0043. The Indiana State Board of Pharmacy placed Costco #347 on probation for having expired medications on its store shelves. No fine was assessed. This was out of Costco policy and is one of the elements on Costco audits. On December 31, 2018, the Indiana State Board of Pharmacy withdrew the terms of the probation.

16. December 13, 2017. Case No. 53-16-143490. The Michigan Board of Pharmacy and Costco #570 entered into a Consent Order based on Costco's failure to disclose a July 2010 action by the Colorado Board of Pharmacy (see above). Costco paid a $250 fine. Costco has improved its disciplinary proceeding tracking and reporting since 2010.

17. August 7, 2018. The Texas State Board of Pharmacy and Costco #570 entered into an Agreed Board Order #F-18-014 based on Costco's failure to disclose a July 2010 action by the Colorado Board of Pharmacy (see above). Costco paid a $1,000 fine. Costco has improved its disciplinary proceeding tracking and reporting since 2010.

18. February 14, 2019. Case Nos. PHA 2018-35-L, PHA 2018-36-L, PHA 2018-37-L, PHA 2018-38-L, PHA 2018-39-L, PHA 2018-40-L, PHA 2018-41-L, PHA 2018-42-L, PHA 2018-43-L, PHA-44-L, PHA 2018-45-L. The Hawaii Board of Pharmacy and Costco's Hawaii pharmacies, mail order pharmacies 581, 562, and 570, and central fill pharmacy 583 entered into settlement agreements based on Costco's failure to disclose within 30 days the August 24, 2016 Stipulated Settlement and Order with the California Board of Pharmacy, January 18, 2017 settlement with the DEA, September 18, 2017 Settlement Agreement with the Indiana Board of Pharmacy (see above). Costco paid a $10,000 in fines. Costco has improved its disciplinary proceeding reporting to Hawaii.

19. February 20, 2019. Case No. 113330. The Alabama Board of Pharmacy and Costco #570 entered into a Consent Order based on Costco's failure to

timely disclose a July 2010 action by the Colorado Board of Pharmacy and based on the similar discipline from Michigan and Texas (see above). Costco paid a $5,000 fine. Costco has improved its disciplinary proceeding tracking and reporting since 2010.

20. April 25, 2019. Case No. 2019-2022. The Colorado Board of Pharmacy and Costco #629 entered into a Stipulation and Final Agency Order based on the failure to timely date invoices for controlled substances upon receipt by the pharmacy. Costco paid a $575 fine. Costco retrained personnel and increased its audits and review of this issue.

21. April 29, 2019. Case No. 2019-1335. The Colorado Board of Pharmacy and Costco #1022 entered into a Stipulation and Final Agency Order based on the failure to timely notify the Board of a change of pharmacy manager. Costco paid a $1,000 fine. Costco reiterated to its Colorado locations the requirement to notify the Board.

22. March 17, 2020. Case 2019-05597. The Texas Board of Pharmacy and Costco #680 entered into an Agreed Board Order based on Costco allowing a pharmacy technician with a delinquent registration to perform the duties of a licensed technician. Costco paid a $3,000 fine and implemented policies and procedures for the verification of valid licensure and registration status for all pharmacy employees.

23. November 5, 2020. The South Carolina Board of Pharmacy issued a citation and penalty based on Costco #1319 in Mount Pleasant, SC failing to have diphenhydramine in its emergency response immunization kit per its protocol. Costco paid a $500 fine and immediately placed an order for delivery of the drug.

24. January 20, 2021. Case No. 2019-PHA-16271. The Maine Board of Pharmacy and Costco #581 entered into a Consent Agreement based on the failure to notify the Board of a disciplinary action from the Hawaii Board of Pharmacy in a timely matter. Costco paid a $250 fine. Costco has improved its disciplinary proceeding reporting to Maine.

25. February 11, 2021. Case No.2020-PHA-1679. The Maine Board of Pharmacy and Costco #562 entered into a Consent Agreement based on the failure to notify the Board of a PIC Change and a disciplinary action from the Hawaii Board of Pharmacy in a timely matter. Costco paid a $1,750 fine. Costco has improved its disciplinary proceeding reporting to Maine.

26. March 26, 2021. Case No. 2020-PHA-17022. The Maine Board of Pharmacy and Costco #570 entered into a Consent Agreement based on misrepresentation to the Board on a renewal application on November 23, 2011 for renewal licensure and the failure to notify the Board of a disciplinary action from the Hawaii Board of Pharmacy in a timely matter. Costco paid a $1,750 fine. Costco has improved its disciplinary proceeding reporting to Maine.

27. April 29, 2021. Case No. 2020 IBP 0044. The Indiana Board of Pharmacy and Costco #570 entered a Consent Agreement based on failure to notify the Board of the disciplinary actions from the Colorado, Michigan, Texas Hawaii and Alabama Pharmacy Boards in a timely matter. Costco paid a $4,005 fine. Costco has improved its disciplinary proceeding reporting to Indiana.

28. May 20, 2021. Case No.2020-000359. The Alaska Board of Pharmacy and Costco #562 entered into an agreed order based on the failure to notify the Board of a PIC Change in a timely matter. Costco paid a $250 fine.

29. August 17, 2021. Agreed Board Order (ABO) #2020-03993. The Texas Board of Pharmacy has reprimanded Costco Pharmacy #1322 for a dispensing error. The pharmacy is following special policies and procedures to prevent this error from happening again in the future.

30. February 15, 2022. The PR Department of Health Bureau of Investigations fined Costco Pharmacy #335 for loss of controlled substances. A fine of $800.00 was paid on 03/01/2022.

31. March 10, 2022. The HI Department of Commerce and Consumer Affairs fined Costco Pharmacy #562 for notifying of a prior violation 3 days later. A fine of $500.00 was paid on 03/10/2022.

32. March 14, 2022. The AL State Board of Pharmacy fined Costco Pharmacy #1032/562 $2000 for failure to timely notify the state of a fine from Alaska for failing to timely notify on PIC changes.

33. June 4, 2022. The VA Board of Pharmacy fined Costco Pharmacy #225 $1000 for not filing change of PIC within the required timeframe.

34. July 6, 2022. The MD Department of Health fined Costco Pharmacy #325 a fine of $1000.00 for violation that occurred on July 21, 2021 of a technician-trainee performing delegated pharmacy acts beyond the 6 month exemption period for a technician trainee. The trainee became registered with the board on July 30, 2021.

35. January 19, 2023. State of Connecticut Department of Consumer Protection. The Commission of Pharmacy fined Costco Pharmacy #324 a total of $15,000 for various noncompliance issues. A Settlement Agreement was filed detailing all issues, Case No. 2021-85.
36. November 7, 2023. State of Texas Board of Pharmacy. The pharmacy board reprimanded Costco Pharmacy #1152 for incorrectly entering into the pharmacy's data processing system the wrong drug for a patient.
37. March 25, 2024 – Minnesota State Board of Pharmacy issued a stipulation and consent order for Costco Pharmacy #1021 because a former PIC diverted some drugs to themselves rather to the inventory of the pharmacy.

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **COSTCO WHOLESALE CORPORATION** as a FOREIGN CORPORATION (80) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 06/08/1987, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 07/25/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202407254829820
You may verify this certificate online at https://www.nvsilverflume.gov/home

UNITED STATES OF AMERICA

The State of Washington

Secretary of State

I, STEVE R. HOBBS, Secretary of State of the State of Washington and custodian of its seal, hereby issue this

CERTIFICATE OF EXISTENCE

OF

COSTCO WHOLESALE CORPORATION

I CERTIFY that the records on file in this office show that the above named entity was formed under the laws of the State of Washington and that its public organic record was filed in Washington and became effective on 05/12/1987.

I FURTHER CERTIFY that the entity's duration is Perpetual, and that as of the date of this certificate, the records of the Secretary of State do not reflect that this entity has been dissolved.

I FURTHER CERTIFY that all fees, interest, and penalties owed and collected through the Secretary of State have been paid.

I FURTHER CERTIFY that the most recent annual report has been delivered to the Secretary of State for filing and that proceedings for administrative dissolution are not pending.

Issued Date: 03/18/2024
UBI Number: 601 024 674

Given under my hand and the Seal of the State of Washington at Olympia, the State Capital

Steve R. Hobbs, Secretary of State

Date Issued: 03/18/2024

Wisconsin Department of Safety and Professional Services

Office Location: 4822 Madison Yards Way
Madison, WI 53705
Phone Number: (608) 266-2112

LicensE Portal: License.wi.gov
Email: dsps@wisconsin.gov
Website: http://dsps.wi.gov

PHARMACY EXAMINING BOARD

PHARMACY SELF-INSPECTION INFORMATIONAL SHEET

The Board no longer requires the Department of Safety and Professional Services to send inspectors to conduct on-site inspections prior to licensure.

The Board does require the Managing Pharmacist to complete this "Pharmacy Self-Inspection Report" (Form #2550). Please complete each line indicating the date of compliance, either actual or anticipated, but in no event later than the proposed opening date indicated on the cover page. If the Pharmacy is in non-compliance with any portions of the "Pharmacy Self-Inspection Report" please indicate why the pharmacy is in non-compliance and when the pharmacy will be in compliance. Return the entire "Pharmacy Self-Inspection Report" to the Board office when completed. Please make a copy for your files.

After the "Pharmacy Self-Inspection Report" has been reviewed and is found to be in order, a license number will be issued if all other requirements have been satisfied.

The Department, on behalf of the Board, will conduct an unannounced audit of the pharmacy location within one year after the date the license was issued to verify that the pharmacy is in compliance with the "Pharmacy Self-Inspection Report" as well as the Wisconsin Statutes and Administrative Code relating to the practice of pharmacy.

This procedure will also be used for remodeling.

Notice To Credential Holders Conducting Self-Inspections

The Division of Legal Services and Compliance in the Department of Safety and Professional Services conducts a follow-up inspection to the self-inspection done by new Pharmacies prior to their opening for business.
Below is a list of the most frequently occurring problems we found during our follow-up inspections. The reference is to the Pharmacy Board Rule or Statute. This list is being provided to assist new businesses in conducting their self-inspections:

- Prescription labels – Not having the correct address of the facility or using the name of the previous pharmacy (Phar 7.02).
- Records – Inadequate recordkeeping of Schedule V substances (Phar 8.02(3)(e)(2)).
- Alarm systems – All facilities must have a functioning alarm system or alternate board approved security system at all times to detect entry after hours. Some facilities were found to have opened without an alarm system in place or the alarm system was not working at various times (Phar 13.10(4)).

Procedure for Reporting Theft or Loss of Controlled Substances

The Managing Pharmacist is responsible for reporting any theft or significant loss of controlled substances to the U.S. Department of Justice, DEA Kluczynski Building, Ste. 1200, 230 S. Dearborn Street, Chicago, IL 60604 (312-353-1236, or 1-800-478-7642 toll free 24 hours). Report the theft or loss on DEA Form #106 (Report of Theft or Loss of Controlled Substances), obtainable from DEA at www.deadiversion.usdoj.gov. In any instance, that a pharmacy, practitioner or other DEA registrant authorized to possess controlled substances is required to file with the DEA a report of theft or loss of controlled substances, the pharmacy, practitioner, or other DEA registrant shall also send a copy to the board within 2 weeks of filing with the DEA.

Procedure for Destroying Controlled Substances

Contact the US Department of Justice, 1000 N. Water Street, Room 1010, Milwaukee, WI 53202, or www.deadiversion.usdoj.gov for the proper forms.

Wisconsin Statutes and Administrative Codes

These can be viewed online at http://dsps.wi.gov/Boards-Councils/Administrative-Rules-and-Statutes/Pharmacy-Administrative-Rules-and-Statutes/.

Approved Prescription Drug Products and Code of Federal Regulations

These publications are obtainable from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20401.

Wisconsin Department of Safety and Professional Services

Office Location: 4822 Madison Yards Way
Madison, WI 53705
Phone Number: (608) 266-2112

LicensE Portal: License.wi.gov
Email: dsps@wisconsin.gov
Website: http://dsps.wi.gov

PHARMACY EXAMINING BOARD

PHARMACY SELF-INSPECTION REPORT

Choose Type: ☐ Change of Ownership ■ New Location ☐ Remodel ☐ Re-Inspection

Applicant Name: Costco Health Solutions

Proposed Opening/Remodel Start Date: 6/1/2024

DBA Name: Costco Health Solutions

Phone Number: 866-443-0060

Hours: (open - close) 7am - 7pm

Pharmacy License Number: (for remodel or re-inspection) ____ - 42

	License #:	Full or Part Time:
Managing Pharmacist Name: Luke Brown	17921 - 40	Full
Other Pharmacists: Samantha Decker	18509 - 40	Full
Katherine Zimny	18466 - 40	Full
Paul Konkol	14645 - 40	Full

Compliance Date:

3/13/24 1. Pharmacy Label (contains all required information)

3/13/24 2. Professional service area 875 Sq. Ft.

3/13/24 3. Professional service area where Pharmacist is absent. See Phar 6.04(3)

3/13/24 4. RX counter surface area 18 sq. ft counters

3/13/24 5. Sink

3/13/24 6. Hot and cold running water

3/13/24 7. Suitable soap or detergent

3/13/24 8. Disposal container for waste

N/A 9. Secure narcotic storage or dispersed throughout stock

3/13/24 10. Centrally monitored alarm system (or prior Board approval for an alternate security system)

3/13/24 11. Operational refrigerator

3/13/24 12. Sufficient storage space

N/A 13. Proper storage of exempted narcotic preparations and poisons

Complaince Date:

3/13/24 14. Equipment of appropriate design and size for intended pharmacy practice and compounding

N/A 15. Exempt Narcotic Register - Schedule V

N/A 16. Poison Register

3/13/24 17. a) Prescription files, Wis. State Stat. § 450.11(2)

b) Controlled Substance RX Files, Wis. Admin. Code, § Phar 8.03(2)

c) Medication profile, Wis. Admin. Code, § Phar 7.07

Wisconsin Department of Safety and Professional Services

Office Location: 4822 Madison Yards Way
Madison, WI 53705
Phone Number: (608) 266-2112

LicensE Portal: License.wi.gov
Email: dsps@wisconsin.gov
Website: http://dsps.wi.gov

PHARMACY EXAMINING BOARD

PHARMACY SELF-INSPECTION

It is recommended that pharmacies use the **Wisconsin Statutes and Administrative Code Relating to the Practice of Pharmacy** to facilitate this continuing educational and evaluation procedure.

Directions for completing Self-Inspection: On the line next to the requirement, please complete each line indicating the date of compliance, either actual or anticipated, but in no event later than the proposed opening date indicated on the cover page of **(Form #2550)**, or **"NA"** for not applicable. If answered **"NA"** please describe why this rule does not apply to your specific pharmacy under **"Self-Inspection Notes"** on the last page of the self-inspection. For clarity, please write down the corresponding item number (listed on the left hand side of each requirement) for each description you write on the **"Self-Inspection Notes."**

CHAPTER PHAR 5 WISCONSIN ADMINISTRATIVE CODE (LICENSE RENEWAL)

Compliance Date:

PHAR 5.03 Display of licenses.

1. 3/13/24 Each pharmacist's license is displayed in public view. (Pharmacists need only display license at primary site of employment.) The current renewal card (and **no other visible renewal card**) is displayed with the license.

PHAR 5.04 Renewal prohibited; relicensure.

2. 3/13/24 A pharmacist whose license is currently suspended or revoked may not renew their license unless it has been reinstated by the Board and they are otherwise qualified for renewal.

PHAR 5.05 Requirements for late renewal; reinstatement.

3. 3/13/24 A pharmacist who files an application for renewal of a license within five (5) years after renewal date must file the following with the Board:
   (a) The DSPS' application for renewal.
   (b) The fee required under Wis. Stat. § 440.08(2), plus the late fee required under Wis. Stat. § 440.08(3).
4. 3/13/24 A pharmacist who files an application for renewal of a license five (5) years or more after the renewal date must file with the Board the requirements under Wis. Admin. Code Phar 5.05(1) and verification of successful completion of examinations and/or educational requirements, required by the Board.

CHAPTER PHAR 6 WISCONSIN ADMINISTRATIVE CODE

PHAR 6.03 Changes in managing pharmacist.

5. 3/13/24 Any change in **managing pharmacist** has been reported to the Pharmacy Examining Board. (This section requires notification within 5 days of the date of change.) (The Pharmacy Examining Board strongly suggests completion of this Pharmacy Self-Inspection by any new managing pharmacist.)

PHAR 6.04 Floor design.

6. 3/13/24 Professional service area has a minimum of 250 sq. ft. (20% limit on space used for storage of bulk pharmaceuticals)
7. _____ (If not, has variance been approved by the Pharmacy Examining Board)
8. 3/13/24 Prescription counter is at least 12 sq. ft. of **free working area** for compounding and dispensing and at least 18 inches wide. (Space for records, computer, and supplies not included)
9. 3/13/24 Professional service area secure **when pharmacist is absent**. If R.Ph. always present, enter "N/A" in item 10, skip items 11 to 17.
10. N/A The pharmacy can convert to a non-prescription or sundry outlet without a pharmacist present if:
11. _____ 1. Present barrier has been approved by the Pharmacy Examining Board
12. _____ 2. Barrier is **locked** in the absence of the pharmacist.
13. _____ 3. Telephone restrictions are observed
14. _____ 4. Signs are posted at the entrance to the building and the professional service area displaying the hours the pharmacist will be on duty.

Wisconsin Department of Safety and Professional Services

Compliance Date:

15. _____ 5. The manner in which the telephone is answered does **not imply** that the location is, at that time, operating as a pharmacy. Note: Pharmacy services are **not** provided: including no prescription being picked up. [Wis. Admin. Code Phar 7.01(c)].
16. _____ 6. Pharmacy Examining Board has been notified of the hours the establishment will be operated as a sundry outlet.
17. _____ 7. The managing pharmacist is responsible for compliance with all professional service area security requirements.
18. 3/13/24 Modifications to the floor plan have been filed with the Board if remodeling has occurred.
19. 3/13/24 Where no pharmacist is present in the professional service area a pharmacy is not required to convert to a non-prescription or sundry outlet if the following requirements are met:
20. 3/13/24 1. The pharmacist is absent for a time period of one half hour or less.
21. 3/13/24 2. The pharmacist must be accessible for communication with the remaining pharmacy staff by phone, pager, or other device.
22. 3/13/24 3. The pharmacy must indicate that the pharmacist is not available in the professional service area and indicate the period of absence and the time of the pharmacist's return.
23. 3/13/24 4. Pharmacy technicians may only perform duties allowed by Wis. Admin. Code Phar 7.015(2).

PHAR 6.05 [Wis. Stat. § 450.09(4)] Sanitation.

24. 3/13/24 Pharmacy is maintained in a clean and orderly manner.
25. 3/13/24 Suitable sink supplied with hot and cold running water, detergent and adequate waste disposal container are provided.

PHAR 6.06 Equipment.

26. 3/13/24 The professional service area of a pharmacy has equipment of appropriate design and size for the intended pharmacy practice consisting of at least the following equipment:
27. 3/13/24 Latest available or immediately accessible version of federal and state pharmacy laws consisting of:
    1. DEA Regulations, 21 CFR 1300 to End: www.access.gpo.gov/nara/cfr/cfr-table-search.html
    2. Wisconsin pharmacy laws (Wis. Stat. § 450): www.legis.state.wi.us/rsb/statutes.html
    3. Wisconsin Controlled Substances Act (Wis. Stat. § 961): www.legis.state.wi.us/rsb/statutes.html
    4. Wisconsin Administrative Code (Rules of the Pharmacy Examining Board): www.legis.state.wi.us/rsb/code/phar/phar.html

    Note: Statutes and rules may be made available via electronic means with immediate accessibility to satisfy this portion of the rule.
28. 3/13/24 References appropriate to the individual pharmacy practice. These references should include, but are not limited to, the following topics: drug interactions, patient counseling, compounding and pharmaceutical calculations, and generic substitution.
29. 3/13/24 Telephone number of a poison center (conspicuously posted in the professional service area).

PHAR 6.07 Storage.

30. 3/13/24 Refrigerator adequate for biologicals and other drugs.
31. 3/13/24 Sufficient shelf, drawer, or cabinet space.
32. N/A Controlled substances are stored in a securely locked, substantially constructed cabinet or dispersed throughout the inventory in a manner that obstructs theft. (Alphabetical storage on open shelves of highly sought after controlled substances are not considered adequate.)

PHAR 6.08 Security.

33. 3/13/24 The Pharmacy has a centrally monitored alarm system in the pharmacy. A security system or plan that does not utilize a centrally monitored alarm system may be used if reviewed by and prior approval is obtained from the Board.
34. 3/13/24 **PHAR 1.02(14)** Hypodermic needles and syringes, poisons and Schedule V controlled substances are **only** in the professional service area.

Wisconsin Department of Safety and Professional Services

Compliance Date:

CHAPTER PHAR 7 WISCONSIN ADMINISTRATIVE CODE

PHAR 7.01 Minimum procedures for compounding and dispensing.

(1) **Only licensed pharmacists** (or interns under supervision),

35. 3/13/24 (a) Reviews all original and renewal prescription orders, whether electronic, written, or oral; and determines therapeutic compatibility and legality of the prescription order. The review shall include, when indicated or appropriate, consultation with the prescriber. (See Wis. Admin. Code PHAR 7.07(4) for responsibility to review profile.)

346. 3/13/24 Wis. Stat. § 450.13(1). Inform the patient of drug product equivalent options.

Note: Wis. Stat. § 450.13(5), amended in 1992 exempts hospitals with formularies for inpatients only.

37. 3/13/24 (b) Read and interpret a prescriber's directions for use for the purpose of accurately transferring instructions to the prescription label.

38. 3/13/24 (c) If an agent of the pharmacist procures, measures or counts prefabricated dosage forms or compounds, mixes and combines ingredients the pharmacist **verifies accuracy** of the agent's actions. (Agent of a pharmacist is allowed to compound, mix and combine ingredients with a **specific written protocol** and **pharmacist verification** as stated in Wis. Admin. Code Phar 7.015(j))

39. 3/13/24 (d) Make a final check on the accuracy and correctness of the prescription and identify the pharmacist responsible for the original or renewed prescription.

40. 3/13/24 (e) Give the patient or agent appropriate consultation relative to the prescription, except that prescriptions may be delivered by an agent of the pharmacist to a patient's residence if the delivery is accompanied by appropriate directions and an indication that consultation is available by contacting the pharmacist. The consultation requirement applies to original and renewal prescription orders and, except when prescriptions are delivered to a patient's residence, is not satisfied by only offering to provide consultation.

41. 3/13/24 (em) Transfer the prescription to the patient or agent of the patient.

42. 3/13/24 (f) Receive, when required by law and standard professional practice, permission to renew from authorized prescribers, and note on reverse side of the prescription order, medication profile record, or uniformly maintained and readily retrievable document, the following information.

1. Date renewed.
2. Name of practitioner authorizing renewal **if different from original prescriber**.
3. Quantity of drug dispensed.
4. Pharmacist renewing the prescription.

43. 3/13/24 (2) Subsection (1)(d) and (e) does not prohibit institutional pharmacists or community pharmacists serving institutions from receiving prescription orders, dispensing and returning prescription medications consistent with accepted inpatient institutional drug delivery systems. Sub (1) applies to any institutional pharmacy dispensing to outpatients, including prescriptions for discharge patients.

44. 3/13/24 (3) Each pharmacist's supervision of compounding and dispensing activities **as defined in (1) (e)** is limited to one pharmacist intern and four pharmacy technicians at any time.

Note: Any higher ratio must be approved by the Pharmacy Examining Board.

PHAR 7.015 Pharmacy technician; defining roles/duties.

45. 3/13/24 (1) The pharmacy technician is a non-pharmacist or non-pharmacist intern who, under the general supervision of a pharmacist, assists the pharmacist in the technical and nonjudgmental functions related to the practice of pharmacy in the processing of prescription orders and inventory management.

Note: Pharmacy technician does not include ancillary persons, which includes: clerks, secretaries, cashiers, or delivery persons who may be present in the pharmacy, unless they are performing technical functions as delineated in Wis. Admin. Code Phar 7.015(2), in which case they are a technician when performing these functions.

46. 3/13/24 (2) The pharmacist delegates technical dispensing functions to a pharmacy technician, but only under the general supervision of the pharmacist where the delegated functions are performed. Technical dispensing functions include:

47. 3/13/24 (a) Accepting written or electronic prescription orders from the prescribing practitioner or from the prescribing practitioner's agent.

48. N/A (b) Accepting original oral prescription orders from the prescribing practitioner or their agent, if the conversation is recorded and listened to and verified by the pharmacist prior to dispensing.

49. 3/13/24 (c) Requesting authorization for a refill from the prescribing practitioner.

50. N/A (d) Accepting oral authorization for a refill from the prescribing practitioner or their agent, provided there are no changes to the original prescription order.

Compliance Date:

51. 3/13/24 (e) Accepting a request from a patient to refill a prescription.
52. 3/13/24 (f) Obtaining and entering patient or prescription data into the patient information system.
53. 3/13/24 (g) Preparing a prescription label.
54. 3/13/24 (h) Retrieving medication from stock, counting or measuring medication and placing the medication in its final container.
55. 3/13/24 (i) Reconstituting prefabricated dosage forms.
56. N/A (j) Compounding pharmaceuticals pursuant to written policies and procedures on file in the pharmacy at the time of compounding.
57. 3/13/24 (k) Affixing a prescription label to its final container.
58. 3/13/24 (l) Placing ancillary information on the prescription label.
59. 3/13/24 (m) Prepackaging and labeling drugs for dispensing by a pharmacist.
60. N/A (n) Preparing unit dose carts for final review by a pharmacist.
61. 3/13/24 (o) Retrieving and transporting stock medication to and from pharmacist approved areas.
62. 3/13/24 (p) Other technical functions that do not require the professional judgment of a pharmacist.
63. 3/13/24 (3) The pharmacy technician may not do any of the following:
64. 3/13/24 (a) Provide the final verification for the accuracy, validity, completeness or appropriateness of a filled prescription or medication order.
65. 3/13/24 (b) Perform any of the following tasks: participation in final DURs; make independent therapeutic alternate drug selections, participation in final drug regimen screening; perform any act necessary to be a managing pharmacist, or administer any prescribed drug products, devices or vaccines.
66. 3/13/24 (c) Provide patient counseling, consultation exercise or patient specific judgment.
67. 3/13/24 (d) Transfer the prescription to the patient or agent of the patient.
68. 3/13/24 (4) The pharmacist provides the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription prior to the delivery of the prescription to the patient or the patient's representative.

PHAR 7.02 Prescription label; name of drug product dispensed.

69. 3/13/24 The prescription label discloses brand name and strength or generic name, strength and **manufacturer or distributor** of the drug or drug product dispensed. Unless prescriber requests omission.

PHAR 7.03 Prescription renewal limitations.

70. 3/13/24 Prescription orders for any drug other than a controlled substance bearing renewal authorization "**prn**" are limited to a period of one year from the date of **original order**.
71. 3/13/24 All renewal authorizations are void when the patient-physician relationship has ceased (includes death or retirement of prescriber).

PHAR 7.04 Return or exchange of health items.

72. 3/13/24 (1) In this section:
73. 3/13/24 (a) "Health items" means drugs, devices, hypodermic syringes, needles, or other objects for injecting a drug, medicine, or items of personal hygiene.
74. 3/13/24 (b) "Inpatient health care facility" means any hospital, nursing home, county homes, county mental hospital, tuberculosis sanitorium, or similar facility, but does not include community-based residential facilities, jails or prison facilities.
75. 3/13/24 (c) "Original container" means the container in which a health item was sold, distributed, or dispensed.
76. 3/13/24 (d) "Resident health care patient" means a patient residing in a community-based residential facility that controls a resident's prescribed and over-the-counter medications as specified by Wis. Stat. § HFS 83.33(3) (b) 2.
77. 3/13/24 (e) "Secured institutional health care patient" means any of the following:
78. 3/13/24 1. A jail inmate patient whose dispensed health items are maintained under the custody and control of the jail pursuant to an approved policy and procedure manual under Wis. Stat. § DOC 350.17, containing policies and procedures for the control and administration of medications complying with Wis. Stat. § DOC 350.20.
79. 3/13/24 2. A juvenile patient who resides in a secured correctional facility, as defined in Wis. Stat. § 938.02(15m; a secured child caring institution, as defined in Wis. Stat. § 938.02(15g); a secured group home, as defined in Wis. Stat. § 938.02(15p); a secured detention facility, as defined in Wis. Stat. § 938.02(16); or a juvenile portion of a county jail whose dispensed health items are maintained under the custody and control of the health services staff as defined in Wis. Stat. § DOC 316.02(6) and provided to a juvenile patient under the provisions of Wis. Stat. § DOC 316.03.

Compliance Date:

80. 3/13/24 (f) "Tamper-resistant package" means a container bearing a beyond use date that is sealed so that the contents cannot be used without obvious destruction of the seal.

81. 3/13/24 (2) No health items after taken from a pharmacy where sold, distributed or dispensed, may be returned, except for any of the following:

82. 3/13/24 (a) From an inpatient health care facility, provided they are in their original containers and the pharmacist determines the contents are not adulterated or misbranded.

83. 3/13/24 (b) Where the health items were dispensed in error, were defective, adulterated, misbranded or dispensed beyond their beyond use date.

84. 3/13/24 (c) When in the professional judgment of the pharmacist substantial harm could result to the public or a patient if they were to remain in the possession of the patient, patient's family or agent, or other person.

85. 3/13/24 (d) For a secured institutional health care patient or resident health care patient where all of the following apply:

86. 3/13/24 1. The health item was never in the possession and control of the patient.

87. 3/13/24 2. The health item was sold, distributed or dispensed in a tamper-resistant package and, for a drug, includes the beyond use date and manufacturer's lot number.

88. 3/13/24 3. The health item is not commingled with a different health item unless the health item will be repackaged and re-dispensed to the same patient.

89. 3/13/24 4. The health item is in its original container and the pharmacist determines the contents are not adulterated or misbranded.

90. 3/13/24 (e) A health item that is prepackaged for consumer use and labeled in compliance with all applicable state and federal laws where all of the following apply:

91. 3/13/24 1. The pharmacist determines that the original package is unopened, sealed, and intact and that package labeling is unaltered.

92. 3/13/24 2. The pharmacist determines the contents are not adulterated.

93. 3/13/24 (3) Health items returned to a pharmacy pursuant to sub. (2) (b) and (c), may not be sold, resold, or repackaged and sold or resold, given away or otherwise distributed or dispensed. Returned health items shall either be destroyed at the pharmacy or delivered for destruction or other disposal by an authorized person or entity.

94. 3/13/24 (3m) Health items returned from a secured institutional health care patient to a pharmacy pursuant to sub. (2)(d), must be segregated in the pharmacy and may not be sold, resold, or repackaged and sold or resold, given away , or otherwise sold, distributed or re-dispensed other than to a secured institutional health care patient.

95. 3/13/24 (4) It is not a "return" for a patient or agent of a patient to deliver a previously dispensed drug or device to a pharmacy for the purpose of repackaging and relabeling of that previously dispensed drug or device, and subsequent return of the drug or device for the same patient's use.
Note: The DEA does not permit the return of controlled substances to a pharmacy from a non-DEA registrant under any circumstances.

96. 3/13/24 (5) It is not a "return" for a patient or agent of a patient to deliver a previously dispensed drug or device to a pharmacy for the purpose of destruction at the pharmacy or other disposal by an authorized person or entity.
Note: Cancer and chronic disease drug returns and re-dispensing pursuant to Ch. HFS 148 are allowed provided the pharmacy follows the requirements in Ch. HFS 148.

PHAR 7.05 Prescription records.

97. 3/13/24 (1) A computerized system may be used for maintaining a record, as required under this section, of prescription dispensing and transfers of prescription order information for the purposes of original or refill dispensing if the system:

98. 3/13/24 (a) Is capable of producing a printout of any prescription data, which the user pharmacy is responsible for maintaining. The system shall be designed so that the pharmacy can receive the printout within 48 hours after requesting the printout.

99. 3/13/24 (b) Is equipped with an auxiliary procedure, which, during periods of down-time, shall be used for documentation of prescription dispensing. The auxiliary procedure shall ensure that prescription refills are authorized by the original prescription order, that the maximum number of prescription refills has not been exceeded and that all of the appropriate data are retained for on-line entry as soon as the computer system is again available for use.

100. 3/13/24 (1m) A record of all prescriptions dispensed shall be maintained for a period of five (5) years after the date of the last refill.

Compliance Date:

(2) All systems used for maintaining a record of any prescription dispensing shall include:
(a) Patient's identification.
(b) Name, strength, and dosage form of the drug product dispensed.
(c) Quantity dispensed.
(d) Date of all instances of dispensing.
(e) Practitioner's identification
(f) Pharmacist's identification
(g) Retrieval designation.

PHAR 7.055 Transfer of prescription order information.

(1) General Requirements. A pharmacist may transfer prescription order information between pharmacies licensed in this state or another state, for the purpose of original or refill dispensing, if all of the following conditions are satisfied:
(a) The transfer is communicated directly between two (2) pharmacists either by verbal transfer or by a computer system transfer meeting the requirements of sub. (4). Communication by facsimile machine is not allowed unless the prescription order information being transferred is verified verbally between two (2) pharmacists.
(b) A computer system used to record a verbal transfer of prescription order information for a non-controlled substance meets the requirements of Wis. Admin. Code Phar 7.05(1)(a) and (b).
(c) The pharmacist receiving the verbal transfer of prescription order information for either a controlled or a non-controlled substance records the transferred information in writing unless a computer system transfer meeting the requirements of sub. (4) is used.
(d) All original and transferred prescription orders are maintained for a period of five (5) years from the date of the last refill.
(e) A written copy of any prescription order for a prescribed drug provided by a pharmacist is identified in writing as **"COPY-FOR INFORMATION ONLY."** No prescribed rug may be dispensed based on an information copy.
(f) A pharmacist making or receiving a transfer of prescription order information is licensed in the state in which he or she performs an act required by this section.

(2) Non-controlled substances. The transfer of prescription order information for non-controlled substances for the purposes of original or refill dispensing is permissible pursuant to the following requirements:
(a) The pharmacist making the transfer records the following information:
1. The word **"VOID"** is written on the face of the invalidated prescription order or recorded in a similar manner to **"VOID"** on a prescription order in a computer system meeting the requirements of Wis. Admin. Code Phar 7.05(1)(a) and (b).
2. The name and address of the pharmacy to which it was transferred, the name of the pharmacist receiving the prescription order, the date, and the name of the pharmacist transferring the information are recorded on the reverse side of the invalidated prescription order or in a computer system meeting the requirements of Wis. Admin. Code Phar 7.05(1)(a) and (b).
3. A transfer of prescription order information for a non-controlled substance for the purposes of refill dispensing is limited to the number of authorized refills.

(b) The pharmacist receiving the transferred prescription order information shall record in writing the following:
1. The word **"TRANSFER"** on the face of the transferred prescription order.
2. The name and address of the patient, the name and address of the prescribing practitioner, and the name and quantity and dosage form of the drug product or device prescribed and the directions for use.
3. The date of issuance of the original prescription order.
4. The original number of refills authorized on the original prescription order.
5. The date of original dispensing if the prescription order has previously been dispensed.
6. The number of valid refills remaining and the date of the last refill.
7. The pharmacy's name, address, and the prescription order number from which the prescription order information was transferred.
8. The name of the pharmacist making the transfer.
9. The name, address, and telephone number of the pharmacy from which the original prescription order was transferred if different from sub (d). 7.

Compliance Date:

131. n/a (3) Controlled Substances. The transfer of prescription order information for controlled substances for the purposes of refill dispensing is permissible pursuant to the following requirements:

132. n/a (a) The transfer of prescription order information is permissible only on a one-time basis unless a computer system meeting the requirements of sub. (4) is used.

133. n/a (b) If a computer system meeting the requirements of sub. (4) is used, a transfer of prescription order information for the purposes of refill dispensing is limited to the number of authorized refills.

134. n/a (c) Unless a computer system meeting the requirements of sub. (4) is used, the pharmacist making the transfer shall record in writing the following information:

135. n/a 1. The word **"VOID"** is written on the face of the invalidated prescription order.

136. n/a 2. The name, address, and DEA registration number of the pharmacy to which it was transferred, the name of the pharmacist receiving the prescription order and the date and the name of the pharmacist transferring the information are recorded on the reverse side of the invalidated prescription order.

137. n/a (d) Unless a computer system meeting the requirements of sub. (4) is used, the pharmacist receiving the transferred prescription order information shall record in writing the following information:

138. n/a 1. The word **"TRANSFER"** on the face of the transferred prescription order.

139. n/a 2. The name and address of the patient, the name, address and DEA number of the prescribing practitioner, and the name, quantity, and dosage form of the drug product or device prescribed and the directions for use.

140. n/a 3. The date of issuance of the original prescription order.

141. n/a 4. The original number of refills authorized on the original prescription order.

142. n/a 5. The date of original dispensing.

143. n/a 6. The number of valid refills remaining and the dates and locations of previous refills, if applicable.

144. n/a 7. The name, address, telephone number, DEA registration number, and prescription order number of the pharmacy from which the prescription order information was transferred if different from the pharmacy from which the prescription order was originally dispensed.

145. n/a 8. The name of the pharmacist making the transfer.

146. n/a 9. The name, address, telephone number, DEA registration number, and prescription order number of the pharmacy from which the prescription order was originally dispensed.

147. 3/13/24 (4) Use of Computer System. A computer system used for transferring prescription order information shall, in addition to meeting the requirements of Wis. Admin. Code Phar 7.05(1)(a) and (b), contain a common central processing unit electronically sharing a real-time, on-line database to which both the transferring and receiving pharmacy have access.

PHAR 7.065 Answering machines in pharmacies.

148. 3/13/24 Oral prescription orders may be received at a pharmacy via telephone answering machine and dispensed by the pharmacist if the voice of the physician or agent is known to the pharmacist and providing other requirements for documenting and filling are met.

PHAR 7.07 Medication profile record system.

Medication profile record **system** for **each** patient includes:

149. 3/13/24 (1) An individual medication profile record system is maintained for all persons for whom prescriptions, original, or renewals are dispensed for outpatient use. The system allows retrieval of the information.

150. 3/13/24 (2) The following minimum information is retrievable: patient name, or other identifying information, address of the patient, birth date of the patient if obtainable, name, strength, dosage form, and quantity of the drug product dispensed, directions for use, retrieval designation assigned to the prescription order, practitioner identification, and the date of each dispensing for original and renewal prescriptions.

151. 3/13/24 (3) Allergies, adverse drug reactions, drug idiosyncrasies and chronic condition.

122. 3/13/24 (4) The pharmacist reviews the profile before dispensing. (See Wis. Admin. Code PHAR 7.01(a))

153. 3/13/24 (5) Medication profile records, if used as the only documentation of renewal dispensing, are maintained for not less than five (5) years following the last entry. If the profile records are not used as the only documentation of renewal dispensing, they are maintained not less than one year past the last entry.

PHAR 7.08 Prescription orders transmitted electronically.

Electronic transmission of prescription orders is available in the pharmacy. If not applicable, enter "N/A" in item 154 and skip to Phar 7.09, item 165

154. 3/13/24 (1) (a) Prescription orders may be accepted and dispensed if they have been transmitted electronically from a practitioner or his or her designated agent to a pharmacy via computer modem or other similar electronic device.

Compliance Date:

155. n/a (b) Prescription orders for schedule II controlled substances may not be transmitted electronically except as emergency orders (Wis. Admin. Code Phar 8.09).

(2) In order to dispense a prescription transmitted electronically, the following must be assured by the pharmacist:

156. 3/13/24 (a) The transmission is only to the pharmacy of the patient's choice, with no intervening person or third party having access to the prescription order other than to forward it to the pharmacy.

157. 3/13/24 (b) The transmission contains the sender's name and telephone number, the time and date of transmission, and the pharmacy intended to receive the transmission.

158. 3/13/24 (c) The transmission is designated "electronically transmitted prescription," or words or abbreviations to that effect.

159. 3/13/24 (d) Contains all other information that is required in a prescription order.

160. 3/13/24 (3) A secure method of validation such as the prescribing physician's electronic signature, accompanies the electronically transmitted prescription.

161. 3/13/24 (4) Any visual or electronic document received electronically are accessible only within the professional service area of the pharmacy (to protect patient confidentiality and assure security).

162. 3/13/24 (5) The pharmacist must ensure the security, integrity, and confidentiality of the prescription order. The electronic system has adequate security and system safeguards to prevent and detect unauthorized access, modification, or manipulation of patient records. Any alterations in the drug order are documented including the identification of the pharmacist responsible for the alteration.

163. 3/13/24 (6) Password(s), known only by those authorized to use the system, is required to gain access to mail containing prescription orders.

164. 3/13/24 (7) The pharmacist does not use any electronic device to circumvent his or her responsibilities with regard to documenting, authenticating and verifying prescription orders or in order to circumvent pharmacy laws.

PHAR 7.09 Automated dispensing systems.

If pharmacy does not use an automated dispensing system (ADS), place "N/A" in item 165 and skip to Phar 7.10, item 184.

165. n/a (1) (a) The "ADS" performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing or distribution of medications, and which collects, controls, and maintains all transaction information.

166. n/a (2) The "ADS" may be used in a community pharmacy, as provided in this section.

167. n/a (3) The "ADS" may be used as provided in this section by an institutional pharmacy serving an inpatient health care facility, that has an established program of receiving prescription orders, and dispensing and returning prescription medications consistent with accepted inpatient institutional drug distribution systems. The "ADS" used by the institutional pharmacy shall only be located in that institutional pharmacy or within the inpatient health care facility.

(4) The managing pharmacist of a community or an institutional pharmacy is responsible for the following:

168. n/a (a) The "ADS" is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed and complies with record keeping and security safeguards pursuant to sub (5).

169. n/a (b) Implementing an ongoing quality assurance program that monitors performance of the "ADS", which is evidenced by written policies and procedures.

170. n/a (c) Providing the Board with prior written notice of the installation or removal of an "ADS" including: name and address of the pharmacy, initial location of the "ADS", and identification of the managing pharmacist.

171. n/a (d) Assigning, discontinuing or changing personnel access to the system.

172. n/a (e) Assuring access to the medications complies with state and federal laws.

173. n/a (f) Assuring the "ADS" is stocked accurately and in accordance with established written policies and procedures.

(5) The "ADS" complies with the following provisions:

174. n/a (a) The pharmacy maintains on-site documentation including: name and address of the pharmacy or inpatient health care facility where the system is being used, the system manufacturer's name, model and serial number, description of how the system is used, written quality assurance procedures to determine continued appropriate use of the system, and except as required pursuant to par (b), written policies and procedures for system operation, safety, security, accuracy, access and malfunction.

175. n/a (b) All written policies and procedures are maintained in the pharmacy responsible for the "ADS".

176. n/a (c) The "ADS" has adequate security systems and procedures, evidenced by written policies and procedures to prevent unauthorized access to maintain patient confidentiality and to comply with federal and state laws.

Compliance Date:

177. n/a (d) Records and data kept by the "AD"S meet the following requirements: all events involving the contents of the ADS are recorded electronically, records are maintained by the pharmacy and are available to the Board (including: the time and location of the system accessed, identification of the individual accessing the system, type of transaction, name, strength, dosage form and quantity of the drug accessed; name of the patient for whom the drug was ordered, such additional information as the managing pharmacist may deem necessary.)

1788. n/a (e) The stocking of all medications in the "ADS" is accomplished by qualified personnel under no less than the general supervision of a licensed pharmacist; except that when an "ADS" is, located within a pharmacy the supervision is direct.

179. n/a (f) A record of medications stocked into the "ADS" is maintained for five (5) years and includes identification of the person stocking and pharmacist checking for accuracy.

180. n/a (g) All containers of medications stored in the "ADS" are packaged and labeled in accordance with state and federal law.

181. n/a (h) All aspects of handling controlled substances meet the requirements of all state and federal laws.

182. n/a (i) The "ADS" provides a mechanism for securing and accounting for medications removed from and subsequently returned to the "ADS", in accordance with state and federal law.

183. n/a (j) The "ADS" provides a mechanism for securing and accounting for medication returned to the system and accounting for wasted medications in accordance with state and federal law.

PHAR 7.10 Administration of drug products and devices other than vaccines.

A pharmacist may administer a drug product or device in the course of teaching a patient self-administration technique. Pharmacists administering a prescribed drug product or device by injection must satisfy each of the following:

184. 3/13/24 Completed a 12-hour course of study and training, approved by the American Council on Pharmaceutical Education (ACPE) or the Board in injection techniques, emergency procedures, and record keeping.

185. 3/13/24 Maintain at least $1,000,000 in liability insurance for each occurrence, and $2,000,000 for all occurrences in any one-policy year, for errors, omissions or neglect in the administration by injection. The pharmacist must maintain proof of this requirement and provide upon request of the Board or Department.

186. 3/13/24 Maintain written procedures regarding the administration by injection of a prescribed drug product or device in the course of teaching self-administration techniques to a patient.

PHAR 7.12 Central fill pharmacy.

187. 3/13/24 (1) In this section:

(a) "Central fill pharmacy" means a pharmacy licensed in this state acting as an agent of an originating pharmacy to fill or refill a prescription.

(b) "Originating pharmacy" means a pharmacy licensed in this state that uses a central fill pharmacy to fill or refill a prescription order.

188. n/a (2) A central fill pharmacy and originating pharmacy may process a request for the filling or refilling of a prescription order received by an originating pharmacy only pursuant to the following requirements:

189. n/a (a) The central fill pharmacy either has the same owner as the originating pharmacy or has a written contract with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy in fulfilling the terms of the contract in compliance with federal and state law.

190. n/a (b) The central fill pharmacy shall maintain a record of all originating pharmacies, including name, address and DEA number, for which it processes a request for the filling or refilling of a prescription order received by the originating pharmacy. The record shall be made available upon request for inspection by the Board or its agent.

191. n/a (c) The central fill pharmacy and originating pharmacy maintain a written filling protocol delineating each pharmacy's assumption of responsibility for compliance with the prescription drug compounding and dispensing requirements of this chapter and Wis. Admin. Code Phar 8.

192. n/a (d) The originating pharmacy shall remain responsible for compliance with the prescription drug compounding and dispensing requirem3ents of this chapter and Wis. Admin. Code Phar 8, and which are not assumed in writing by the central fill pharmacy pursuant to a written filling protocol.

193. n/a (e) The originating pharmacy shall at all times remain solely responsible to perform and comply with the requirements of Wis. Admin. Code Phar 7.01(1)(e) and (em).

194. n/a (f) Unless the central fill pharmacy shares a common central processing unit with the originating pharmacy, it may not perform processing functions such as the medication profile record review of the patient, drug initialization review, refill authorizations, interventions and drug interactions.

Compliance Date:

195. n/a (g) The prescription label attached to the container shall contain the name and address of the originating pharmacy as the licensed facility from which the prescribed rug or device was dispensed for purposes of s. 450.11(4)(a)1., Stats. The date on which the prescription was dispensed for purposes of s. 450.11(4)(a)2., Stats., shall be the date on which the central fill pharmacy filled the prescription order.

196. n/a (h) The originating pharmacy shall maintain the original of all prescription orders received for purposes of filing and recordkeeping as required by state and federal law.

197. n/a (i) The central fill pharmacy shall maintain all original fill and refill requests received from the originating pharmacy and shall treat them as original and refill prescription orders for purposes of filing and recordkeeping as required by state and federal law.

198. n/a (j) In addition to meeting the other recordkeeping requirements required by state and federal law, the central fill pharmacy and originating pharmacy shall each maintain records to identify each of its pharmacists responsible for receiving and reviewing prescription orders and compounding dispensing pursuant to a prescription order and track the prescription order during each step in the dispensing process.

199. n/a (k) The central fill pharmacy and originating pharmacy shall adopt a written quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, resolve identified problems and insure compliance with this section.

200. n/a (l) The originating pharmacy shall provide the patient with the name and address of the central fill pharmacy and obtain consent as required by applicable state and federal law.

UNIFORM CONTROLLED SUBSTANCES ACT

Wis. Stat. § 961.23, Dispensing of schedule V substances. (Non-legend)

201. n/a (1) Products are **sold in good faith as a medicine**.
Even without 48-hour violations, pharmacists must be prepared to substantiate the clinical need for frequent sales to the same individual. (Wis. Stat. § 961.38(4))

202. n/a (2) Sold only by the pharmacist.

203. n/a (3) The name and address of the pharmacy is attached to the **immediate** container.

204. n/a (4) **The pharmacist** records the name and address of the purchaser, as well as the name and quantity of product sold.

205. n/a If purchaser is unknown to the pharmacist, identification is validated.

206. n/a The pharmacist and the purchaser sign the record.

n/a (5) Sales are restricted:

207. n/a (a) 8 ounces of a produce containing opium.

208. n/a (b) 4 ounces of any other Schedule V substance.

209. n/a (c) 48-hour interval is observed.

CHAPTER PHAR 8 WISCONSIN ADMINISTRATIVE CODE

PHAR 8.02 Records for controlled substances.

210. n/a (1) Records are **complete and accurate** for each controlled substance received, distributed, dispensed or disposed of in any other manner.

(2) Records required by federal controlled substances act and Wis. Stat. § 961, are:

211. n/a (a) Maintained at the pharmacy location where **received and dispensed or manufactured**.

212. n/a (b) Available **for inspection** for at least five (5) years.

213. n/a (c) Includes a biennial inventory of all Schedule II, III, IV, and V substances (readily retrievable). Wisconsin DEA district office, 1000 N. Water St., Suite 1010, Milwaukee, WI 53202, (414-297-3395) provides instructions and forms for destruction of controlled substances.

(3) Records are maintained as follows:

214. n/a (a) Records of Schedule II controlled substances (other than prescription orders) are maintained separately.

215. n/a (b) Records of Schedule III, IV, and V controlled substances are separate or are readily retrievable.

216. n/a (c) Executed Schedule II order forms **(DEA Form #222) completed and kept in** the pharmacy.

217. n/a (d) Records of controlled substances distributed or dispensed include:

218. n/a 1. Name of the substance.

219. n/a 2. Dosage form, strength, and quantity.

220. n/a 3. Quantity and date of distribution, as well as name, address and DEA registration number to whom distributed.

Compliance Date:

221. n/a
222. n/a
223. n/a
224. n/a
225. n/a

4. Number of units, date of receipt, and name, address and DEA registration number from whom received.
5. Name and address to whom **dispensed**, date, quantity dispensed, and name or initials of pharmacist dispensing.

(e) Records for dispensed Schedule V substances:
1. If dispensed as a prescription, it is filed the same as Schedule III and IV orders.
2. If dispensed other than pursuant to prescription order, the required entry (see Wis. Stat. § 961.23) is placed in a **bound Schedule V register** at the time of transaction.

(f) In any instance that a pharmacy authorized to possess controlled substances is required to file with the DEA a report of theft or loss of controlled substances, the pharmacy shall also send a copy to the Board within 2 weeks of filing with the DEA.

PHAR 8.03 Filing prescription orders.

226. n/a Controlled Rx orders are filed chronologically, are readily accessible; and maintained for at least five (5) years.
227. n/a Schedule II prescription orders are filed separately **or** are filed with Schedule III, IV, and V orders (which have a one-inch red "C" in the lower right corner).
228. n/a Schedule III, IV and V prescription orders are filed separately **or** have a one-inch red "C" if filed with non-controlled Rx orders. (Schedule II Rx orders are **not** filed with non-controlled Rx orders.) The requirement to mark with a red "C" may be waived if the pharmacy has an automated processing system or electronic record keeping that permits identification by prescription order number and retrieval of original documents by prescriber's name, patient name, drug dispensed and date filled.

PHAR 8.04 Purpose of issue of prescription.

229. n/a Pharmacists are aware of their responsibility to dispense for legitimate medical purposes.
230. n/a Controlled substances are **not** dispensed **(pursuant to a prescription order)** to a practitioner for the purpose of administration or general dispensing to patients.
231. n/a Controlled substances (Schedule II, III, or IV) are **not** dispensed pursuant to a prescription order to a practitioner for their own personal use. [Wis. Stat. § 961.38(5)]

PHAR 8.05 Dispensing controlled substances.

232. n/a (1) Written prescription orders for all controlled substances are **dated** and **signed** on the day issued and contain the following:
(a) Full name and address of patient.
(b) Name, address, and DEA number of practitioner.
(c) Name, strength, dosage form and quantity of drug prescribed.
(d) Directions for use.

Prescription orders (in ink or typewritten) are **signed by the practitioner**.
DEA registration of practitioner is validated by pharmacist.

233. n/a (2) The **pharmacist** initials and dates prescription orders for **all** controlled substances.
Note: If the party receiving a Schedule II prescription is not personally known to the pharmacist, the printed name, signature and address of that person is recorded on the reverse side of the prescription order.

234. n/a (3) Prescriptions containing Schedule II substances are dispensed pursuant to **written prescription orders signed by the practitioner**.

235. n/a Controlled substance prescriptions must be dispensed within 60 days following the date of issue of the prescription order.
Note: Date of receipt on face of Rx order.

236. n/a (4) Prescription orders for controlled substances are not dispensed unless the prescription order contains all of the information required in sub. (1). For any controlled substances prescription order, a pharmacist may not add, modify or clarify the patient's name, drug prescribed, except for generic substitution as permitted by law and the prescribing practitioner's signature. After consultation with the prescribing practitioner, a pharmacist may add, modify, or clarify the strength, dosage form, quantity prescribed, date of issuance and directions for use for a schedule II controlled substance prescription order. For a schedule II controlled substance prescription order, a pharmacist may add, modify, or clarify the registration number of the practitioner, and the address of the practitioner and the patient if that information is verifiable and retrievable from information maintained by the pharmacist or is obtained through consultation with the practitioner. A pharmacist may add, modify, or clarify any information allowed in this subsection missing from a prescription order for a Schedule III, IV, or V controlled substance that is verifiable and retrievable from information maintained by the pharmacist or that is obtained through consultation with a practitioner. A patient may only provide information to a pharmacist to add, modify or clarify the patient" address. The prescription order shall be initialed and dated by the pharmacist and shall indicate the addition, modification or clarification of information and the manner by which the pharmacist obtained that information.

Compliance Date:

PHAR 8.06 Renewing prescriptions for controlled substances.

237. n/a (1) Prescriptions for Schedule II controlled substances are **not** renewed.

238. n/a (2) The prescribing practitioner may authorize renewals of Schedule III or IV controlled substances on the original prescription order or through an electronic or oral renewal authorization.

239. n/a (a) The pharmacist obtaining an electronic or oral authorization notes the following on the prescription order, medication profile, or document:

240. n/a 1. Date authorization is received.

241. n/a 2. Quantity of drug authorized.

242. n/a 3. Number of renewals.

243. n/a 4. Identification of practitioner authorizing the renewals if different from the original prescriber.

244. n/a 5. Identification of the pharmacist who received the authorization.

245. n/a (b) The quantity of each renewal authorized is equal to or less than the quantity authorized for the initial dispensing of the original prescription.

246. n/a (3) Renewal of prescriptions for Schedule III and IV substances is limited to:

247. n/a (a) Within 6 months of date of **original order**.

248. n/a (b) No more than five (5) **authorized** renewals.

249. n/a (4) Prescriptions for Schedule V substances are renewed **only** as expressly authorized by the practitioner.
Note: The 6-month/5 renewal limitations do not apply to prescription orders for Schedule V substances.

PHAR 8.07 Partial dispensing of controlled substances.

250. n/a (1) Substances in Schedules III, IV, and V may be partially dispensed.

251. n/a (2) Partial dispensing of Schedule II substances is permissible: If pharmacist unable to supply full quantity ordered. Remaining portion may be dispensed within 72 hours of the first partial dispensing (or prescriber notified).
No further quantity dispensed after 72 hours. A new prescription order will be required.

252. n/a (3) Partial dispensing of Schedule II substances is permissible if patient is in long term care facility (LTCF), or has a medical diagnosis documenting a "terminal illness". Valid for 60-day period.
Pharmacist enters each partial dispensing. Enter "LTCF" or "terminal illness" on prescription.

253. n/a (4) Information pertaining to current prescription orders for Schedule II controlled substances for patients in an "LTCF" or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if the system has the capability to permit:

254. n/a (a) Display or printout of: the original prescription order designation, date of issue, identification of prescribing practitioner, identification of patient, name and address of the "LTCF" or name of address of the hospital or residence of the patient, identification of medication authorized, including dosage form, strength and quantity; listing of partial quantities that have been dispensed under each prescription order and the information required in sub. (3).

255. n/a (b) Immediate updating of the prescription order record each time there is partial dispensing of the prescription.

256. n/a (c) Retrieval of partially dispensed Schedule II prescription information identical to that required by Wis. Admin. Code Phar 7.05(2) for all prescription renewal information.

PHAR 8.08 Labeling prescriptions containing controlled substances.

257. n/a The prescription label for controlled substances includes: Date dispensed, pharmacy name and address, Rx number; full name of patient; name of the practitioner; directions for use; and appropriate cautionary statements.

PHAR 8.09 Emergency dispensing of Schedule II substances.

(1) The pharmacists understand the criteria for "emergency" to mean that the practitioner has determined that:

258. n/a (a) Immediate administration of the CS II substance is necessary.

259. n/a (b) No appropriate alternative, including non-Schedule II substance.

260. n/a (c) Not possible to provide written order prior to dispensing.

Note: It is important for pharmacists to be aware that the "emergency" procedure should not be used for routine dispensing of Schedule II substances.

(2) In an emergency when the pharmacist dispenses a Schedule II substance with an electronic or oral authorization:

261. n/a (a) The quantity prescribed and dispensed is limited to the amount adequate for the emergency situation.

262. n/a (b) The Rx order is immediately reduced to writing by the pharmacist, including all information listed in Wis. Admin. Code Phar 8.05 except the signature of the practitioner.

Compliance Date:

263. n/a (3) If the practitioner is not known to the pharmacist, reasonable effort is made to authenticate the prescriber.
264. n/a (4) The pharmacist assures receipt of a written order within 7-days after the authorized emergency dispensing (or it is postmarked within 7-days). The written order will include:
265. n/a (a) "authorization for emergency dispensing" on the front.
266. n/a (b) date of the electronic or oral order.
267. n/a Upon receipt, the pharmacist attaches the written order to the oral emergency prescription order.
268. n/a **If the practitioner fails to deliver the written order**, the Department of Safety and Professional Services is notified. **(Failure to provide this notification voids the authority to dispense emergency orders.)**

PHAR 8.11 Controlled substances in emergency kits for long-term care facilities.
If you do not service a "LTCF," place "N/A" in item 269 and skip to Phar 8.12, item 274.
Long-term care facilities, which are not registered with the DEA, meet the following requirements regarding emergency kits containing controlled substances:

269. n/a (1) The source of supply must be a DEA registered hospital, pharmacy or practitioner.
270. n/a (2) The pharmaceutical services committee of the facility have security safeguards for each emergency kit stored in the "LTCF", which include the designation of the individuals who may have access to the kits and a specific limitation on the type and quantity of controlled substances permitted to be placed in each emergency kit.
271. n/a (3) A pharmacist is responsible for control and accountability for kits within the "LTCF", which includes the requirement that the "LTCF" and the providing DEA registered hospital, pharmacy or practitioner maintain complete and accurate records of the controlled substances placed in the emergency kits, the disposition of those controlled substances, plus the requirement to take at least monthly physical inventories.
272. n/a (4) The pharmaceutical services committee established the emergency medical conditions under which the controlled substances may be administered to patients in the "LTCF", which shall include the requirement that medication be administered by authorized personnel only as expressly authorized by an individual DEA registered practitioner and in compliance with all applicable federal and state laws.
273. n/a (5) The pharmacist is aware that noncompliance with these rules may result in revocation, denial or suspension of the privilege of having or placing emergency kits, containing controlled substances, in "LTCF".

PHAR 8.12 Facsimile Transmission.

274. 3/19/24 (1) A pharmacist may dispense a prescription, other than a Schedule II based on a fax prescription from a practitioner or their agent.
275. 3/19/24 (a) It shall contain all the information of a valid written prescription as well as the date and time of transmission and the telephone number and name of the transmitter.
276. 3/19/24 (b) If fading paper, it must be copied and attached to the copy received.
277. n/a (2) Schedule II prescriptions may be received if all the requirements of section (1) are met and any of the following:
278. n/a (a) The prescription is to be compounded for the direct parenteral, intravenous, intra muscular, subcutaneous or intra spinal infusion to a patient.
279. n/a (b) The patient resides in a long term care facility or meets the eligibility requirements for placement in a long term care facility but elects to reside at home, and is transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile.
280. n/a (c) The patient is enrolled in a hospice certified by Medicare under title XVIII or licensed by this state.
281. 3/13/24 (3) A prescription order transmitted by facsimile shall be considered the original written prescription order.

CHAPTER PHAR 10 WISCONSIN ADMINISTRATIVE CODE (STANDARDS OF PROFESSIONAL CONDUCT)

282. 3/13/24 All pharmacists at this pharmacy are aware of the specific practices enumerated in Wis. Admin. Code Phar 10.03.
283. 3/13/24 The pharmacist avoids dispensing or **causing to be dispensed** a drug, which is outdated or contaminated or known by the pharmacist to be unsafe for consumption.
Note: While it is not the objective of this self-inspection project to enumerate conduct considered unprofessional, as listed in Wis. Admin. Code Phar 10, there is a need to identify problems created when a pharmacy's inventory includes examples of long-outdated and/or unacceptable numbers of outdated pharmaceuticals and chemicals. Reasonable effort should be demonstrated to remove such items from regular inventory and expedite their return or destruction. In the opinion of the Pharmacy Examining Board, antique containers and display pieces containing crude drugs are not viewed as violations. But good faith requires the removal of chemicals (undated or outdated) from containers in the professional service area unless they are conspicuously set apart in display containers.

284. 3/13/24 Pharmacists are required to report to the Board any information that reasonably suggests there is a probability that a prescription drug or device dispensed by a pharmacist has caused or contributed to substantial bodily injury or death of a patient.

CHAPTER PHAR 15 WISCONSIN ADMINISTRATIVE CODE (STERILE PHARMACEUTICALS)

These rules apply to pharmacies engaged in the preparation of sterile pharmaceuticals. If pharmacy does not compound sterile pharmaceuticals, please place "NA" in item 285 and skip to Phar 16, item 329.

Compliance Date:

PHAR 15.03 Policy and procedure manual

285. n/a Pharmacy prepares and maintains a policy and procedure manual for compounding, dispensing, delivery, administration, storage, and use of sterile pharmaceuticals.

286. _____ The manual includes a quality assurance program for the purpose of monitoring personnel qualifications, training and performance, product integrity, equipment, facilities, guidelines regarding patient education and provision of pharmaceutical services and up-to-date information on preparation of sterile pharmaceuticals.

287. _____ The policy and procedure manual is available to all personnel and updated annually or as needed to reflect current practice.

288. _____ The policy and procedure manual is available for inspection by the Board or its designee.

PHAR 15.04 Physical requirements

289. _____ (1) The pharmacy has a structurally isolated area designated for preparation and documentation associated with sterile pharmaceuticals. Entry and access is restricted to designated personnel to avoid traffic and airflow disturbances. The designated area is of sufficient size to accommodate a laminar airflow hood and proper storage of drugs and supplies.

(2) Environment maintains:

290. _____ (a) A class 100 environment during the normal activity in the workplace where critical objects are exposed and critical activities are performed.

291. _____ (b) Appropriate disposal containers as required by OSHA in 29 CFR Part 1910 for timely disposal of needles, syringes, infectious and cytotoxic wastes.

292. _____ (c) Appropriate environmental controls, including a class II biological safety cabinet if cytotoxic drug products are prepared.

293. _____ (d) Temperature-controlled delivery containers as necessary.

294. _____ (e) For hand washing, a sink with hot and cold running water in close proximity.

295. _____ (f) Administration devices, if necessary.

296. _____ (3) Sufficient reference materials related to sterile pharmaceuticals are available.

297. _____ (4) The designated area is closed and disinfected regularly with appropriate agents.

PHAR 15.05 Records and Reports

298. _____ (1) Maintains records and reports of:

299. _____ (a) Training and competency evaluations of personnel.

300. _____ (b) Documentation of refrigerator and freezer temperatures.

301. _____ (c) Certification of laminar flow hoods.

302. _____ (2) Minimal labeling requirements for sterile pharmaceuticals prepared for a single patient if the pharmaceuticals are to be completely administered within 28 hours:

303. _____ (a) The identity of all solutions and ingredients and their corresponding amounts, concentration or volumes on the final preparation container in such a manner as to allow the locating of problematic final products.

304. _____ (b) The identity of personnel involved in preparation.

305. _____ (c) The date and time of pharmacy preparation where applicable.

306. _____ (d) The final sterile pharmaceuticals expiration date and storage requirements, where applicable.

PHAR 15.06 Delivery of service

307. _____ The pharmacist assures the appropriate environmental control of all products shipped.

PHAR 15.07 Emergency kits

308. _____ When sterile pharmaceuticals are provided to home care patients, the dispensing pharmacy supplies the patient or the patient's agent with emergency drugs, when authorized by the physician under protocol, if an emergency situation has been anticipated by either the physician, nurse or pharmacist.

309. _____ The pharmacy provides written instructions on the storage and record keeping requirements for the emergency kit.

Compliance Date:

PHAR 15.08 Cytotoxic drugs

If pharmacy does not compound cytotoxic drugs, place "NA" in item 320 and skip to Phar 15.09, item 326.

310. _____ All cytotoxic drugs are compounded in a vertical flow, class II biological safety cabinet. If non-exposed surfaces become contaminated with cytotoxic drugs, no products other than cytotoxic drugs are compounded in this cabinet until the cabinet is decontaminated utilizing appropriate techniques

311. _____ Personnel are protected by a protective barrier or apparel which includes gloves, gowns and other applicable protective apparel as described in 29 CFR PART 1910 of OSHA regulations.

312. _____ Appropriate safety and containment techniques for compounding cytotoxics are used in conjunction with aseptic techniques required for preparation of sterile pharmaceuticals.

313. _____ Pharmacy disposal and patient and caregiver education regarding disposal of cytotoxic waste complies with all applicable local, state, and federal requirements.

314. _____ Written procedures for the handling of both major and minor spills of cytotoxic drugs are included in the pharmacy policy and procedure manual.

315. _____ Prepared doses of cytotoxic drugs are dispensed, labeled with proper precautions on the primary and shipping container and are shipped in a manner that minimizes the risk of accidental rupture of the primary container.

PHAR 15.09 Labeling

In addition to the labeling requirements of Wis. Stat. § 450.11(4).

316. _____ Control or lot number.

317. _____ Expiration date and time, when applicable

318. _____ Appropriate auxiliary labeling, including precautions.

319. _____ Storage requirements.

320. _____ Identification of the responsible pharmacist

PHAR 15.10 Patient training

321. _____ A Pharmacist is responsible for documenting the patient's training and competency in managing the type of therapy provided by the pharmacist to the patient if administered by the patient or a caregiver. Pharmacists are responsible for the provision or supervision of the patient training process in any area that relates to compounding, administration, labeling, storage, stability, or incompatibility. A pharmacist is responsible for seeing that the patient's competency in the above areas is reassessed on an ongoing basis.

PHAR 15.11 Quality Assurance

322. _____ There is a documented, ongoing quality assurance control program that monitors personnel performance, equipment, and facilities. Appropriate samples of finished products shall be examined to assure that the pharmacy is capable of consistently preparing sterile pharmaceuticals meeting specifications.

323. _____ The area designated in Wis. Admin. Code Phar 15.04 (2)(a) for preparing sterile pharmaceuticals is certified by an independent contractor. Certification takes place before initial use or after relocation and at least annually.

324. _____ The pharmacy has written procedures requiring sampling for microbial contamination through a validation procedure, simulation of actual aseptic preparation, and by using bacterial growth medium to culture environmental samples.

325. _____ If compounding of parenteral solutions is performed using non-sterile chemicals, extensive end product sterility testing is documented. Quarantine procedures shall be developed if there is a test failure.

326. _____ A pharmacy has written justification of the assigned expiration date for pharmacy prepared sterile pharmaceuticals.

327. _____ A pharmacy has documentation of quality assurance audits, including infection control and sterile technique audits at least annually.

328. _____ A pharmacy has procedures to assure consistent preparation of sterile pharmaceuticals.

CHAPTER PHAR 16 WISCONSIN ADMINISTRATIVE CODE (CONTINUING EDUCATION)

PHAR 16.02 Continuing education required; waiver

329. 3/13/24 (1) At the time of making application for renewal of a license: Each pharmacist required to complete the continuing education requirement provided under Wis. Stat. § 450.085, shall:

330. 3/13/24 (a) Sign a statement on the application for renewal certifying that the pharmacist has completed at least 30 hours of acceptable continuing education programs within the 2-year period immediately proceeding the date of his or her application for renewal. (This subsection does not apply to an application for renewal of a license that expires on the first renewal date after the date on which the Board initially granted the license.)

Note: The PEB will grant 15 hours of continuing education credit for every one credit of academic training received in coursework, which leads to a degree granted by an American Council on Pharmaceutical Education (ACPE) approved school of pharmacy.

Wisconsin Department of Safety and Professional Services

Compliance Date:

331. 3/13/24 (2) A pharmacist may apply to the Board for waiver of the requirements of this chapter on grounds of exceptional circumstances such as prolonged illness, disability or other similar circumstances that the pharmacist indicates have prevented him or her from meeting the requirements. The Board will consider each application for waiver individually on its merits.

PHAR 16.03 Acceptable continuing educational programs

332. 3/13/24 The educational programs used for CE are approved by the American Council on Pharmaceutical Education (ACPE) at the time of the pharmacist's attendance or other Board approved programs. To date the Board has only approved ACPE as a provider.

PHAR 16.04 Evidence of compliance

333. 3/13/24 The Board accepts as evidence of compliance with this chapter certification by a providing institution or organization that a pharmacist has attended and completed approved continuing education programs. Certification may be the original or verified copies of, documents certifying attendance and completion.

PHAR 16.05 Retention requirement

334. 3/13/24 The pharmacist shall retain evidence of compliance for 3 years following the renewal date for the biennium for which 30 hours of credit are required for renewal of a license.

PHAR 16.06 Audit

335. 3/13/24 The Board may require any pharmacist to submit his or her evidence of compliance with the continuing education requirements to audit compliance.

In the space provided below, for each item that received "NA" following your inspection, indicate why this rule does not apply to your pharmacy. (Attach additional pages if necessary.)

Costco does not dispense/stock controlled substances: 9, 13, 15, 16, 32, 131-146, 201-273, 277-280
10. the pharmacy always has a pharmacist present.
48 and 50: Original oral prescription orders and oral refill authorizations are only received by licensed pharmacists or pharmacy interns under the supervision of licensed pharmacists.
56. Costco does not compound any medications
60. Costco does not prepare unit dose carts
155: Costco does not dispense medications considered to be schedule drugs in WI
165. Costco does not utilize an automated dispensing system.
188-200: Costco does not utilize a central fill pharmacy
285: Costco does not engage in the preparation of sterile pharmaceuticals

Certification of Applicant:

The undersigned attests that the facts and statements herin contained are true and correct based upon personal knowledge of the undersigned.

Luke Braun | 03/19/2024

Signature (If unable to provide a digital signature print and sign form.) **Date**

United States of America

State of Wisconsin

DEPARTMENT OF FINANCIAL INSTITUTIONS

Division of Corporate & Consumer Services

To All to Whom These Presents Shall Come, Greeting:

I, Craig Heilman, Administrator of the Division of Corporate and Consumer Services, Department of Financial Institutions, do hereby certify that

COSTCO WHOLESALE CORPORATION

is a foreign corporation or foreign limited liability company authorized or registered to transact business in Wisconsin and that its date of qualification or registration is March 06, 2007.

I further certify that said organization has, within its most recently completed report year, filed an annual report required under ss. 180.1622, 181.0214 or 183.0212, Wis. Stats.; that it has not applied for a certificate of withdrawal under ss. 180.1520, 181.1520, 183.0904 or 183.0911, Wis. Stats.; and that it is not the subject of a proceeding under ss. 180.1531, 181.1531 or 183.09102, Wis. Stats., to revoke or terminate its certificate of authority or registration.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the official seal of the Department on August 02, 2024.

CRAIG HEILMAN, Administrator
Division of Corporate and Consumer Services
Department of Financial Institutions

DFI/Corp/33

To validate the authenticity of this certificate

Visit this web address: https://apps.dfi.wi.gov/apps/ccs/verify/

Enter this code: **395172-471EB56B**

COSTCO WHOLESALE CORPORATION
PRINCIPAL OFFICERS AND DIRECTORS

Title	First	Last	Company Address	Work Phone
CEO/President/ Director	Roland	Vachris	999 Lake Drive Issaquah, WA 98027	(425) 313-8100
Exec VP/CFO	Gary	Millerchip	999 Lake Drive Issaquah, WA 98027	(425) 313-8100
Exec VP/Assistant Secretary	Patrick	Callans	999 Lake Drive Issaquah, WA 98027	(425) 313-8100
Exec VP/Secretary	John	Sullivan	999 Lake Drive Issaquah, WA 98027	(425) 313-8100
VP/Treasurer	Jeffrey	Elliott	999 Lake Drive Issaquah, WA 98027	(425) 313-8100
AVP/Assistant Secretary	Margaret	McCulla	45940 Horseshoe Drive, Suite150 Sterling, VA 20166	(703) 406-6817
VP/Assistant Secretary	Gail	Tsuboi	999 Lake Drive Issaquah, WA 98027	(425) 313-8100
Assistant Secretary	Gary	Swearingen	999 Lake Drive Issaquah, WA 98027	(425) 313-8100
Director	Walter	Jelinek	999 Lake Drive Issaquah, WA 98027	(425) 313-8100
Director	Richard	Galanti	999 Lake Drive Issaquah, WA 98027	(425) 313-8100
Director	Susan	Decker	999 Lake Drive Issaquah, WA 98027	(650) 798-3842
Director	Kenneth	Denman	50 Cherry Hills Farm Dr. Englewood, CO 80113	(650) 886-9892
Director	Hamilton	James	345 Park Avenue New York, NY 10154	(212) 583-5455
Director	Sarah	Jewell	2201 Sunset Ave. SW Seattle, WA 98116	(206) 851-5887
Director	Jeffrey	Raikes	2157 N Northlake Way, Suite 220 Seattle, WA 98103	(206) 709-3288
Director	John	Stanton	155 108th Ave NE, Ste 400 Bellevue, WA 98004	(425) 586-8383
Director	Maggie	Wilderotter	19890 Shenandoah School Road Plymouth, CA, 95669	(209) 245-6016
Director	Helena	Foulkes	20 Cooke Street Providence, RI 02906	(401) 965-4575

PRINCIPAL SHAREHOLDERS

The following table sets forth information regarding ownership of the common stock by each person or group known to the Company to own more than 5% of the outstanding shares of the common stock on November 10, 2023.

Name and Address of Beneficial Owner	Shares	Percent[1]
Vanguard Group, Inc. P.O. Box 2600, V26 Valley Forge, PA 19482	39,875,117[(2)]	8.98%
BlackRock, Inc. 55 East 52nd Street New York, NY 10055	30,017,172[(3)]	6.76%

As a publicly traded company, we are only required to list the shareholders that own 5% or more of the outstanding shares in the company so we are unable to provide the top 4.

NO. 10071 - 42

THE STATE OF WISCONSIN

PHARMACY EXAMINING BOARD

Hereby certifies that

COSTCO PHARMACY #1710

LUKAS J BROWN
310 INTEGRITY DRIVE , SUITE 105, MADISON , WISCONSIN

was granted a license to operate as a

PHARMACY

in the State of Wisconsin in accordance with Wisconsin Law

on the 10th day of April in the year 2024.

The authority granted herein must be renewed each biennium by the granting authority.

In witness thereof, the State of Wisconsin
Pharmacy Examining Board
has caused this certificate to be issued under
the seal of the Department of Safety and Professional Services

Dan Hereth, Secretary

Tony Evers, Governor

This certificate was printed on the 30th day of April in the year 2024

State of Wisconsin

DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES

COMMITTED TO EQUAL OPPORTUNITY IN EMPLOYMENT AND LICENSING

PHARMACY

NO. 10071 - 42 Expires: 05/31/2026

COSTCO PHARMACY #1710
LUKAS J BROWN
310 INTEGRITY DRIVE, SUITE 105
MADISON, WISCONSIN 53717-1452
UNITED STATES

The person whose name appears on this document has complied with the provisions of the Wisconsin Statutes and holds the credential specified on the front of this card. To verify the current status of this credential, use "Lookup a License" at dsps.wi.gov.

The named person has complied with Wisconsin Statutes and holds the credential specified.
Signature: Costco Wholesale Corporation

Ch 440.11, Wis Statutes, requires you to notify the Department of a name or address change within 30 days. Please submit corrected information via the web at dsps.wi.gov or by mail to DSPS at PO Box 8935, Madison WI 53708-8935.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC4160014	08-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-17-2024

COSTCO WHOLESALE CORPORATION
DBA COSTCO PHARMACY #1710
310 INTEGRITY DR STE 105
MADISON, WI 537171452

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC4160014	08-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-17-2024

COSTCO WHOLESALE CORPORATION
DBA COSTCO PHARMACY #1710
310 INTEGRITY DR STE 105
MADISON, WI 537171452

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NABP ACCREDITED
DIGITAL PHARMACY

Costco Wholesale Corporation

with headquarters located at

999 Lake Drive, Issaquah, WA 98027

This business has met all the digital pharmacy criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accredited locations may also be verified by visiting the digital pharmacy section on the NABP website, located at: www.nabp.pharmacy/programs/digital-pharmacy/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

09/14/2021 - 09/13/2024
Period of Accreditation

4XX

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-Nevada	☒ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 04163		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Cottrill's Pharmacy, Inc

Physical Address: 4919 Ellicott Rd

City: Orchard Park State: NY Zip: 14127

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 716-508-8481 Toll Free # (NAC 639.708, NRS 639.23286): 844-268-8745

Fax: 716-508-8482 Contact Email: licensing@cottrillspharmacy.com

Website: www.cottrillspharmacy.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Erin Mellerski

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24308

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Erin Mellerski	NV Pharmacist Registration #: 24308
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New York

Parent Company (if any): _____

Corporation/Organization Name: Cottrill's Pharmacy, Inc

Mailing Address: 4919 Ellicott Rd

City: Orchard Park State: NY Zip: 14127

Telephone: 716-508-8481 Email: licensing@cottrillspharmacy.com

Contact Person Name: Erin Mellerski

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CCO/SVP of Operations (title) for Cottrill's Pharmacy, Inc (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Erin Mellerski

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

9/24/2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Erin Mellerski hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CCO/SVP of Operations (title) for Cottrill's Pharmacy, Inc (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

E Mellerski
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 24th day of September, 2024

Elaine A. Ursin
Notary Public

ELAINE A. URSIN
Notary Public, State of New York
Qualified in Erie County
My Commission Expires 1/14/2028

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Erin Mellerski

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

9/24/2024

Date

Board Use Only	Date Received: 9/30/24	Amount: $500-cc

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, WALTER T. MOSLEY, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	COTTRILL'S PHARMACY, INC.
DOS ID Number:	192888
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	11/26/1965
Statement Status:	PAST DUE
Statement Due Date:	11/30/2021

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on June 25, 2024 at 02:10 P.M.

WALTER T. MOSLEY
Secretary of State

Brendan C. Hughes

BRENDAN C. HUGHES
Executive Deputy Secretary of State

Authentication Number: 100005966278 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2023-26

SUPERVISING PHARMACIST
ERIN E. MELLERSKI

THIS IS TO CERTIFY

COTTRILL'S PHARMACY INC.
4919 ELLICOTT RD.
ORCHARD PARK, NY 14127

is duly recorded as a

REGISTERED PHARMACY

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE FIRST DAY OF FEBRUARY, 2023.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF JANUARY, 2026.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

2345

REGISTRATION NUMBER
035270

Dina Joyce
EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC6577792	08-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	07-13-2022

COTTRILL'S PHARMACY, INC
4919 ELLICOTT RD
ORCHARD PARK, NY 141273357

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC6577792	08-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	07-13-2022

COTTRILL'S PHARMACY, INC
4919 ELLICOTT RD
ORCHARD PARK, NY 141273357

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

COTTRILL'S PHARMACY INC. X

GENERAL INFO | ENFORCEMENT ACTIONS

Type	Pharmacy
Legal Name	COTTRILL'S PHARMACY INC.
Trade Name	---
Street Address	4919 ELLICOTT RD. ORCHARD PARK NY 14127
Registration No	035270
Date First Registered	February 13, 2017
Registration Begins	February 01, 2023
Registered Through	January 31, 2026
Supervisor	060006 - MELLERSKI ERIN EILEEN
Establishment Status	Active
Successor	NONE

COTTRILL'S PHARMACY INC. X

GENERAL INFO | ENFORCEMENT ACTIONS

Registration No: 035270

No Enforcement Actions Found

September 26, 2024 11:48 AM (ET)
https://eservices.nysed.gov/professions/verification-search?pharmacyRegistrationNumber=035270&professionCode=020

COTTRILL'S
PHARMACY, INC.

Corporate Officers & Ownership

Cottrill's Pharmacy, Inc
4919 Ellicott Rd.
Orchard Park, NY 14127
716-508-8481

Bethany Obrochta - Owner/CEO-100% shares
[redacted] Meadowbrook Rd.
Orchard Park, NY 14127
[redacted]

Erin Mellerski PharmD, CSP - Chief Clinical Officer/SVP of Operations
[redacted] Edswood Ct.
Orchard Park, NY 14127
[redacted]

urac ACCREDITED Specialty Pharmacy Accreditation 02/01/2027

ACHC ACCREDITED

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Cottrill's Pharmacy, Inc

Pharmacy/Wholesaler License # (if applicable): PH04163

Physical Address: 4919 Ellicott Rd

City: Orchard Park State: NY Zip: 14127

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 716-508-8481 Website: www.cottrillspharmacy.com

Licensing Company Email: licensing@cottrillspharmacy.com

Section 2: Personal Information

First: Erin Middle: Last: Mellerski

Alias(es, nicknames, name changes, etc.): Erin Stack (Maiden name)

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Addres: [redacted] Edswood Ct

City: Orchard Park State: NY Zip: 14127

Telephon: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Lake Erie College of Osteopathic Medicine		08/08-05/11	
Address	**City**	**State**	**Zip**
1858 Grandview Blvd	Erie	PA	16509
Diploma/Degree obtained, if any			
PharmD			
School Name		**From - To (MM/YY – MM/YY)**	
University at Buffalo		08/06-05/08	
Address	**City**	**State**	**Zip**
University at Buffalo	Amherst	NY	14260
Diploma/Degree obtained, if any			
Pre-Pharmacy coursework (no degree)			
School Name		**From - To (MM/YY – MM/YY)**	
Saint John Fisher University		08/02-08/06	
Address	**City**	**State**	**Zip**
3690 East Ave	Rochester	NY	14618
Diploma/Degree obtained, if any			
BS, Psychology			
School Name		**From - To (MM/YY – MM/YY)**	
Mount Mercy Academy		09/98-06/02	
Address	**City**	**State**	**Zip**
88 Red Jacket Pkwy	Buffalo	NY	14220
Diploma/Degree obtained, if any			
High School Regents Diploma			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/23-present	[redacted]Edswood Ct	Orchard Park	NY	14127
07/17-09/23	[redacted]Harvard Place	Orchard Park	NY	14127
11/15-07/17	[redacted]Harvard Place	Orchard Park	NY	14127
09/15-11/15	[redacted]Downing St	Buffalo	NY	14220
06/13-09/15	[redacted]Pelham Springs Place	Greenville	SC	29615
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Cottrill's Pharmacy, Inc			09/15-present	
Business Address		**City**	**State**	**Zip**
4919 Ellicott Rd		Orchard Park	NY	14127
Phone	**Title**		**Number of Employed Hours**	
716-508-8481	Chief Clinical Officer/SVP of Operations		18,720	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Erin Mellerski, **certify that as the designated representative for**

Cottrill's Pharmacy, Inc,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ERM I am at least 21 years of age;
3. ERM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ERM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ERM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ERM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ERM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Erin Mellerski

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/24/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Erin Mellerski

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/24/2024

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Erie

I, Erin Mellerski, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/24/24

Date

Subscribed and Sworn to before me this 24th day of September 2024

Notary Public Signature

ELAINE A. URSIN
Notary Public, State of New York
Qualified in Erie County
My Commission Expires 1/14/2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Cottrill's Pharmacy, Inc

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH04163

Physical Address: 4919 Ellicott Rd

City: Orchard Park State: NY Zip: 14127

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 716-508-8481 Website: www.cottrillspharmacy.com

Licensing Company Email: licensing@cottrillspharmacy.com

Section 2: Personal Information

First: Bethany Middle: Last: Obrochta

Alias(es, nicknames, name changes, etc.): Bethany DeRoo (maiden name)

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] Meadowbrook Rd

City: Orchard Park State: NY Zip: 14127

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Michigan State University		09/86-05/90	
Address	**City**	**State**	**Zip**
220 Trowbridge Rd	East lansing	MI	48824
Diploma/Degree obtained, if any			
Bachelor of Arts with Defree in Advertising			

School Name		From - To (MM/YY – MM/YY)	
Lahser High School		09/82-06/86	
Address	**City**	**State**	**Zip**
3456 Lahser Rd	Bloomfield Hills	MI	48304
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/99-present	[redacted]Meadowbrook Rd	Orchard Park	NY	14127
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Cottrill's Pharmacy, Inc			06/24-present	
Business Address		**City**	**State**	**Zip**
4919 Ellicott Rd		Orchard Park	NY	14127
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bethany Obrochta

Print Name (First, Last)

Bethany Obrochta

Original Signature (electronic, copies or stamps not accepted)

9/25/2024

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Erie

I, Bethany Obrochta, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Bethany Obrochta

Original Signature

9/25/24

Date

Subscribed and Sworn to before me this 25th day of September 2024

Elaine A. Ursin

Notary Public Signature

ELAINE A. URSIN
Notary Public, State of New York
Qualified in Erie County
My Commission Expires 1/14/2028

(Seal)

© National Association of Boards of Pharmacy® (NABP®) All rights reserved. NABP developed this inspection form for sole use by NABP® the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party, or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Pharmacy e-Profile ID:	1371283		**Inspection Information**
Legal Business Name:	Cottrill's Pharmacy Inc	**Conference Call Date:**	3/14/2023
Doing Business As (DBA):	Cottrill's Pharmacy Inc	**Start Time: 24-hour format (13:00)**	14:10
Address:	4919 Ellicott Rd	**End Time: 24-hour format (13:00)**	15:45
City:	Orchard Park	**Onsite Inspection Date:**	3/15/2023
State:	NY	**Start Time: 24-hour format (13:00)**	9:35
Zip Code:	14127	**End Time: 24-hour format (13:00)**	14:20
Telephone number:	716 508-8481	**Inspector Name:**	Dhafer Almaklani, RPh
Toll free number:	844 268-8745	**Inspection Performed by (NABP, State, etc):**	NABP
Fax number:	716 508-8482	**Observer Name/Affiliation (if applicable):**	N/A
Website:	www.cottrillspharmacy.com	**Observer Name/Affiliation (if applicable):**	N/A

Pharmacy Hours of Operation — **Check if 24/7** ☐

	Open		Closed
	Start Time: (24-hour format)	**End Time: (24-hour format)**	**(X)**
Sunday			X
Monday	8:00	17:00	
Tuesday	8:00	17:00	
Wednesday	8:00	17:00	
Thursday	8:00	17:00	
Friday	8:00	17:00	
Saturday			X

Key Pharmacy Personnel	**Name**	**Contact (e-mail)**	**e-Profile ID**
Pharmacist in Charge	Erin Mellerski	emellerski@cottrillspharmacy.com	280463
Nonsterile Compounding Supervisor	David Williams	dwilliams@cottrillspharmacy.com	587385
Sterile Compounding Supervisor	N/A	N/A	N/A
Hazardous Compounding Supervisor	David Williams	dwilliams@cottrillspharmacy.com	587385

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Elizabeth Murphy	Staff pharmacist	Y
2	Michelle Sedar-Parkes	Staff pharmacist	Y
3	Tina Depretta	Shipping Coordinator	N/A
4	Melissa Bartolucci	Pharmacy Technician	Y
5	Morgan Beres	Pharmacy Intern	Y
6	Elaine Ursin	Office Manager	N/A
7	Luz Gonzales	Licensing Specialist	N/A
8	Ann Marie Skalski	Registered Nurse	Y
9	Jim Pohlman	Procurement Specialist	N/A
10	Erin Mellerski	PIC	Y

In addition: Chief Strategy Officer, 1 Business Development Director, 1 Account Manager, and 1 Data Analyst.

Business Licensure Information for State of Residence and Federal (board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	License Type/Number	Expiration Date
US DOJ/DEA	Cottrill's Pharmacy, Inc	Controlled Substance-Retail Pharmacy/FC6577792	8/31/2025
State of New York	Cottrill's Pharmacy, Inc	Pharmacy/035270	1/31/2026

Pharmacy business model is primarily focused on dispensing specialty medications. In addition, pharmacy conducts nonsterile compounding (hazardous and non-hazardous). Currently, all compounding is conducted within one GermFree CVE that is not vented to the outside (or redundant HEPA filter) and is not located within a negative pressure room see photo01. However, according to the PIC, effective 04/01/2023, all nonsterile compounding operations will be conducted at a new licensed pharmacy space to be located in Suite A of the current building, (see photo02). The new licensed pharmacy will have an externally vented hood located within a proposed negative pressure room and will operate as a separate business entity, in addition to the current pharmacy. Pharmacy holds non-resident licenses in all required states and DC, except California (CA).

© National Association of Boards of Pharmacy® (NABP®) All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Attachments
(NO PHI, including prescription numbers)

Attachment Name	Description
Photo01_PI56_CottrillsPharmacyIncOrchardPark_NY	Photo of CVE used for all non-sterile compounding.
Photo02_PI56_CottrillsPharmacyInc_OrchardPark_NY	Photos of new licensed pharmacy with externally vented hood and proposed negative pressure room.
Doc01_Gen10_CottrillsPharmacyInc_OrchardPark_NY	Sample patient label for Botox
Doc02_NS21.01_CottrillsPharmacyInc_OrchardPark_NY	Sample Certificate of Analysis (COA)
Doc03_NS54.00and54.01CottrillsPharmacyInc_OrchardPark_NY and Doc04_NS58.00_CottrillsPharmacyInc_Orchard Park_NY	Documentation of training records; and Updated hood certification label.

	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail		Telepharmacy	
Open to the Public	X	Central Fill/Processing/Shared Services	
Closed Door		Specialty Pharmacy	X
Drive-through window		Handles Medical Marijuana	
Mail/Deliver (in state)	X	Nuclear Pharmacy	
Mail/Deliver (out-of-state list below)	X	Manufacturer	
Veterinary Pharmacy	X	Wholesale Distributor	
Investigational Drugs, Clinical Trials/Research		Provide products for "Office Use"	
Institutional		Outsourcing Facility	
Long-Term Care		Nonsterile Compounding	X
HMO/PBM only		Nonsterile Hazardous Drug Compounding	X
Internet Pharmacy (New Rx)		Sterile Compounding	
Internet Pharmacy (Refill Rx)		Sterile Hazardous Drug Compounding	

© National Association of Boards of Pharmacy® (NABP®) All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Facility Size in Square Feet and Number of PECs		Personnel	
Total Pharmacy size:	558	Total Pharmacists:	4
Nonsterile Compounding Room size:	N/A	Number of Compounding Pharmacists	2
Nonsterile Compounding powder hoods number:	1	Total Graduate Students or Residents:	0
Nonsterile Hazardous Drugs (HD) Compounding Room size:	N/A	Total Student Interns:	1
Nonsterile HD Compounding BSC/CACI hoods number:	0	Total Technicians:	1
Sterile Compounding Ante Room size:	N/A	Number of Compounding Technicians	0
Sterile Compounding Clean/Buffer Room size:	N/A	Of technicians, how many are certified?	1
Sterile Compounding Number LAFW hoods/areas:	0	Of technicians, how many are techs-in-training?	0
Sterile Compounding Number BSC hoods:	0	Total Other Licensed Personnel:	1
Sterile Compounding Number CAI/CACI hoods:	0	Total Other Unlicensed Personnel:	14
Negative Pressure Sterile HD Room size:	N/A	Ratio #tech:#RPh present at time of inspection:	1:3
Sterile HD Compounding Number of BSC hoods:	0	Total Pharmacist Hours Per Week:	135
Sterile HD Compounding Number of CACI hoods:	0	Total Technician Hours Per Week:	40

Volume Dispensed		Volume Distributed	
Total Prescriptions Dispensed/day:	20	Total Orders Distributed/day:	0
% Veterinary Prescriptions	10%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	<1%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	20%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	0%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	<1%	% Hazardous Drugs (HD) Orders	0%

Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific, is not labeled with the patient name at the pharmacy.

© National Association of Boards of Pharmacy® (NABP®) All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month): Note: if not available, request information be sent to VPP and note that information was requested in grid.			
State	**Volume Dispensed**	**Volume DISTRIBUTED**	**/day, week, month**
Alabama (AL)	1	0	February 2023
Alaska (AK)	0	0	February 2023
Arizona (AZ)	1	0	February 2023
Arkansas (AR)	1	0	February 2023
California (CA)			
Colorado (CO)	4	0	February 2023
Connecticut (CT)	9	0	February 2023
Delaware (DE)	0	0	February 2023
District of Columbia (DC)	0	0	February 2023
Florida (FL)	7	0	February 2023
Georgia (GA)	1	0	February 2023
Hawaii (HI)	0	0	February 2023
Idaho (ID)	0	0	February 2023
Illinois (IL)	1	0	February 2023
Indiana (IN)	8	0	February 2023
Iowa (IA)	5	0	February 2023
Kansas (KS)	0	0	February 2023
Kentucky (KY)	3	0	February 2023
Louisiana (LA)	2	0	February 2023
Maine (ME)	7	0	February 2023
Maryland (MD)	49	0	February 2023
Massachusetts (MA)	0	0	February 2023
Michigan (MI)	2	0	February 2023
Minnesota (MN)	0	0	February 2023
Mississippi (MS)	0	0	February 2023
Missouri (MO)	2	0	February 2023
Montana (MT)	1	0	February 2023

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Dissemination of this form as a blank copy or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)	0	0	February 2023
Nevada (NV)	0	0	February 2023
New Hampshire (NH)	0	0	February 2023
New Jersey (NJ)	3	0	February 2023
New Mexico (NM)	1	0	February 2023
New York (NY)	119	0	February 2023
North Carolina (NC)	11	0	February 2023
North Dakota (ND)	0	0	February 2023
Ohio (OH)	16	0	February 2023
Oklahoma (OK)	0	0	February 2023
Oregon (OR)	0	0	February 2023
Pennsylvania (PA)	60	0	February 2023
Rhode Island (RI)	1	0	February 2023
South Carolina (SC)	2	0	February 2023
South Dakota (SD)	0	0	February 2023
Tennessee (TN)	6	0	February 2023
Texas (TX)	23	0	February 2023
Utah (UT)	1	0	February 2023
Vermont (VT)	0	0	February 2023
Virginia (VA)	2	0	February 2023
Washington (WA)	0	0	February 2023
West Virginia (WV)	1	0	February 2023
Wisconsin (WI)	2	0	February 2023
Wyoming (WY)	0	0	February 2023
Other:			

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
	General Pharmacy		
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	Conference call was conducted with staff pharmacist David Williams and onsite visit with PIC Erin Mellerski.
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Unknown	PIC is a full-time employee of Cottrill's Pharmacy Inc. However, they are not involved in the day to day operations of the pharmacy. According to the PIC, most of her work is "outside" of the pharmacy and it is not clear how many hours per week are spent onsite.
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	Yes	A retail pharmacy that is currently licensed but not operational, will be located in suite A. According to the PIC, all nonsterile compounding operations will be conducted at the new pharmacy, which will operate as an affiliate of Cottrill's Pharmacy Inc.
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	No	
4.01	Does the pharmacy hold .pharmacy verification?	No	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	No	
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	No	Patients can order refills via pharmacy mobile application not linked to website.
8.00	Are photographs allowed during the inspection (no PHI)?	Yes	
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**		David Williams-Staff Pharmacist; Kelly Zwack-Compliance Officer (via phone); Michelle Sedar-Staff Pharmacist; Elizabeth Murphy-Staff Pharmacist; Leanne Donohue-Staff Pharmacist

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
	Types of Practice Additional Questions **If any part of a question is no, enter "No" and explain the observation.**		
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	Yes	<1% in NY, none out of state; one patient on Botox, see Doc01
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
	General Operations and Licensure **If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	Yes	
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	09/12/2016; no routine inspections
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	No	No deficiencies noted

© National Association of Boards of Pharmacy® (NABP®) All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	Yes	Zero reporting waiver for states that allow. Per pharmacist Williams, no controlled substances are shipped out of state.
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	Yes	ACHC-Specialty Pharmacy - 04/15/2021; URAC-Specialty Pharmacy - 02/02/2021 & 02/03/2021
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	Yes	No longer hold ACHC-DEMPOS accreditation due to change in business model.
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	Yes	New York Department of Health Limited Services Laboratory Registration issued to Cottrill's Pharmacy Inc; CLIA #: 33D2209654; Exp: 12/13/2023; Director: Chester H Fox, MD

© National Association of Boards of Pharmacy® (NABP). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of this form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	All records kept 10 years onsite
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	Yes	
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Both
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronically
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Can deactivate but not delete in the system.
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	N/A	
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	Per P&P, Corporate Compliance Plan v1, pharmacy must follow most stringent law.
	Personnel **If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	Posted in the pharmacy and included in employee file
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process*	Yes	Intake and Licensing Specialist conducts annual verifications.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	Yes	COVID testing by PTCB certified pharmacy technicians; Immunizations- by APhA certified pharmacists
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	Yes	2:1; maximum 4 staff

© National Association of Boards of Pharmacy® (NABP). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
	Facility and Security **If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	Sonitrol Alarm 24/7 monitoring; glass break sensors, motion sensors, contact alarms, cameras throughout, and key fob access.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	Yes	Locked cabinet
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Unknown	It is not clear if pharmacy staff are appropriately trained on pharmacy's disaster recovery policy. Staff pharmacist Williams was not familiar with contingency plan to secure drug products in the event building cannot be secured. States, he is only familiar with policy for protecting employees during emergency. However, the PIC indicated that a pharmacist would remain onsite until secure, or relocate drug products to another sister location if needed.
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	N/A	No onsite destruction
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	Return Solutions
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	Yes	Biosan Disposal; come out as needed, approximately 3 to 4 times per year

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	Yes	Pharmacy has very little pick ups, but will use a private office as needed.
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Yes	Thermostatically controlled, Observed Temp: 22.7°C
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	No	Electronic continuous monitoring via DicksonOne, email excursion alerts sent to supervising pharmacists and compliance officer, records maintained for 3 years. Excursion alarm range was not set at the time of inspection. Note: Pharmacy subsequently corrected the range during the inspection.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	No	Quarantine product, and reference manufacturer stability data. However, no excursion range was set for controlled room temperature (CRT) at the time of inspection.
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	Electronic continuous monitoring via DicksonOne, email excursion alerts sent to supervising pharmacists and compliance officer, records maintained for 3 years. Range: 2°C to 8°C
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	Yes	Cooler #1: 2.6°C; Cooler #2: 6.3°C
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	No	Subzero freezer for vaccines is monitored electronically via DicksonOne, email excursion alerts sent to supervising pharmacist and compliance officer, records maintained for 3 years. Excursion alarm range was not set at the time of inspection. Note: Pharmacy subsequently corrected the range during the inspection.
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection*	Yes	Sub-zero freezer for vaccine: -19.6°C; within vaccine requirement of -25°C to -15°C.

© National Association of Boards of Pharmacy® (NABP®) All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	Whole building generator and redundant refrigerators
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes*	Yes	On-call HVAC contractor for repairs
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	No	Alarm alert ranges for CRT and freezer were not set at the time of inspection to identify past excursions.
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types*	No	
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	N/A	
	Product Receipt and Inventory **If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	Yes	According to Compliance Officer, procurement policy is followed, which includes referrals, reference checks, conducting a risk assessment, and obtaining copies of licensure.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	No	
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase*	No	
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	Yes	Cardinal, McKesson, Hercules Rx and Anda
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	Yes	This is verified via transaction data
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	No	

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of this form by a third party without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	No	Per Compliance Officer, pharmacy obtains copy of licenses from source vendors, no primary source verification.
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	No	Per Compliance officer, pharmacy does not conduct primary source verification of FDA reporting. Pharmacy relies on language in their contract that source vendors will comply with this requirement.
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	Products are examined during receiving, any suspect product is quarantined, and wholesale distributor (WD) is contacted by compliance team.
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	Yes	Retrieved from WD portal
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	Yes	Power of Attorney is with PIC; stored in locked cabinet within the pharmacy
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	No	
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	Yes	
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	Yes	

® National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	Perpetual inventory for controlled substances and API
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	Reported to NY Bureau of Narcotic Enforcement (BNE), DEA, and Board of Pharmacy (BOP)
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	Yes	
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	No	Per pharmacist Williams, only one Schedule-II controlled substance is in stock, pharmacy maintains a perpetual inventory but it is not reconciled.
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	Yes	05/01/2023, annually
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	Yes	
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	Monthly
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	All checked drugs were within date.
60.02	How often is active-stock examined for drugs past the expiration date?		Monthly
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	No	
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	N/A	
	Prescription Processing **If any part of a question is no, enter "No" and explain the observation.**		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	The pharmacy intake team creates initial profile then pharmacists add any clinical related data; profile is updated each month with each fill and patient assessment.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	Yes	There is a drop down functionality in profile to indicate species, as well as include owners name on labeling.
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Yes	Report to BOP, DEA if required, law enforcement, and Bureau of Narcotic Enforcement (BNE)

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	Intake process includes reviewing clinic notes and patient interviews to establish a prescriber-patient relationship.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	Both
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	Yes	
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	Verified by pharmacist at PV1
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	At PV1 and final verification
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	Yes	
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	Yes	Lab values and weight
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	Facts and Comparisons, Plumbs Veterinary Handbook, Hemophilia Guidelines, and PCCA subscription.
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	Electronic or manual reporting per state requirements

© National Association of Boards of Pharmacy® (NABP®) All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility. Its VPP. Disclosure of this form to a third party or use of the form by a third party, sale by any entity not listed without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Yes	
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	Only pharmacist can override, documented electronically using credentials
67.07	Is the DUR process performed electronically by the computer system? ***Identify integrated drug database used.***	Yes	Medispan
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	N/A	
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	Yes	Plumb's Veterinary Handbook
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	Final verification is by pharmacist at PV2, documented electronically using credentials.
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	Contain required information
70.00	**Confidentiality**: Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	Prime Rx and PK software, password protected by job function
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	The pharmacy uses a cross cut shredder in house.
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	

® National Association of Boards of Pharmacy® (NABP). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
	Patient Counseling and Communication **If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all <u>new</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	Yes	
75.01	Is an "offer" to counsel made for all <u>new</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer"*	N/A	
76.00	Does the pharmacist provide counseling for all <u>refilled</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	Yes	

© National Association of Boards of Pharmacy® (NABP®) All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
76.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy? *Indicate who makes the "offer"*	N/A	
77.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	Yes	
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer".*	N/A	
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Patient is contacted prior to delivery, as well as printed information, and toll-free number provided.
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Patient is contacted prior to delivery, as well as printed information, and toll-free number provided.
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	Yes	Provided with original packaging in bag.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	Yes	Printed automatically
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin or Tikosyn).*	Yes	Enrolled in Vigabatrin REMs but currently no patients on the program.
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	Yes	Documented in patient profile
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).*	Yes	On-call pharmacist via toll-free number
85.00	Are processes in place to handle a drug recall?	Yes	
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	

© National Association of Boards of Pharmacy® (NABP®) All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	
	Quality Assurance/Quality Improvement Program **If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	Overseen by Kelly Zwack-Compliance Officer
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	Electronic
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	

© National Association of Boards of Pharmacy® (NABP®) all rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic*	Yes	Documented on hard copy template that is uploaded and stored electronically.
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc)*	Yes	Quality management team analyzes quarterly
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	Yes	

© National Association of Boards of Pharmacy® (NABP®) All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	Quarterly meetings
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	Yes	Board of Pharmacy and ISMP
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	MedWatch and VAERS
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	N/A	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	Yes	Annual patient satisfaction survey via mail.
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	

© National Association of Boards of Pharmacy® (NABP®) All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party, or use of the form by a third party, is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
	General Operations and Information		
1.00	Does the pharmacy **dispense** nonsterile compounded preparations pursuant to a prescription?	Yes	
1.01	Are patient profiles complete and DUR performed for each prescription? *View selected files for profile to include allergies, disease states/conditions, other medications taken not dispensed by this pharmacy.*	Yes	
1.02	Do the compounded prescriptions produce a significant difference from a commercially available drug that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner?	Yes	
1.03	Are nonsterile compounded prescriptions picked up at the pharmacy?	Yes	
1.04	Are nonsterile compounded prescriptions delivered to patients in their homes or residential facilities?	No	
1.05	Are nonsterile compounded prescriptions mailed to patients in their homes or residential facilities?	Yes	
1.06	Are nonsterile compounded prescriptions delivered to the practitioner for administration to the patient in the office, clinic, or facility?	No	
1.07	Are nonsterile compounded prescriptions mailed to the practitioner for administration to the patient in the office, clinic, or facility?	No	
2.00	Does the pharmacy **distribute** nonsterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.*	No	
2.01	Does the pharmacy distribute nonsterile compounded preparations to practitioners for office use?	N/A	
2.02	Does the pharmacy distribute nonsterile compounded preparations to hospitals, clinics, or surgery centers?	N/A	
2.03	Does the pharmacy have a sales force that promotes compounded preparations? *List compounds promoted.*	N/A	

® National Association of Boards of Pharmacy® (NABP®) All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
2.04	Does the pharmacy distribute non-patient specific compounded preparations for promotional purposes? *List compounds provided.*	N/A	
2.05	If yes, does the sales force hand-deliver these compounds? *List compounds provided.*	N/A	
2.06	If yes, are any of these controlled substances? *List compounds provided.*	N/A	
3.00	Does the pharmacy provide nonsterile compounded preparations to other pharmacies for dispensing?	No	
3.01	If so, does the pharmacy have central fill/shared services contracts or agreements with these pharmacies for patient specific preparations? *Provide List.*	N/A	
4.00	Does the pharmacy compound oral preparations (tablets, capsules, liquids, lozenges, etc.)? *Provide List.*	Yes	Liquids, capsules, and lollipops
5.00	Does the pharmacy compound topicals (gels, creams, ointments, inserts, suppositories, patches, sprays including nasal sprays, etc.)? *Provide List.*	Yes	Creams, ointments, and suppositories
6.00	Does the pharmacy compound vitamin or nutritional supplements? *Provide List.*	No	
7.00	Does the pharmacy sell any compounds over-the-counter? *Provide list.*	No	
8.00	Does the pharmacy compound investigational drugs? *Provide List.*	No	
9.00	Does the pharmacy only make essential copies of a commercially available drug product on the Drug Shortage List or that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner? *Indicate volume or percent compounded currently.*	No	
9.01	If yes, products are verified as appearing on the Drug Shortage List in effect under 506E of the Federal Act at the time of compounding, distribution, and dispensing.	N/A	

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party, or use of the form by a third party, is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
9.02	If yes, the Drug Shortage List is monitored and when a drug product is no longer on the list, any remaining stock is quarantined and not available for distribution or dispensing. *Note: Per FDA guidance, 503B facilities may continue to distribute for 60 days following drug shortage list removal for existing orders.*	N/A	
10.00	Does the pharmacy perform compounding identified as **simple?** *Indicate percentage of simple compounding* 1. Making a preparation that has a USP compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate beyond-use dates (BUD)s. 2. Reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer. *Examples include Captopril Oral Solution, Indomethacin Topical precautions. Gel, and Potassium Bromide Oral Solution (Veterinary).*	Yes	15%
11.00	Does the pharmacy perform compounding identified as **moderate?** *Indicate percentage of moderate compounding.* 1. Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units. 2. Making a preparation for which stability data for that specific formula is not available. *Examples include Morphine Sulfate Suppositories, diphenhydramine hydrochloride troches, and mixing two or more manufactured cream products when the stability of the mixture is not known.*	Yes	85%
12.00	Does the pharmacy perform compounding identified as **complex**? *Indicate percentage of complex compounding.* Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. *Examples of possible complex preparation types include transdermal dosage forms, modified-release preparations, and some inserts and suppositories for systemic effects.*	No	0%
13.00	Does the pharmacy perform compounding with **hazardous drugs**? *Indicate percentage of compounding with hazardous drugs* NIOSH list of hazardous drugs including chemotherapy, hormones, etc.	Yes	5%
13.01	Is the pharmacy aware of the more stringent requirements of the proposed USP Chapter <800>?	Yes	Per PIC, pharmacy is aware of USP 800, but indicates that NY state has not implemented USP 800 and pharmacy only ships to patients within NY State.

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
14.00	Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.*	Yes	Electronic
15.00	Does the pharmacy compound using any **controlled substances**? *Indicate percentage of controlled substance nonsterile compounding.*	Yes	<1%
16.00	**APIs:** Does the pharmacy make any nonsterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?	Yes	
16.01	Does the pharmacy purchase APIs directly from the manufacturer/repackager? *Indicate the source of APIs*	Yes	PCCA and Letco
16.02	Does the pharmacy verify that the manufacturer/repackager of the API is an FDA-registered facility? *If so, list how this verified.*	Yes	Via FDA website
16.03	Does the pharmacy use active ingredients that are not from an FDA-registered facility? *If so, indicate sources*	No	
16.04	Does the computer track on-hand quantities of APIs used for compounding? *If not, explain.*	Yes	
17.00	Does the pharmacy perform any testing in-house (not sent to an outside lab)? *If so, what tests are performed in house?*	No	
18.00	Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what testing is performed.*	Yes	Eagle Analytical for potency
19.00	Does the pharmacy use scales/balances for nonsterile compounding?	Yes	
19.01	If so, what type of scale/balanced is used? *List manufacturer and model number*		Ohaus Explorer EX423N
19.02	If the scale/balance is electronic, does the pharmacy use the automatic calibration? *Describe process and indicate frequency*	Yes	Calibrated once a day with records maintained in Pk software, as well as annual certification by State of NY.

© National Association of Boards of Pharmacy® (NABP) all rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for this inspection. Disclosure of this form to a third party or use of this form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
19.03	Describe the pharmacist checks for the measurement of each ingredient		Only pharmacists compound; also electronic scale integration with PK software.
20.00	**Quality Assurance/Quality Improvement:** Does the pharmacy continuous quality improvement program include nonsterile compounding measures? **Note: If the facility indicates "yes", please ask each question below to verify.**	Yes	
20.01	Does the pharmacy continuous quality improvement program include QREs related to the preparation of compounded products?	Yes	
20.02	Does the pharmacy continuous quality improvement program include personnel testing and verification?	Yes	
20.03	Does the pharmacy continuous quality improvement program include equipment calibration, testing, etc?	Yes	
20.04	Does the pharmacy continuous quality improvement program include end product testing (such as: pH, weight, potency, particulates, consistency, etc.)?	Yes	
20.05	Does the pharmacy continuous quality improvement program include patient or prescriber reports or complaints regarding nonsterile compounded products?	Yes	
20.06	Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded including a recall system?	Yes	
20.07	Does the recall system include communication with both the patient and the physician/prescriber regarding the affected nonsterile compounded preparation?	Yes	
20.08	Are QREs involving nonsterile compounded preparations or are recalled by the pharmacy reported to the Board of Pharmacy?	Yes	

© National Association of Boards of Pharmacy® (NABP®) All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
Component Selection and Use			
	Total Non-Compliant (Includes Unknowns)	0	
21.00	**Active Pharmaceutical Ingredients (APIs), bulk drug substances:** All bulk drug substances (APIs) used are: 1) Compliant with the standards of an applicable USP or NF monograph, if one exists; or 2) A component of an FDA-approved human drug product; or 3) On the list of bulk drug substances for use in compounding developed by the FDA and issued through regulation (note: must comply with (1) or (2) above until the FDA list is issued)	Compliant	
21.01	Certificates of analysis (COAs) obtained for all bulk APIs used for compounding. *Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.* NOTE: The COA for an API should be reviewed upon receipt of the API to verify the quality of the API before using to compound.	Compliant	See Doc02.
21.02	USP- or NF-grade substances used, if available	Compliant	
21.03	If compendia quality components are not available, chemically pure, analytical reagent grade or American Chemical Society-certified components are used and are determined to be free from impurities.	N/A	All compendial
21.04	APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate "for research purposes only", "not for drug use", or are handwritten labels from other pharmacies. *Photograph and describe if found. Request copies of the invoices for products with questionable labels.*	Compliant	
21.05	If compounding for both humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding	Compliant	
21.06	All substances and components have a complete label including a batch control or lot number, and an expiration date.	Compliant	
21.07	For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned does not exceed three (3) years for ingredients used for non-sterile compounding and does not exceed one (1) year for ingredients used for sterile compounding. *Note: purity and quality testing may be performed to extend.*	N/A	All contained expiration date

© National Association of Boards of Pharmacy® (NABP®) All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility. Distribution of this form to a third party or use of the form by a third party is prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
21.08	All APIs and components received without an expiration date are labeled with the date they were received.	N/A	
21.09	If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration from the original container). Product may be tested to extend the expiration date but may not exceed the original package expiration date.	N/A	
21.10	Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated (including hormones).	Compliant	
22.00	Where water is an ingredient, purified or distilled water is used.	Compliant	Distilled water
23.00	Ingredients used for dietary or nutritional supplements meet USP, Food Chemicals Codex (FCC), or NF standards, or the pharmacy has alternate means to determine if the ingredients meet food-grade quality.	N/A	
24.00	Pharmacy confirms that there are no preparations for human use made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons (facility has a copy of the list or other way to determine).	Compliant	
25.00	When manufactured products are used for compounding, all the other excipients in the product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made.	Compliant	
26.00	For **animal compounding:** The compounding meets the same standards as compounding for human patients.	Compliant	
26.01	The pharmacist is knowledgeable or has references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used.	Compliant	
26.02	It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet.	Compliant	Only pets

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
26.03	The pharmacist familiar with, or has a reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals.	N/A	
26.04	The facility has a list of drugs and components not allowed when compounding for food-producing animals.	N/A	
26.05	The pharmacist is familiar with, or has a reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs)	N/A	
	Beyond Use Dating (BUD)		
	Total Non-Compliant (Includes Unknowns)	**0**	
27.00	BUDs are assigned from the day of preparation.	Compliant	
28.00	BUDs are assigned based on dispensing in tight, light-resistant containers/overpacks.	Compliant	
29.00	Extended BUDs are supported by testing data. *View documentation used, preparation must exactly match formulation upon which data was obtained.*	Compliant	
29.01	Extended BUDs are assigned and the facility has performed its own stability testing. *View records, preparation must exactly match the preparation tested by the facility including concentration of all active ingredients, excipients, etc.*	N/A	
30.00	BUDs for nonaqueous formulations are not later than the remaining time until the earliest expiration date of any API and not later than six (6) months.	Compliant	
31.00	BUDs for water-containing oral formulations are not later than 14 days when stored at controlled cold temperatures (refrigerated).	Compliant	
32.00	BUDs for water-containing topical/dermal and mucosal liquid and semisolid formulations not later than 30 days.	Compliant	

© National Association of Boards of Pharmacy® (NABP®) All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of this form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
Environment			
	Total Non-Compliant (Includes Unknowns)	**3**	
33.00	The non-sterile compounding area is a controlled environment and separate from the general pharmacy.	Compliant	
34.00	There sufficient space available for the type and amount of compounding performed and the space is orderly to prevent mix-ups between ingredients, containers, labels, in-process materials, and finished preparations.	Compliant	
35.00	Only one preparation compounded at a time.	Compliant	
36.00	Procedures are implemented to prevent cross-contamination, especially when compounding with drugs such as hazardous drugs and known allergens like penicillin that require special precautions.	Compliant	Clean between uses
37.00	The compounding area is well lit.	Compliant	
38.00	The pharmacy performs **hazardous** non-sterile compounding in a ventilated cabinet such as a BSC, CAI, or CACI. *Note: CAI may not be used for hazardous drugs that may volatilize.(NIOSH requirement referenced in USP<795>. Note that proposed USP Chapter <800> will change hazardous drug compounding requirements.)*	Non-Compliant	Conducted in a CVE that is not externally vented and not in a negative pressure room.
38.01	Ventilated cabinets (BSC, CAI, CACI) used for hazardous compounding are certified or tested periodically.	N/A	
38.02	If the hoods or isolators are not located in a closed, controlled room environment, there is documentation from the manufacturer and site testing to verify proper functioning of equipment under dynamic conditions for the safety of personnel.	N/A	
39.00	Appropriate protective attire (gowns, gloves, masks, etc.) is available.	Compliant	
39.01	If hazardous drugs are used, appropriate protective attire is available (gowns, gloves, hair and shoe covers, eye and face protection, etc.).	Compliant	
40.00	There is a sink in the compounding area with hot and cold potable water, soap or detergent, and air-driers or single-use towels.	Compliant	

© National Association of Boards of Pharmacy® (NABP®) All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility in VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
41.00	There is adequate space to wash equipment and utensils including access to water for rinsing. *(Purified water is **recommended** - not required)*	Compliant	
42.00	The temperature of the compounding area is controlled by a thermostat and an air conditioning system is in place.	Compliant	
43.00	**Temperature** in the compounding area is maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements.	Compliant	
43.01	Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.	Non-Compliant	Excursion alarm range was not set at the time of inspection.
43.02	Excursion action plan in place including evaluating excursion effects on drug product integrity.	Non-Compliant	Excursion alarm range was not set at the time of inspection to identify past excursions.
43.03	Temperature monitoring is also performed in **drug storage areas** (if separate from the compounding areas) and maintained within 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements.	N/A	Not separate
43.04	Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.	N/A	
43.05	Excursion action plan in place including evaluating excursion effects on drug product integrity.	N/A	
44.00	**Humidity** in the compounding area is maintained to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally **recommended** range is 35-60%.	Compliant	
44.01	Humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.	Compliant	
44.02	Excursion action plan in place including evaluating excursion effects on drug product integrity.	Compliant	

© National Association of Boards of Pharmacy® (NABP). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of this form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
44.03	Humidity monitoring is also performed in **drug storage areas** (if separate from the compounding areas) to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally recommended range is 35-60%.	N/A	Not separate
44.04	Humidity monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.	N/A	
44.05	Excursion action plan in place including evaluating excursion effects on drug product integrity.	N/A	
45.00	The bulk component storage area is adequately arranged and maintained in a clean and sanitary condition.	Compliant	
46.00	All components, equipment, and containers are stored off the floor, and handled and stored to prevent contamination.	Compliant	
47.00	All components and packaging containers and closures are properly rotated to use oldest first.	Compliant	
48.00	Hazardous drugs are appropriately identified and marked, received, handled and stored by appropriately trained personnel. (OSHA regulations and NIOSH Alerts)	Compliant	
49.00	Trash is disposed of in a safe, sanitary, and timely manner.	Compliant	
49.01	Hazardous waste is disposed of in a safe, sanitary, and timely manner.	Compliant	
	Training *-Verify records of all compounding personnel (up to 10).*		
	Total Non-Compliant (Includes Unknowns)	**0**	
50.00	Have all personnel of reproductive capability who handle or compound hazardous drugs or chemicals confirmed in writing that they understand the risks of handling hazardous drugs? Teratogenicity, carcinogenicity, reproductive issues.	Compliant	
51.00	There is documentation that all personnel that perform compounding are appropriately trained including policies and procedures, documentation, hazardous drug handling, and compounding technique and not allowed to compound or supervise compounding until training is successfully completed.	Compliant	According to the PIC, only two pharmacists conduct nonsterile compounding. One pharmacist conducts both hazardous and non-hazardous compounding. The other pharmacist only performs non-hazardous compounding.

® National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
52.00	There is documentation that the training process for the preparation of compounds includes demonstration of the compounding procedure first, followed by the trainee performing the procedure under supervision successfully before being allowed to perform compounding.	Compliant	
53.00	There is documentation that training includes the operation of any equipment that may be used when preparing compounded products. *Documentation includes operation and troubleshooting.*	Compliant	
54.00	There is documentation available showing employees performing non-sterile compounding are evaluated at least annually.	Compliant	See Doc03.
54.01	If performing hazardous nonsterile compounding, there is documentation available showing employees are evaluated at least annually.	Compliant	See Doc03.
55.00	If the pharmacy uses relief personnel from outside agencies to perform non-sterile compounding there is documentation that training is verified.	N/A	
	Compounding Equipment		
	Total Non-Compliant (Includes Unknowns)	**0**	
56.00	Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (including capsule machines, autoclaves, ovens, etc.) are periodically inspected and calibrated.*	Compliant	
57.00	Scales, balances, or other types of equipment used for measurement shall be routinely inspected, calibrated as necessary (per manufacturer instructions), and checked to ensure proper performance. *Describe procedure used.*	Compliant	Calibrated once a day with record maintained in Pk software, as well as annual certification by State of NY.
58.00	Powder hoods used for nonsterile compounding are certified or tested periodically to ensure proper function.	Compliant	Certified twice a year by Fathom Testing, last certification was 03/01/2023, see Doc04.
58.01	Hood filters are checked regularly and replaced when necessary.	Compliant	
59.00	All equipment is cleaned promptly after each use. *Equipment and utensils washed using potable water with a soap or detergent, and rinsed.* ***Recommended*** *rinsed with purified water.*	Compliant	
60.00	The pharmacy uses separate equipment and utensils to compound allergenic, cytotoxic, or hazardous products, or has detailed procedures for meticulous cleaning of equipment and utensils immediately after use to prevent cross-contamination or exposure.	Compliant	

© National Association of Boards of Pharmacy® (NABP®) All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
Documentation			
	Total Non-Compliant (Includes Unknowns)	**1**	
61.00	The pharmacy creates a master formulation record the first time before compounding a new preparation	Compliant	
61.01	Every formulation is evaluated for incompatibilities and the potential for being ineffective or toxic.	Compliant	
61.02	The **master formulation record** includes:		
61.03	Official or assigned name, strength, and dosage form	Compliant	
61.04	All necessary calculations	Compliant	
61.05	Description of all ingredients and their quantities	Compliant	
61.06	Compatibility and stability information including references (when available)	Compliant	
61.07	Equipment used for the preparation	Compliant	
61.08	Mixing instructions (order of mixing, temperatures, duration of mixing, and other pertinent factors)	Compliant	
61.09	Container used and packaging requirements	Compliant	
61.10	Assigned BUD information	Compliant	
61.11	Labeling information including the name of and quantity or concentration of each active ingredient	Compliant	
61.12	Description of the finished preparation	Compliant	
61.13	Storage requirements	Compliant	
61.14	Quality control procedures and expected results (e.g. dose measurement of capsule in the dose calibrator).	Compliant	
62.00	The pharmacy creates a compounding record for each compound prepared	Compliant	

® National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
62.01	The **compounding record** includes:		
62.02	Official or assigned name, strength and dosage of the preparation	Compliant	
62.03	Master Formulation Record reference	Compliant	
62.04	Sources, lot numbers, and expiration dates of all components	Compliant	
62.05	Total quantity or number of dosage units compounded	Compliant	
62.06	Person compounding the preparation	Compliant	
62.07	Person performing the quality control procedures	Compliant	
62.08	Person who approved the preparation	Compliant	
62.09	Date of compounding	Compliant	
62.10	Assigned internal identification number or prescription number	Compliant	
62.11	Description of the final preparation	Compliant	Manually written on the compounding record.
62.12	Assigned BUD	Compliant	
62.13	Duplicate label	Non-Compliant	Missing
62.14	Results of quality control procedures (weight range of filled capsules, pH of aqueous liquids, etc.)?	Compliant	
62.15	Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver including investigation and recall, if appropriate	Compliant	

© National Association of Boards of Pharmacy® (NABP). All rights reserved. NABP developed this inspection form for use by NABP and the United States boards of pharmacy and for internal use by the named facility. Disclosure of this form to a third party or use of this form by a third party is prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
Compounding Procedures			
	Total Non-Compliant (Includes Unknowns)	**0**	
63.00	The Master Formulation Record and the Compounding Record has been reviewed by the compounder to ensure it is error free.	Compliant	
64.00	Compounding personnel ascertain that ingredients for compounded preparations are of the correct identity and appropriate quality including a unit-by-unit inspection of the components.	Compliant	
65.00	The containers and closures selected meet USP standards (from container supplier).	Compliant	
66.00	Container selection determined by physical and chemical properties of the preparation.	Compliant	
67.00	Compounding personnel maintain good hand hygiene and wear clean and appropriate clothing for the compounding being performed.	Compliant	
68.00	Personnel don appropriate protective garb when performing compounding.	Compliant	
68.01	If hazardous compounding, personnel don appropriate protective garb when compounding.	Compliant	
69.00	Routine compounding procedures for batch preparation completed and verified according to written procedures. Including: *Calculations correct, weighing and measuring performed correctly, order of mixing correct, compounding techniques performed correctly*	Compliant	
70.00	Procedures for in-process checks followed. *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product, and documentation of the compounding accuracy is performed to ensure proper measurement, reconstitution and component usage.* ***Recommended:*** *compounding accuracy checked by a person other than the compounder.*	Compliant	Only pharmacists compound
71.00	There are no deviations from the master formulation record, unless they are approved and deemed appropriate by a pharmacist and a new master formulation record is created.	Compliant	

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
72.00	There is a procedure for cleaning which is followed. *After each preparation, daily tasks, monthly tasks, etc.*	Compliant	
73.00	Personnel are appropriately garbed for protection when cleaning.	Compliant	
74.00	Compounding employees are using appropriate techniques. *Inspector to observe compounding procedures, documentation, appropriate garb, cleanliness of compounding area and equipment.* ***Compounding MUST be observed****. If compounding is not being performed at the time of survey, mark as "Non-Compliant".*	Compliant	Observed: Metronidazole 50mg/ml in Oil.
74.01	If compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for you to observe the compounding process. *If the pharmacy staff refuses or is unable to perform compounding for you to observe, document on the "* ***Denial of Authorization****" form. List individual who signs the Denial of Authorization.*		
	Finished Preparation Release Checks and Tests		
	Total Non-Compliant (Includes Unknowns)	**0**	
75.00	The finished preparation is observed to appear as expected in the master formulation record and documented.	Compliant	
76.00	As appropriate, the final completed preparation assessed for quality control and is documented, such as weight, mixing, clarity, odor, color, consistency, pH, and strength.	Compliant	
77.00	There are established written processes that describe test or examinations conducted on the compounded preparation (degree of weight variation in capsules, for example) to ensure uniformity and integrity.	Compliant	
78.00	Preparations with extended BUDs that are not supported by testing data are sampled and tested for physical, chemical, and microbiological characteristics.	N/A	

© National Association of Boards of Pharmacy® (NABP). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
78.01	If any failed tests or discrepancies are observed, there is an investigation and appropriate corrective actions taken before dispensing to patient	N/A	
78.02	If products being tested are dispensed or distributed before the test results are obtained, there is a recall procedure if the test results indicate an issue.	N/A	
79.00	There are appropriate quality control procedures to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations. *Review validation of equipment and personnel performance documentation.*	Compliant	
80.00	Labels on immediate patient-specific containers include identifiers for the persons preparing the compound and performing the final verification, BUD, an indication that this is a compounded preparation, special requirements for storage, and appropriate packaging and labeling of hazardous materials.	Compliant	
80.01	Labeling contains generic name and quantity or concentration of each active ingredient.	Compliant	
80.02	Labeling contains assigned BUD.	Compliant	
80.03	Labeling contains storage and handling information.	Compliant	
80.04	If hazardous, labeling contains storage and handling information.	Compliant	
80.05	Labeling contains prescription or control number, whichever is applicable.	Compliant	
81.00	Batch preparations (in anticipation of prescriptions) are of an appropriate volume and batch products in stock are all within their BUD (not outdated).	Compliant	

® National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cottrill's Pharmacy Inc dba Cottrill's Pharmacy Inc
e-Profile ID: 1371283
Inspection Date: 03/14/2023 - 03/15/2023

		Finding	Notes
82.00	Labels on batch preparations include the name and quantity of all contents, date and time of preparation (or internal code/lot number indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.	Compliant	
83.00	Preparations are stored and secured properly prior to dispensing based upon conditions upon which BUD was assigned.	Compliant	
84.00	Preparations are examined immediately after preparation **AND** again immediately prior to dispensing for any signs of instability.	Compliant	
	Patient Counseling and Communication		
	Total Non-Compliant (Includes Unknowns)	**0**	
85.00	Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of products such as fentanyl, hormones and chemotherapy medications?	Compliant	
86.00	Are the required printed drug information materials (drug information sheets, Patient Package Inserts, MedGuides, etc.) provided for the compounded products?	Compliant	
87.00	Are patients instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?	Compliant	
88.00	Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated compounded product are notified of the potential risk.	Compliant	

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Acronym	Definition
ACD	Automated Compounding Device
ACOEM	American College of Occupational and Environmental Medicine
ACPH	Air Changes Per Hour
ADA	Americans with Disabilities Act
ADR	Adverse Drug Reaction
ALARA	As Low As Reasonably Achievable
API	Active Pharmaceutical Ingredient
ASHP	American Society of Health-System Pharmacists
ASTM	American Society for Testing and Materials
AU	Authorized User
BOP	Board of Pharmacy
BSC	Biological Safety Cabinet
BUD	Beyond Use Date
CACI	Compounding Aseptic Containment Isolator
CAI	Compounding Aseptic Isolator
CDC	Center for Disease Control and Prevention
CETA	Controlled Environment Testing Association
CFR	Code of Federal Regulations
CFU	Colony-forming unit
CLIA	Clinical Laboratory Improvement Amendment
COA	Certificate of Analysis
C-PEC	Containment Primary Engineering Control
CQI	Continuous Quality Improvement
CS	Controlled substance
C-SCA	Containment Segregated Compounding Area
C-SEC	Containment Secondary Engineering Control
CSOS	Controlled Substance Ordering System
CSP	Compounded Sterile Preparation
CSTD	Closed-System drug-Transfer Device
CVE	Containment Ventilated Enclosure
DBA	Doing business as
DCA	Direct Compounding Area
DEA	Drug Enforcement Administration
DME	Durable medical equipment
DOT	Department of Transportation
DUR	Drug Utilization Review

EMT	Emergency medical technician
EPA	Environmental Protection Agency
FCC	Food Chemicals Codex
FDA	Food and Drug Administration
GHS	Globally Harmonized System (of classification and labeling of chemicals)
HazMat	Hazardous Materials
HCS	Hazardous Communication Standard
HD	Hazardous Drug
HEPA	High Efficiency Particulate Air (filter)
HIPAA	Health Insurance Portability and Accountability Act
HMO	Health maintenance organization
IPA	Isopropyl Alcohol
IV	Intravenous
LAFW	Laminar Air Flow Workbench
LOD	Line of Demarcation
MSDS	Material Safety Data Sheet
MTM	Medication Therapy Management
NF	National Formulary
NIOSH	National Institute for Occupational Safety and Health
NRC	Nuclear Regulatory Commission
NSAID	Non-steroidal anti-inflammatory drug
NVLAP	National Voluntary Laboratory Accreditation Program
OIG	Office of the Inspector General
ONS	Oncology Nursing Society
OSHA	Occupational Safety and Health Administration
OTC	Over-the-Counter
P&P	Policies and Procedures
PBM	Pharmacy benefits manager
PDMP	Prescription drug monitoring program
PEC	Primary Engineering Control
PHI	Protected Health Information
PIC	Pharmacist-in-charge
PMP	Prescription Monitoring Program
PPE	Personal Protective Equipment
PPI	Patient Package Insert
QA	Quality Assurance
QI	Quality Improvement
QRE	Quality Related Event

RAM	Radioactive Material
RCRA	Resource Conservation and Recovery Act
REMS	Risk evaluation mitigation strategy
RSO	Radiation Safety Officer
Rx	Prescription
SDS	Safety Data Sheet (formerly MSDS – Material Safety Data Sheet)
SOP	Standard Operating Procedure
ULPA	Ultra Low Particulate Air (filter)
USP	United States Pharmacopeia
VAERS	Vaccine Adverse Event Reporting System
VFC	Vaccines for Children Program
WD	Wholesale distributor

CPE Monitor Activity Transcript

Participant Name: DAVID john williams
NABP e-Profile ID: 587385
CPE Activity Date Range: 08/01/2019 to 03/16/2023
Total CPE Hours Earned: 60.00

Recorded CPE activity for the period of 08/01/2019 to 03/16/2023 . Please allow 35 days for the CPE Provider to process your CPE and submit it through the CPE Monitor System. If it has been more than 35 days since you submitted the necessary information for CPE credit, please contact the CPE Provider.

							ACPE/Non-ACPE Credits	
Activity Date	Activity #	Credit Type	Source	Title	Topic	Provider	Live Hours	Home Hours
2/23/2023	JA0006454-0000-23-502-L01-P	IPCE	ACPE	Pharmacy Essential Updates February 2023	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00
2/21/2023	JA0006454-0000-23-582-L01-P	IPCE	ACPE	Emerging Recommendations Panel February 2023	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00
2/7/2023	JA0006454-0000-23-501-L01-P	IPCE	ACPE	Pharmacy Essential Updates January 2023	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00
1/23/2023	JA0006454-0000-23-581-L01-P	IPCE	ACPE	Emerging Recommendations Panel January 2023	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00
12/8/2022	JA0006454-0000-22-512-L01-P	IPCE	ACPE	Pharmacy Essential Updates December 2022	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00
11/14/2022	JA0006454-0000-22-591-L01-P	IPCE	ACPE	Emerging Recommendations Panel November 2022	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00
11/9/2022	JA0006454-0000-22-511-L01-P	IPCE	ACPE	Pharmacy Essential Updates November 2022	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00
11/3/2022	JA0006454-0000-22-509-L01-P	IPCE	ACPE	Pharmacy Essential Updates September 2022	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00

10/13/2022	JA0006454-0000-22-510-L01-P	IPCE	ACPE	Pharmacy Essential Updates October 2022	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00
9/12/2022	JA0006454-0000-21-314-H05-P	ACPE	ACPE	High-Alert Medication Safety	Patient Safety	TRC Healthcare	0.00	1.00
9/12/2022	JA0006454-0000-22-315-H07-P	ACPE	ACPE	Non-sterile Compounding Basics	Compounding	TRC Healthcare	0.00	1.00
8/18/2022	JA0006454-0000-22-588-L01-P	IPCE	ACPE	Emerging Recommendations Panel August 2022	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00
8/16/2022	JA0006454-0000-20-336-H05-P	ACPE	ACPE	Medication Error Prevention in Special Populations	Patient Safety	TRC Healthcare	0.00	1.00
8/16/2022	JA0006454-0000-21-315-H05-P	ACPE	ACPE	Just Culture and Reporting Errors	Patient Safety	TRC Healthcare	0.00	1.00
8/16/2022	JA0006454-0000-22-508-L01-P	IPCE	ACPE	Pharmacy Essential Updates August 2022	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00
7/26/2022	JA0006454-0000-22-513-L01-P	ACPE	ACPE	Optimize Care for Patients with Diabetes	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00
7/21/2022	0798-0000-21-270-L01-P	ACPE	ACPE	Hands-on Diabetes: A Practical Way to Manage Diabetes Module 1 - Introduction	Disease State Mgmt/Drug Therapy	PharmCon	1.00	0.00
7/21/2022	JA0006454-0000-22-587-L01-P	IPCE	ACPE	Emerging Recommendations Panel July 2022	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00
7/19/2022	0798-0000-22-048-L04-P	ACPE	ACPE	The Expanding Clinical Role of Pharmacy Technicians in the Community Pharmacy Setting	General Pharmacy Topics	PharmCon	1.00	0.00
7/18/2022	0798-0000-21-289-L07-P	ACPE	ACPE	Pearls of Wisdom: Compounding for Womens Health	Compounding	PharmCon	1.00	0.00
7/18/2022	0798-0000-22-039-L03-P	ACPE	ACPE	Pharmacy Related Legal Concerns and Case Law Examples	Law (Related to Pharm)	PharmCon	1.00	0.00
7/15/2022	0798-0000-21-141-L01-P	ACPE	ACPE	Long-Acting Injectable Specialty Pharmacist Module 2: Emergency Response to Mental Health	Disease State Mgmt/Drug Therapy	PharmCon	1.00	0.00
7/13/2022	JA0006454-0000-22-507-L01-P	IPCE	ACPE	Pharmacy Essential Updates July 2022	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00
6/27/2022	JA0003680-9999-22-007-L01-P	ACPE	ACPE	The Value of Streamlined Coverage for Real-Time CGM to Optimize Outcomes & Resource Utilization for Members with Diabetes	Disease State Mgmt/Drug Therapy	Medical Education Resources, Inc.	1.50	0.00

6/23/2022	JA0006454-0000-22-506-L01-P	IPCE	ACPE	Pharmacy Essential Updates June 2022	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00
5/18/2022	JA0006454-0000-22-585-L01-P	IPCE	ACPE	Emerging Recommendations Panel May 2022	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00
5/16/2022	JA4008162-9999-22-181-L01-P	ACPE	ACPE	Achieving Appropriate Access for the Treatment of Atopic Dermatitis: Medical and Pharmacy Management Strategies for Managed Care and Payer Professionals	Disease State Mgmt/Drug Therapy	Postgraduate Institute for Medicine	1.50	0.00
5/12/2022	JA0006454-0000-21-625-H07-P	IPCE	ACPE	Compounding: USP 800 and Hazardous Drugs Overview On Demand Webinar	Compounding	TRC Healthcare	0.00	1.00
5/12/2022	JA0006454-0000-22-505-L01-P	IPCE	ACPE	Pharmacy Essential Updates May 2022	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00
4/20/2022	JA0006454-0000-20-337-H01-P	ACPE	ACPE	Mental Health Awareness in Pharmacy Practice	Disease State Mgmt/Drug Therapy	TRC Healthcare	0.00	1.00
4/19/2022	JA0006454-0000-22-504-L01-P	IPCE	ACPE	Pharmacy Essential Updates April 2022	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00
3/21/2022	JA0006454-0000-21-343-H04-P	ACPE	ACPE	Addressing Ethical Issues in the Pharmacy	General Pharmacy Topics	TRC Healthcare	0.00	1.00
3/21/2022	JA0006454-0000-22-583-L01-P	IPCE	ACPE	Emerging Recommendations Panel March 2022	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00
3/15/2022	JA0006454-0000-20-307-H01-P	ACPE	ACPE	Introduction to Specialty Drugs	Disease State Mgmt/Drug Therapy	TRC Healthcare	0.00	1.00
3/15/2022	JA0006454-0000-21-339-H04-P	ACPE	ACPE	Your Role in Preventing Sexual Harassment	General Pharmacy Topics	TRC Healthcare	0.00	1.00
3/15/2022	JA0006454-0000-22-503-L01-P	IPCE	ACPE	Pharmacy Essential Updates March 2022	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00
3/14/2022	JA0006454-0000-20-312-H04-P	ACPE	ACPE	Quality Measures in Pharmacy Practice	General Pharmacy Topics	TRC Healthcare	0.00	1.00
3/8/2022	JA0006454-0000-20-316-H05-P	ACPE	ACPE	Safety from the Start: Data Entry	Patient Safety	TRC Healthcare	0.00	1.00
3/8/2022	JA0006454-0000-20-317-H04-P	ACPE	ACPE	Essential Skills for Leaders	General Pharmacy Topics	TRC Healthcare	0.00	1.00
3/8/2022	JA0006454-0000-21-335-H04-P	ACPE	ACPE	Human Trafficking Awareness in the Pharmacy	General Pharmacy Topics	TRC Healthcare	0.00	1.00

3/8/2022	JA0006454-0000-22-501-L01-P	IPCE	ACPE	Pharmacy Essential Updates January 2022	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00
2/27/2022	0044-0000-21-040-L03-P	ACPE	ACPE	Pharmacy Law Update 2022	Law (Related to Pharm)	University at Buffalo School of Pharmacy and Pharmaceutical Sciences	3.00	0.00
2/24/2022	JA0006454-0000-20-309-H04-P	ACPE	ACPE	Skills for Communicating with Other Healthcare Professionals	General Pharmacy Topics	TRC Healthcare	0.00	1.00
2/24/2022	JA0006454-0000-20-310-H04-P	ACPE	ACPE	Conflict Resolution Skills	General Pharmacy Topics	TRC Healthcare	0.00	1.00
2/24/2022	JA0006454-0000-21-305-H04-P	ACPE	ACPE	Providing Empathetic Care	General Pharmacy Topics	TRC Healthcare	0.00	1.00
2/24/2022	JA0006454-0000-21-341-H04-P	ACPE	ACPE	Skills for Communicating Effectively with Patients	General Pharmacy Topics	TRC Healthcare	0.00	1.00
2/24/2022	JA0006454-0000-22-502-L01-P	IPCE	ACPE	Pharmacy Essential Updates February 2022	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00
2/22/2022	JA0006454-0000-20-311-H07-P	ACPE	ACPE	Compounding Basics for Non-sterile Products	Compounding	TRC Healthcare	0.00	1.00
2/22/2022	JA0006454-0000-21-208-H04-P	ACPE	ACPE	Supporting Medication Adherence	General Pharmacy Topics	TRC Healthcare	0.00	1.00
2/22/2022	JA0006454-0000-21-309-H04-P	ACPE	ACPE	USP 800 and Hazardous Meds	General Pharmacy Topics	TRC Healthcare	0.00	1.00
2/22/2022	JA0006454-0000-21-318-H07-P	ACPE	ACPE	Nonsterile Compounding Basics	Compounding	TRC Healthcare	0.00	1.00
2/22/2022	JA0006454-0000-21-319-H07-P	ACPE	ACPE	Complex Nonsterile Compounding: Oral Dosage Forms (per official 2014 USP 795)	Compounding	TRC Healthcare	0.00	1.00
2/22/2022	JA0006454-0000-21-323-H07-P	ACPE	ACPE	Nonsterile Compounding: Topical and Oral Liquid Preparations (per 2014 USP 795)	Compounding	TRC Healthcare	0.00	1.00
2/22/2022	JA0006454-0000-21-336-H05-P	ACPE	ACPE	Preventing Medication-Related Errors	Patient Safety	TRC Healthcare	0.00	1.00
2/22/2022	JA0006454-0000-21-340-H05-P	ACPE	ACPE	Preventing Medication Errors	Patient Safety	TRC Healthcare	0.00	2.00
2/22/2022	JA0006454-0000-22-582-L01-P	IPCE	ACPE	Emerging Recommendations Panel February 2022	Disease State Mgmt/Drug Therapy	TRC Healthcare	1.00	0.00

Pharmacy Name: Cottrill's Pharmacy, Inc.

Pharmacy Address: 4919 Ellicott Road, Orchard Park, NY 14127

NABP Facility e-Profile ID: 1371283

VPP Inspection Date: 3/14/2023, 3/15/2023

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Clarification or Further Explanation	7	2.00	PIC is on-site 40+ hours per week	N/A	N	
Clarification or Further Explanation	11	36.00	cannot be secured. The plan includes a pharmacist supervision of medication products until the building can be secured if security can be	N/A	N	
Clarification or Further Explanation	12	39.01 and 39.02	monitor were not set at the time of the survey. However, the electronic monitoring log showed appropriate temperature had been maintained	3/15/2023	N	
Clarification or Further Explanation	12	42	manually logged twice a day. At the time of inspection there was a disconnect between the monitor and the online portal. The device	3/15/2023	N	
Updates/New SOPs or P&Ps	14	47.06 and 47.07			Y	Medication Procurement and Storage
Clarification or Further Explanation	15	56	item and keeps a perpetual inventory that IS reconciled with each and every fill.	N/A	N	
Photos	32	38	The negative pressure room is complete and operational.	4/1/2023	Y	Negative pressure room
Clarification or Further Explanation	33	43.01 and 43.02	This issue is the same as items 39.01 and 39.02 above and has been resolved.	N/A	N	
Clarification or Further Explanation	37	62.13	A duplicate label is attached to each compounding record.	3/15/23	Y	

This VPP Inspection response and documentation has been provided directly by the pharmacy in response to its VPP Inspection. The content of this response has not been verified or modified by NABP at this point in time, except to check for completeness of any attachments provided.

4YY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.) * Current license #: PH PH03761	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: FF6493605 ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☒ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Fertility Pharmacy of America, LP

Physical Address: 525 Metroplex Drive, Ste 201

City: Nashville State: TN Zip: 37211-3140

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 844-449-8767 Toll Free # (NAC 639.708, NRS 639.23286): 844-449-8767

Fax: 844-357-0573 Contact Email: compliancemgt@rxpartnersmgt.com

Website: https://www.fertilitypharmacyofamerica.com/

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Hailey Gray

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23481

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Hailey Gray	NV Pharmacist Registration #: 23481
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: NA

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NA

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: Fertility Pharmacy of America, LP

Mailing Address: 525 Metroplex Drive

City: Nashville State: TN Zip: 37211

Telephone: 615-734-0321 Email: compliance@medipakrx.com

Contact Person Name: William Weimer II

Please check type of partnership (NAC 639.214) ☐ General ☒ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☑ Yes ☐ No

Section 8: Sole Owner

Owner's Name: NA

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CFO (title) for Fertility Pharmacy of America, LP (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

William Weimer II

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

10/16/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, William Weimer II hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CFO (title) for Fertility Pharmacy of America, LP (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 14th day of October, 2024

Notary Public

LINDA MENDOZA
STATE OF TENNESSEE
NOTARY PUBLIC
My Commission Expires on 09/05/2028
DAVIDSON COUNTY

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

William Weimer II

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

William Weimer II

Original signature of Authorized Person (copies or stamps not accepted)

10/16/24

Date

Board Use Only	Date Received: 10/21/24	Amount: $1000-cc

Tre Hargett
Secretary of State

Division of Business Services
Department of State
State of Tennessee
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

KESLEY RESHA
525 METROPLEX DRIVE
NASHVILLE, TN 37211

June 27, 2024

Request Type: Certificate of Existence/Authorization
Request #: 0589838

Issuance Date: 06/27/2024
Copies Requested: 1

Document Receipt

Receipt # : 009094206 — Filing Fee: $20.00

Payment-Credit Card - State Payment Center - CC #: 3876789237 — $20.00

Regarding: **Fertility Pharmacy of America LP**
Filing Type: LP 1988 Act - Domestic
Formation/Qualification Date: 02/22/2017
Status: Active
Duration Term: Expires: 02/22/2067
Business County: DAVIDSON COUNTY

Control # : 890069
Date Formed: 02/22/2017
Formation Locale: TENNESSEE
Inactive Date:

CERTIFICATE OF EXISTENCE

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

Fertility Pharmacy of America LP

* is a Limited Partnership duly created under the law of this State, whose Certificate of Limited Partnership was filed with this office on the date given above;

* has paid all fees, interest, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;

* has appointed a registered agent and registered office in this State;

* has not filed Articles of Dissolution or Articles of Termination. A decree of judicial dissolution has not been filed.

Tre Hargett
Secretary of State

Processed By: Cert Web User

Verification #: 068350729

DEPARTMENT OF HEALTH
TENNESSEE BOARD OF PHARMACY
COMMUNITY INSPECTION
COMPLIANCE INSPECTION

PHARMACY	Fairfield Pharmacy of Smyrna
STREET	525 Molloy Pl. Suite 201
CITY	Nashville
ZIP	37211
DATE OPENED	
TELEPHONE NO.	(844) 449 8767
LICENSE NO.	5924
EXPIRY DATE	12/31/2024
DEA NO.	FF6493605
EXPIRY DATE	9/30/2025
PHARMACIST IN CHARGE/Duty	Haley Gray
LIC NO.	46615
EXPIRY DATE	7/31/2026

Inspected by	Date
Andrea Miller	10/9/2024

This Inspection Satisfactory: Yes ☑ No ☐

☐ Opening ☐ Relocation
☑ New Ownership ☐ Follow-up
☐ Counseling Compliance
☐ Periodic ☐ Remodeling

Compliance Yes	Compliance No	PERSONNEL
✓		1. Appropriate identification/Name Tags
✓		2. D. Ph./Tech ration
✓		3. Personnel/apparel clean.
✓		4. Tech registry & Affidavit

Compliance Yes	Compliance No	PHYSICAL REQUIREMENTS
✓		5. Certificates Displayed
✓		6. RX Dept. – Sufficient Space/Counseling
✓		7. Fully enclosed when applicable
✓		8. Key Lockable/Key Control – Shelly

Compliance Yes	Compliance No	DRUGS AND EQUIPMENT
✓		9. Dispensing area clean, orderly, well lighted
✓		10. Sink, hot and cold water
✓		11. Refrigeration
✓		12. References, periodicals
✓		13. Vials and closures (child-proof)
✓		14. Shelves and drug stock clean
✓		15. Drugs in-date
✓		16. Labels correct on repackaging
✓		17. Legend drugs stored in RX Dept.
✓		18. Syringes/insulin, restricted products non-accessible

Pharmacy Hours: M-F 8-430

Compliance Yes	Compliance No	
✓		19. RXs numerically filed
✓		☐ All C's together ☐ C-11's separate ☐ Multiple file method
✓		20. Patients identifiable
✓		21. Prescribers identifiable
✓		22. New verbal RXs initialed by appropriate personnel
✓		23. Date of original dispensing
✓		24. Initials of dispensing D.Ph.
✓		25. Quantity dispensed indicated
N/A		26. Appropriate Emergency C-11 RXs
✓		27. Computer labels applied appropriately to RXs
✓		28. Pharmacist Signature Log
N/A		29. Daily Print Out

Compliance Yes	Compliance No	DRUG PRODUCT SUBSTITUTION
✓		30. Authorization documented on Rx
✓		31. Manufacturer indicated on Rx or System
✓		32. Approved products used.

Compliance Yes	Compliance No	PATIENT COUNSELING
✓		33. Patient profiles
✓		34. Drug Utilization Review
✓		35. Patient Counseling

Compliance Yes	Compliance No	CONTROLLED SUBSTANCE RECORDS
✓		36. Readily retrievable
N/A		37. All C-11 records separate
N/A		38. DEA Form 222 Copy 3 on hand & completed
✓		39. Drug Receipt date on invoices
✓		40. Record of drug transfers
DX		41. ☐ Schedule V sales record book ☐ Methamphetamine Sales Log
✓		42. Last DEA Inventory (date) 10/1/2024
✓		42. Last Theft/loss report (date) N/A
✓		43. Access to Control Substance Monitoring Database

ITEMS TO BE CORRECTED: **RESPONSE REQUIRED** **YES ☐** **NO ☑**

Immediately
Needs Improvement
Within 30 Days

Remarks or Recommendations: No CII, all compounding, reviewed DSCSA

I Haley Gray hereby acknowledge and understand all notations made on this report; and confirm that
Pharmacist Signature
I will notify the Board of Pharmacy within 30 days, in writing, of the correction of all deficiencies. (If noted.)

PH-4031 REV 01/18 RDA SW-30

State of Tennessee
Department of Health

1366837

56632

BOARD OF PHARMACY

PHARMACY

FERTILITY PHARMACY OF AMERICA LP

525 METROPLEX DR

SUITE 201

NASHVILLE TN 37211

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000005924

EXPIRATION DATE: 12/31/2025

CONTROLLED SUBSTANCE REGISTRATION

Jennifer L. Putnam Esq

ASSISTANT COMMISSIONER, HEALTH LICENSURE & REGULATION

COMMISSIONER, DEPARTMENT OF HEALTH

DCF171

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
DIVISION OF HEALTH LICENSURE AND REGULATION
OFFICE OF HEALTH RELATED BOARDS
665 Mainstream Drive, Second Floor
Nashville, TN 37243
http://www.tn.gov/health

Board of Pharmacy
Pharmacy
1-800-778-4123 or

September 26, 2024

Fertility Pharmacy of America LP
Attn: Hailey Gray
525 Metroplex Dr. Ste. 201
Nashville, TN 37211

TO WHOM IT MAY CONCERN:

This verification can be considered primary source. To expedite the verification process, this is the standard format used by the Tennessee Board of Pharmacy. We are pleased to furnish the following information from our files:

PROFESSION:	Pharmacy
NAME:	Fertility Pharmacy of America, LP
ADDRESS:	525 Metroplex Dr., Ste. 201 Nashville, TN 37211
LICENSE NUMBER:	5924
ISSUE DATE:	December 12, 2016
EXPIRATION DATE:	December 31, 2025
CURRENT STATUS:	Licensed
STATUS DATE:	December 12, 2016
SPECIAL ENDORSEMENT:	Controlled Substance Registration

COMMENTS: There is no derogatory information in our files concerning this facilty.

Sincerely,

Tennessee Board of Pharmacy

VERFFACLTY

Last Updated: 9/25/2024

For more information, please contact
Health Care Facilites
(615)741-7221 or 800-310-4650

Health Care Facilities

Licensed Facilities

Current Listings

Type = Pharmacy
County = All
Results = 1

Click here to return to the search page

1

Fertility Pharmacy of America LP
525 Metroplex Dr Suite 201
Nashville, TN 37211
844-449-8767

Qualifications
Controlled Subs

Pharmacist: GRAY, HAILEY ANN

Facility License Number: 00005924
Status: Licensed
Date of Original Licensure: 12/12/2016
Date of Expiration: 12/31/2025
No Disciplinary Actions

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FF6493605	09-30-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	08-04-2022

FERTILITY PHARMACY OF AMERICA, LP
525 METROPLEX DR
STE 201
NASHVILLE, TN 372113140

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALIO AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FF6493605	09-30-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	08-04-2022

FERTILITY PHARMACY OF AMERICA, LP
525 METROPLEX DR
STE 201
NASHVILLE, TN 372113140

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Fertility Pharmacy of America, LP

Pharmacy/Wholesaler License # (if applicable): PH03761

Physical Address: 525 Metroplex Drive, Ste 201

City: Nashville State: TN Zip: 37211-3140

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 844-449-8767 Website: https://www.fertilitypharmacyofamerica.com/

Licensing Company Email: compliancemgt@rxpartnersmgt.com

Section 2: Personal Information

First: Hailey Middle: Ann Last: Gray

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: 525 Metroplex Drive, Ste 201

City: Nashville State: TN Zip: 37211

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Waubonsie Valley High School		08/12 - 05/16	
Address	**City**	**State**	**Zip**
2590 Ogden Ave	Aurora	IL	60504
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Purdue University College of Pharmacy		08/16 - 05/22	
Address	**City**	**State**	**Zip**
610 Purdue Mall	West Lafayette	IN	47907
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/22 - current	[redacted] Demonbreun ST, APT 1727	Nashville	TN	37203
10/14 - 08/22	[redacted] Kingbird Court	Naperville	IL	60564
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Fertility Pharmacy of America, LP			05/24 - current	
Business Address		**City**	**State**	**Zip**
525 Metroplex Drive, Ste 201		Nashville	TN	37211
Phone	**Title**		**Number of Employed Hours**	
844-449-8767	Pharmacist in charge		1000 +	
Description of Duties				
verified medication orders and ensured pharmacy operated in compliance w/ pharmacy regulations				

Business Name			From - To (MM/YY – MM/YY)	
RARx, LLC			08/23 - 05/24	
Business Address		**City**	**State**	**Zip**
525 Metroplex Drive, Ste 202		Nashville	TN	37211
Phone	**Title**		**Number of Employed Hours**	
844-319-2259	Pharmacist in charge		1440	
Description of Duties				
verified medication orders and complied to pharmacy regulations				

Business Name			From - To (MM/YY – MM/YY)	
US Renal Care Pharmacy			08/22 - 08/23	
Business Address		**City**	**State**	**Zip**
525 Metroplex Drive, Ste 204		Nashville	TN	37211
Phone	**Title**		**Number of Employed Hours**	
615-301-5910	Pharmacist		2080	
Description of Duties				
verified medication orders				

Business Name			From - To (MM/YY – MM/YY)	
Franciscan Health			04/19 - 05/22	
Business Address		**City**	**State**	**Zip**
1701 S Creasy Lane		Lafayette	IN	47905
Phone	**Title**		**Number of Employed Hours**	
765-502-4000	Pharmacy Intern		~2100	
Description of Duties				
filled, compounded, and stocked medication orders for hospital patients				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Hailey Gray, **certify that as the designated representative for**

Fertility Pharmacy of America, LP,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. HG I am at least 21 years of age;
3. HG I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. HG I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. HG I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. HG I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. HG I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Halley Gray

Print Name (First, Last)

Hailey Gray

Original Signature (electronic, copies or stamps not accepted)

10/14/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hailey Gray

Print Name (First, Last)

Hailey Gray — 10/14/24

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Davidson

I, Hailey Gray, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Hailey Gray — 10/14/24

Original Signature — **Date**

Subscribed and Sworn to before me this 14th day of October 2024.

Linda Mendoza

Notary Public Signature

LINDA MENDOZA
STATE OF TENNESSEE
NOTARY PUBLIC
My Commission Expires on 09/05/2028
DAVIDSON COUNTY

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Fertility Pharmacy of America, LP

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH03761

Physical Address: 525 Metroplex Drive, Ste 201

City: Nashville State: TN Zip: 37211-3140

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 844-449-8767 Website: https://www.fertilitypharmacyofamerica.com/

Licensing Company Email: compliancemgt@rxpartnersmgt.com

Section 2: Personal Information

First: William Middle: Milton Last: Weimer II

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: 525 Metroplex Drive

City: Nashville State: TN Zip: 37211

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)
VIRGINIA COMMONWEALTH UNIVERSITY	09/2012 – 05/2014

Address	City	State	Zip
907 FLOYD AVE	RICHMOND	VA	23284

Diploma/Degree obtained, if any: MASTERS OF SCIENCE IN HEALTH ADMINISTRATION

School Name	From - To (MM/YY – MM/YY)
UNIVERSITY OF VIRGINIA	09/1993 – 06/1997

Address	City	State	Zip
1827 UNIVERSITY AVE	CHARLOTTESVILLE	VA	22903

Diploma/Degree obtained, if any: BACHELORS OF SCIENCE IN COMMERCE

School Name	From - To (MM/YY – MM/YY)
LEE-DAVIS HIGH SCHOOL	09/90 – 06/93

Address	City	State	Zip
7052 MECHANICSVILLE TPKE	MECHANICSVILLE	VA	23111

Diploma/Degree obtained, if any: ADVANCED HIGH SCHOOL DIPLOMA

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2007 – CURRENT	[redacted] FLEMING CROSSROADS LN	KENTS STORE	VA	23084
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: MEDIPAK HOLDINGS LLC			From - To (MM/YY – MM/YY): 08/24-PRESENT	
Business Address: 525 METROPLEX PR	City: NASHVILLE		State: TN	Zip: 37211
Phone: 615-734-0321	Title: CFO			
Description of Duties: FINANCIAL MANAGEMENT				

Business Name: ECONOMEDICAL, INC.			From - To (MM/YY – MM/YY): 01/09-PRESENT	
Business Address: 5012 FLEMING CROSSROADS LN	City: KENTS STORE		State: VA	Zip: 23084
Phone: 804-908-6245	Title: PRESIDENT & CEO			
Description of Duties: OWNER				

Business Name: COMMONSHARE, INC			From - To (MM/YY – MM/YY): 07/19-PRESENT	
Business Address: 1602 SKIPWITH RD #201	City: HENRICO		State: VA	Zip: 23229
Phone: 804-416-6255	Title: EXECUTIVE DIRECTOR			
Description of Duties: EXECUTIVE MANAGEMENT & OVERSIGHT				

Business Name: HOME RECOVERY HOME AID, INC			From - To (MM/YY – MM/YY): 5/19 - 8/24	
Business Address: 816 E. THIRD ST.	City: FARMVILLE		State: VA	Zip: 23901
Phone: 434-392-7336	Title: CONTROLLER			
Description of Duties: FINANCIAL MANAGEMENT & HEATHCARE ADMINISTRATION				

Business Name: BON SECOURS HEALTH SYSTEM			From - To (MM/YY – MM/YY): 12/06 - 2/19	
Business Address: 8580 MAGELLAN PKWY	City: RICHMOND		State: VA	Zip: 23227
Phone:	Title:			
Description of Duties: FINANCIAL MANAGEMENT & HEALTHCARE ADMINISTRATION				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	X	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1997	1997	VA	CHARLOTTESVILLE	CITY OF

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
DON'T REMEMBER	CITY OF CHARLOTTESVILLE POLICE

Reason/Charge
DESTRUCTION OF PROPERTY / ASSAULT & BATTERY

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
SELF	MISDEMEANOR CRIMINAL

Name of Business/Industry/Entity
UNIVERSITY OF VIRGINIA MEDICAL CENTER

Provide explanation below:

TRIED TO LEAVE ER AGAINST MEDICAL ADVICE AND WAS STOPPED BY SECURITY AT WHICH POINT I ASSAULTED OFFICERS DESTROYING PROPERTY AND WAS DETAINED)

6 MONTHS SUSPEND SENTENCE COMPLETED

[signature] II

Original signature (electronic, copies or stamps not accepted)

10/16/24

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1999	1999	DC	WASHINGTON DC	CITY OF
Case #	**Governing, licensing, Arresting Presiding Body/Agency/Court**			
DON'T REMEMBER	WASHINGTON DC POLICE			
Reason/Charge				
ASSAULT & BATTERY (2)				
Plaintiff/Defendant/Claimant/Respondent	**Lawsuit/Arbitration/Bankruptcy**			
SELF	MISDEMEANOR			
Name of Business/Industry/Entity				
DC ATTORNEY				

Provide explanation below:

I WAS IN A PHYSICAL ALTERCATION WITH MY WIFE OF THE TIME. AT WHICH POINT OFFICER IN THE AREA TRIED TO DETAIN ME AND I RESISTED THEN FLEYED THE SCENE.
1 MONTH JAILTIME & 11 MONTHS SUSPEND SENTENCE WITH COURT ORDERED GROUP THERAPY & PROBATION.

Original Signature (electronic, copies or stamps not accepted)

10/16/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2000	2000	VA	RICHMOND	CITY OF

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
DONT REMEMBER	RICHMOND POLICE DEPARTMENT

Reason/Charge
DRUNK IN PUBLIC

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
SELF	MISDEMEANOR

Name of Business/Industry/Entity
CITY OF RICHMOND

Provide explanation below:

I CONSUMED MORE ALCHOL THAN THE LEGAL LIMIT AND WAS INCARCERATED OVERNIGHT. PAID FINE & WAS RELEASED.

Original Signature (electronic, copies or stamps not accepted)

10/16/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

WILLIAM WEIMER
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/14/24
Date

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Davidson

I, William Weimer, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/14/24
Date

Subscribed and Sworn to before me this 14th day of October 2024

Notary Public Signature

LINDA MENDOZA
STATE OF TENNESSEE
NOTARY PUBLIC
My Commission Expires on 09/05/2028
DAVIDSON COUNTY

(Seal)

4ZZ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Specialty Mailorder	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: PANTHERx Specialty LLC dba Pantherx Specialty Pharmacy

Physical Address: 280 Moore Lane

City: Collierville State: TN Zip: 38017

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 855-726-8479 Toll Free # (NAC 639.708, NRS 639.23286): 855-726-8479

Fax: 855-246-3986 Contact Email: tnlicensing@pantherxrare.com

Website: www.pantherxrare.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Rose M. Blake

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 20992

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Rose M. Blake	NV Pharmacist Registration #: 20992
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: n/a	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Pennsylvania

Parent Company (if any): _____

Corporation/Organization Name: PANTHERx Specialty LLC

Mailing Address: 24 Summit Park Drive Suite 101

City: Pittsburgh State: PA Zip: 15275

Telephone: 855-726-8479 Email: tnlicensing@pantherxrare.com

Contact Person Name: Rose M. Blake

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☒ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Director of Fullfillment/PIC (title) for PANTHERx Specialty LLC dba Pantherx Specialty Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Rose M. Blake

Print Name of Authorized Person

Rose M. Blake

Original signature of Authorized Person (copies or stamps not accepted)

9-30-24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Rose M. Blake hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Director of Fullfillment/PIC (title) for PANTHERx Specialty LLC dba Pantherx Specialty Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Rose M Blake

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 18 day of Oct., 2024

Notary Public

SHIRLEY N. MARAVILLA
STATE OF TENNESSEE NOTARY PUBLIC
SHELBY COUNTY
MY COMMISSION EXPIRES 8-21-2027

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bansi Nagji, Chief Executive Officer

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Bansi Nagji

Original signature of Authorized Person (copies or stamps not accepted)

10-16-2024

Date

Board Use Only	Date Received: 10/21/24	Amount: $500-CK 14582

DEPARTMENT OF HEALTH
TENNESSEE BOARD OF PHARMACY
COMMUNITY INSPECTION
COMPLIANCE INSPECTION

PHARMACY: PANTHER Rx SPECIALTY PHARMACY		
STREET: 280 MOORE		
CITY: COLLIERVILLE	ZIP: 38017	
DATE OPENED:	TELEPHONE NO.: (855) 726-8477	
LICENSE NO.: N/A	EXPIRY DATE: N/A	
DEA NO.: N/A	EXPIRY DATE: N/A	
PHARMACIST IN CHARGE/Duty: ROSE BLAKE	LIC NO.: 7709	EXPIRY DATE: 7/31/25

Inspected by: DEREK JOHNSTON — Date: 8/15/24

This Inspection Satisfactory: Yes ☑ No ☐

☑ Opening ☐ Relocation ☐ New Ownership ☐ Follow-up ☐ Counseling Compliance ☑ Periodic ☐ Remodeling

Compliance Yes	Compliance No	PERSONNEL
		1. Appropriate identification/Name Tags
N/A		2. D. Ph./Tech ration
		3. Personnel/apparel clean
		4. Tech registry & Affidavit

Compliance Yes	Compliance No	PHYSICAL REQUIREMENTS
N/A		5. Certificates Displayed
✓		6. RX Dept. – Sufficient Space/Counseling
✓		7. Fully enclosed when applicable
✓		8. Key Lockable/Key Control

Compliance Yes	Compliance No	DRUGS AND EQUIPMENT
✓		9. Dispensing area clean, orderly, well lighted
✓		10. Sink, hot and cold water
✓		11. Refrigeration
✓		12. References, periodicals
		13. Vials and closures (child-proof)
N/A		14. Shelves and drug stock clean
		15. Drugs in-date
		16. Labels correct on repackaging
✓		17. Legend drugs stored in RX Dept.
✓		18. Syringes/insulin, restricted products non-accessible

Compliance Yes	Compliance No	
		19. RXs numerically filed
		☐ All C's together ☐ C-11's separate ☐ Multiple file method
		20. Patients identifiable
		21. Prescribers identifiable
N/A		22. New verbal RXs initialed by appropriate personnel
		23. Date of original dispensing
		24. Initials of dispensing D.Ph.
		25. Quantity dispensed indicated
		26. Appropriate Emergency C-11 RXs
		27. Computer labels applied appropriately to RXs
		28. Pharmacist Signature Log
		29. Daily Print Out

Compliance Yes	Compliance No	DRUG PRODUCT SUBSTITUTION
N/A		30. Authorization documented on Rx
		31. Manufacturer indicated on Rx or System
		32. Approved products used.

Compliance Yes	Compliance No	PATIENT COUNSELING
N/A		33. Patient profiles
		34. Drug Utilization Review
		35. Patient Counseling

Compliance Yes	Compliance No	CONTROLLED SUBSTANCE RECORDS
		36. Readily retrievable
N/A		37. All C-11 records separate
		38. DEA Form 222 Copy 3 on hand & completed
		39. Drug Receipt date on invoices
		40. Record of drug transfers
		41. ☐ Schedule V sales record book ☐ Methamphetamine Sales Log
		42. Last DEA Inventory (date) _____
		42. Last Theft/loss report (date) _____
✓		43. Access to Control Substance Monitoring Database

Pharmacy Hours: 8-5 M-F

ITEMS TO BE CORRECTED: **RESPONSE REQUIRED** YES ☐ NO ☑

Immediately
Needs Improvement
Within 30 Days

Remarks or Recommendations: _____

I Rose M Blake hereby acknowledge and understand all notations made on this report; and confirm that
Pharmacist Signature
I will notify the Board of Pharmacy within 30 days, in writing, of the correction of all deficiencies. (If noted.)

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
DIVISION OF HEALTH LICENSURE AND REGULATION
OFFICE OF HEALTH RELATED BOARDS
665 Mainstream Drive, Second Floor
Nashville, TN 37243
http://www.tn.gov/health

Board of Pharmacy
Pharmacy
1-800-778-4123 or

October 2, 2024

Pantherx Speciality LLC
dba Pantherx Specialty Pharmacy
280 Moore Ln
Collierville, TN 38017

TO WHOM IT MAY CONCERN:

This verification can be considered primary source. To expedite the verification process, this is the standard format used by the Tennessee Board of Pharmacy. We are pleased to furnish the following information from our files:

PROFESSION:	Pharmacy
NAME:	Pantherx Speciality LLC
ADDRESS:	dba Pantherx Specialty Pharmacy 280 Moore Ln Collierville, TN 38017
LICENSE NUMBER:	7821
ISSUE DATE:	August 16, 2024
EXPIRATION DATE:	August 31, 2026
CURRENT STATUS:	Licensed
STATUS DATE:	August 16, 2024
SPECIAL ENDORSEMENT:	Controlled Substance Registration

COMMENTS: There is no derogatory information in our files concerning this facilty.

Sincerely,

Sheila W Bass

Tennessee Board of Pharmacy

VERFFACLTY

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
DIVISION OF HEALTH LICENSURE AND REGULATION
OFFICE OF HEALTH RELATED BOARDS
665 Mainstream Drive, Second Floor
Nashville, TN 37243
http://www.tn.gov/health

Board of Pharmacy
Pharmacist
1-800-778-4123 or 615-253-1299

October 2, 2024

Pantherx Specialty LLC
dba Pantherx Specialty Pharmacy
280 Moore Ln
Collierville, TN 38017

TO WHOM IT MAY CONCERN:

This verification can be considered primary source. To expedite the verification process, this is the standard format used by the Board of Pharmacy. The Board of Pharmacy is pleased to furnish the following information from our files:

PROFESSION:	Pharmacist
NAME:	ROSE M BLAKE
RANK:	Pharmacist
LICENSE NUMBER:	7709
ISSUE DATE:	August 04, 1989
EXPIRATION DATE:	July 31, 2025
CURRENT STATUS:	Licensed
STATUS DATE:	January 01, 1993
SPECIAL ENDORSEMENTS:	Controlled Substance Qualifications

COMMENTS: There is no history of disciplinary action on this license. The State of Tennessee only provides the above information. Any other information needed must be obtained from the licensee.

Sincerely,

Board of Pharmacy
VERIFICATN

TENNESSEE DEPARTMENT OF HEALTH
PANTHERX SPECIALTY LLC DBA PANTHERX

ID NUMBER: 7821

EXPIRATION DATE: 08/31/2026

THIS IS TO CERTIFY THAT ALL REQUIREMENTS OF THE STATE OF TENNESSEE HAVE BEEN MET.
BOARD OF PHARMACY
PHARMACY
ALL APPLICABLE QUALIFICATIONS AND/OR SPECIALTIES PRINTED ON BACK.

COMMISSIONER OF HEALTH

PANTHERX SPECIALTY LLC DBA PANTHERX
SPECIALTY PHARMACY
280 MOORE LANE
COLLIERVILLE, TN 38017

State of Tennessee
Department of Health

14064754
Renewal No. 58212

Board of Pharmacy
Pharmacy

PANTHERX SPECIALTY LLC DBA PANTHERX
SPECIALTY PHARMACY, 280 MOORE LANE,
COLLIERVILLE, TN 38017

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 7821

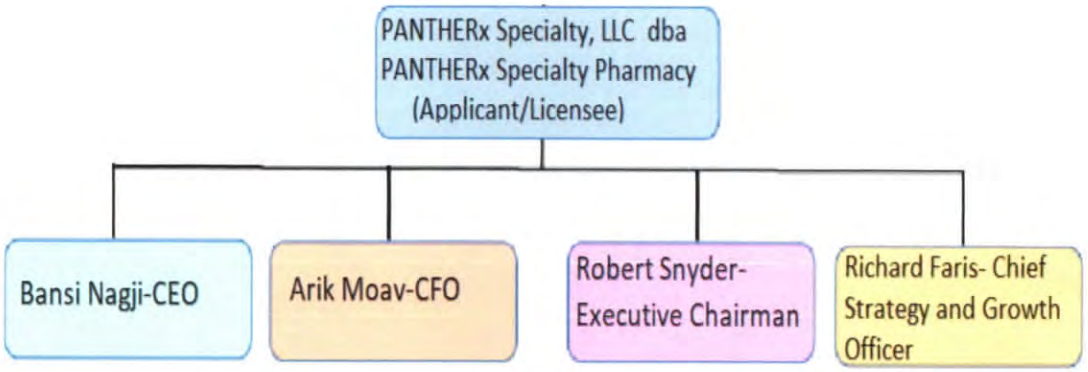
EXPIRATION DATE: August 31, 2026

CONTROLLED SUBSTANCE REGISTRATION

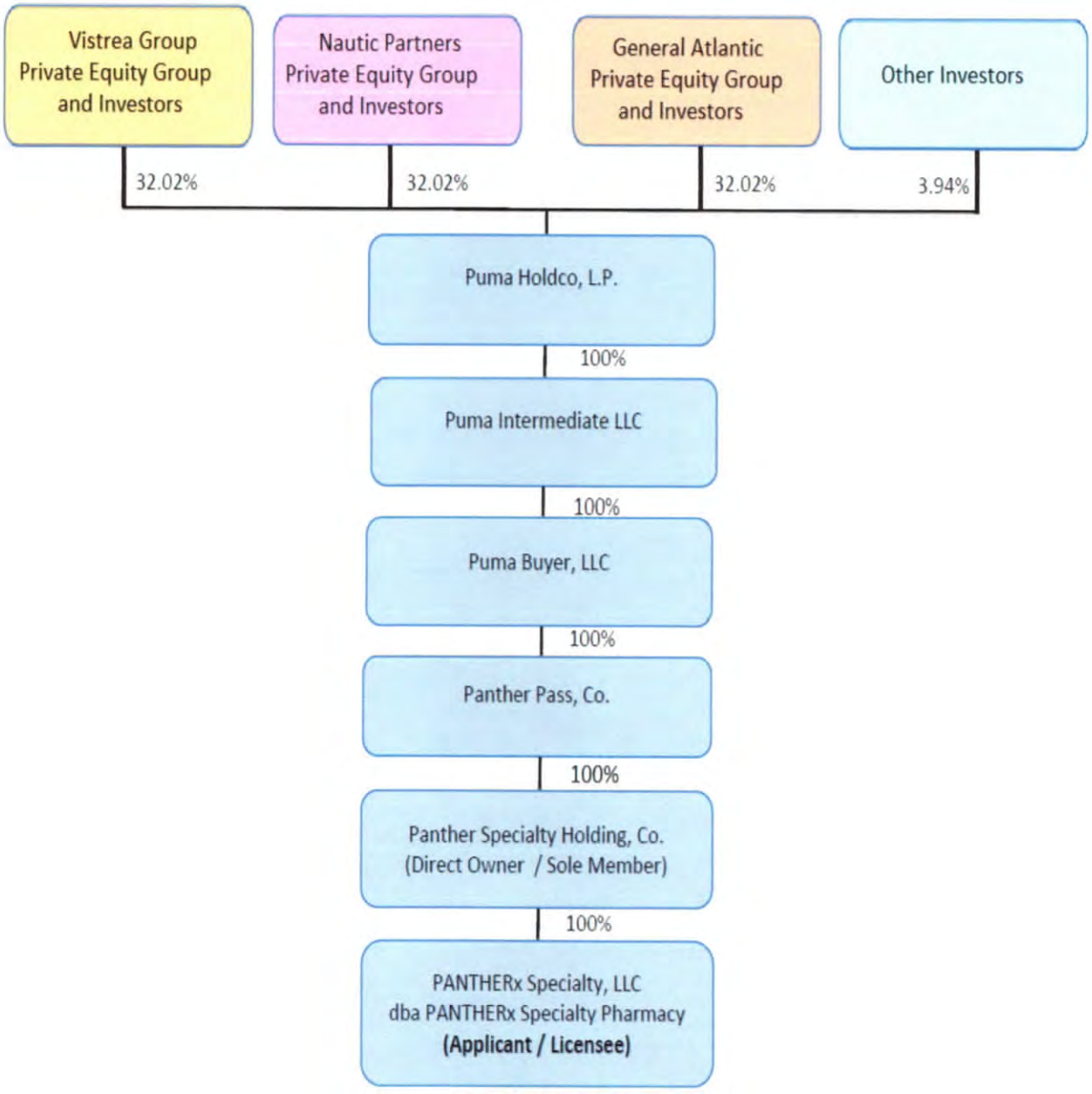
Commissioner, Dept. of Health

Jennifer L. Rotramel Esq
Assistant Commissioner, Health Licensure & Regulation

Officers of Panther Specialty LLC



PANTHERx Specialty, LLC dba PANTHERx Specialty Pharmacy
Organizational Chart



NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler PANTHERx Specialty LLC dba Pantherx Specialty Pharmacy
Pharmacy/Wholesaler License # (if applicable) applied for
Physical Address 280 Moore Lane
City Collierville State TN Zip 38017
Mailing Address (if different from physical address) _____
City _____ State _____ Zip _____
Telephone _____ Website _____
Licensing Company Email _____

Section 2: Personal Information

First Rose Middle Marie Last Blake
Alias(es, nicknames, name changes, etc.) Thompson
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X
Mailing Address [redacted]ghthouse Lane
City Lakeland State TN Zip 38002
Telephone [redacted] Email [redacted]
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Mississippi		08/1982 to May, 1989	
Address	**City**	**State**	**Zip**
145 Martindale	University	MS	38677
Diploma/Degree obtained, if any			
B.S. Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Shannon High School		08/ 1979 to May 1982	
Address	**City**	**State**	**Zip**
218 East Cherry Street	Shannon	MS	38868
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2021 to present	[redacted]ighthouse Lane	Lakeland	TN	38002
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
PANTHERx Specialty LLC dba Pantherx Specialty Pharmacy			7/24 to present	
Business Address	**City**		**State**	**Zip**
280 Moore Lane	Collierville		TN	38017
Phone	**Title**		**Number of Employed Hours**	
855-726-8479	Director of Fullfillment/PIC		400	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
HPC Specialty Infusion			4/20 to 6/2023	
Business Address	**City**		**State**	**Zip**
6423 Shelby View Drive Suite 104	Memphis		TN	38134
Phone	**Title**		**Number of Employed Hours**	
800-757-9192	Director		6240	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I, Rose M. Blake, **certify that as the designated representative for**

PANTHERx Specialty LLC dba Pantherx Specialty Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. X I am at least 21 years of age;
3. X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Rose Blake

Print Name (First, Last)

Rose M. Blake

Original Signature (electronic, copies or stamps not accepted)

9-30-24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rose M. Blake

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10-1-24

Date

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Shelby

I, Rose M Blake, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10-1-24

Date

Subscribed and Sworn to before me this 1st day of Oct 2024.

Notary Public Signature

SHIRLEY N. MARAVILLA
STATE OF TENNESSEE NOTARY PUBLIC
SHELBY COUNTY
MY COMMISSION EXPIRES 8-21-2027

(Seal)

4AAA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
☑ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	■ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FR7458400
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 03913		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: RARX II, LLC

Physical Address: 525 METROPLEX DRIVE, STE 206

City: NASHVILLE State: TN Zip: 37211

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 800-610-2164 Toll Free # (NAC 639.708, NRS 639.23286): 800-610-2164

Fax: 800-837-7445 Contact Email: compliance@medipakrx.com

Website: _____

Nevada Business License # (if applicable) PH03913

Supervising/Managing Pharmacist Name (NRS 639.220): DOUGLAS RAWL

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24074

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: DOUGLAS RAWL	NV Pharmacist Registration #: 24074
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: TN

Parent Company (if any): MEDIPAK HOLDINGS LLC

Corporation/Organization Name: RARX II, LLC

Mailing Address: 525 METROPLEX DRIVE

City: NASHVILLE State: TN Zip: 37211

Telephone: 800-610-2164 Email: Compliance@medipakrx.com

Contact Person Name: William Weimer

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CFO (title) for RARX II (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

William Weimer II

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

10/14/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, WILLIAM N. WEIMER, II hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CFO (title) for RARX II (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 14th day of October, 2024

Notary Public

LINDA MENDOZA
STATE OF TENNESSEE
NOTARY PUBLIC
My Commission Expires on 09/05/2028
DAVIDSON COUNTY

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

William Weimer II

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

9-26-2024

Date

Board Use Only	Date Received: 10/21/24	Amount: $500 ck 1254

RARX II, LLC
525 Metroplex Dr Ste 206
Nashville, TN 37211
800.610.2164

I

The following incidents need to be disclosed:

1. **Vincent Jackson**: On October 1, 1997, during an inspection at CVS Pharmacy #1377, Vincent Jackson was cited for failing to provide documentation of continuing education.
2. **CommonShare Inc.**: On June 5, 2023, during a routine inspection, CommonShare Inc., a non-profit pharmacy in Virginia owned by William Weimer II, was cited for a deficiency in maintaining records of dispensing as required.

Both disciplinary actions are attached for your review.

Thank you for your attention to this matter.

VIRGINIA:

BEFORE THE BOARD OF PHARMACY

IN RE: VINCENT E. JACKSON, PHARMACIST
License No. 0202-011625

CONSENT ORDER

Now comes the Virginia Board of Pharmacy ("Board") and Vincent E. Jackson and as evidenced by their signatures affixed below, enter into this Consent Order affecting the license of Mr. Jackson to practice pharmacy in the Commonwealth of Virginia.

FINDINGS OF FACT

1. Vincent E. Jackson holds License No. 0202-011625 issued by the Board to practice pharmacy in the Commonwealth of Virginia.

2. On October 1, 1997, an inspection was conducted at Mr. Jackson's principal place of practice, CVS/pharmacy #1377, 9871 Georgetown Turnpike, Great Falls, Virginia, and he was not able to provide documentation for having obtained continuing pharmacy education for 1996.

3. Subsequently, Mr. Jackson provided the Board office with continuing pharmacy education documentation for 13.5 hours for 1996.

4. On the 1997 renewal notice processed by the Board on January 2, 1997, Mr. Jackson indicated "Yes" to the statement, "I certify that I have met all continuing education requirements to renew this license".

CONCLUSIONS OF LAW

The Board concludes that Findings of Fact #2 and #3 constitute a violation of § 54.1-3314.1(A), § 54.1-3316(5), (7) and (10) of the Code of Virginia, (1950), as amended, and 18 VAC 110-20-90(A), (F) and (G) of the Board of Pharmacy Regulations.

CONSENT

Vincent E. Jackson, by affixing his signature hereon, agrees to the following:

1. He has been advised specifically to seek the advice of counsel prior to signing this document;

2. He is fully aware that without his consent, no legal action can be taken against his except pursuant to the Virginia Administrative Process Act, § 9-6.14:1 et seq of the Code of Virginia;

3. He has the following rights, among others:

a. the right to a informal fact-finding conference before the Board;
b. the right to representation by counsel; and
c. the right to cross-examine witnesses against his.

4. He waives all rights to an informal hearing;

5. He admits the truth of the above Findings of Fact; and

6. He consents to the following Order affecting his license to practice pharmacy in the Commonwealth of Virginia.

ORDER

WHEREFORE, on the basis of the foregoing Findings of Fact, Conclusions of Law, and with the consent of the licensee, it is hereby ORDERED that Mr. Jackson is REPRIMANDED. It is further ORDERED that Mr. Jackson complete an additional one and one-half contact hours of continuing pharmacy education prior to December 31, 1998, with the one and one-half contact hours being applied to the 1996 year for a total of 15 contact hours. Mr. Jackson shall provide original documentation of said contact hours of continuing pharmacy education to the Board office prior to January 15, 1999. Further, Mr. Jackson shall be assessed a monetary penalty of TWO HUNDRED FIFTY DOLLARS ($250.00). If said monetary penalty is not received within the prescribed deadline, an additional $100.00 late fee shall be assessed weekly, up to a maximum of $1,000.00. Failure to complete the contact hour of continuing pharmacy education as indicated above and/or pay the full monetary penalty plus any additional assessment within 100 days of the date of entry of this Consent Order shall constitute grounds for an administrative proceeding.

Pursuant to § 9-6.14:14 of the Code of Virginia, the signed original of this Consent Order shall remain in the custody of the Department of Health Professions as a public record and shall be made available for public release, inspection and copying upon request.

FOR THE BOARD:

for Cathy M. Reniers-Day
Elizabeth Scott Russell
Executive Director

Entered: October 22, 1998

SEEN AND AGREED TO:

Vincent E. Jackson

STATE OF MARYLAND
CITY/COUNTY OF MONTGOMERY

Subscribed and sworn to before me, a Notary Public in and for the ~~city~~/county of MONTGOMERY, this 21st day of October, 1998, by Vincent E. Jackson.
My commission expires the 10th day of August 2002.

Mohammad Tasleem
Notary Public

MOHAMMAD TASLEEM
NOTARY PUBLIC STATE OF MARYLAND
My Commission Expires August 10, 2002

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing Consent Order was mailed to Vincent E. Jackson, 1311 Smith Village Road, Silver Spring, Maryland 20904, on this 22nd day of OCTOBER, 1998.

Cathy M. Reniers-Day
Deputy Executive Director

Department of Health Professions
FINANCE DIVISION
RECEIVED
JUL 27 2023
ORIGINAL DOCUMENT
☐ US MAIL ☑ WALK-IN PAYMENT

Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, VA 23233
804-367-4456
804-527-4472 (Fax)
pharmbd@dhp.virginia.gov
June 5, 2023

Received
VA Board of Pharmacy
JUL 31 2023

Commonshare Inc dba Commonshare HDH
Permit Number: 0201005013

Notice

After an inspection conducted on June 5, 2023 at Commonshare Inc dba Commonshare HDH, the deficiencies identified in the inspection summary that was provided to the facility were found. Those deficiencies constitute violations of the statutes and regulations cited below:

1. ($250) Deficiency 18: Records of dispensing not maintained as required; 18 VAC 110-20-250

If you wish to contest the violations cited above and in the inspection summary that was provided to the facility, you may submit documentation for the Board's consideration within 14 days of the date of this notice. In the alternative, you may request, in writing, an informal conference to further discuss this matter before a committee of the Board within 30 days of the date of this notice. Documents for consideration or a request for an informal conference should be mailed to:

Virginia Board of Pharmacy
9960 Mayland Drive
Suite 300
Henrico, Virginia 23233

If you do not want to contest the cited violations, in lieu of proceeding to an informal conference, you may sign the Consent Order below, submit a total penalty of $250.00 by check or money order, made payable to the Treasurer of Virginia, and provide documentation of corrective action taken to remedy all of the cited violations. The Consent Order, the penalty, and documentation of corrective action should be sent in one mailing to the address provided above within 30 days of the date of this Notice.

Failure to respond to this document within thirty (30) days of the date of this Notice will result in an informal conference being scheduled to determine whether violations of the statutes and regulations of the Board of Pharmacy have occurred. A notice of the informal conference will be mailed to the attention of the facility's Pharmacist-in-Charge [or the Owner if no PIC] with the scheduled date and time. If it is determined at the conclusion of the informal conference that the pharmacy is in violation of the laws and regulations of the Board of Pharmacy, the permit holder may be subject to disciplinary sanctions by the Board in addition to the penalty listed above. If you have any questions, please contact the Board office.

Consent Order

The Virginia Board of Pharmacy ("Board") and Commonshare Inc dba Commonshare HDH ("Pharmacy") enter into the following Consent Order as evidenced by the signature of the Pharmacist-in-Charge [or the Owner if no PIC] hereto. The deficiencies cited in the Notice above and the inspection summary that was provided to the facility constitute violations of the statutes and regulations as cited above in the Notice. These violations were identified during an inspection conducted on June 5, 2023.

DO NOT MAKE ANY CHANGES TO THIS DOCUMENT:

Pharmacy, by affixing the signature of the Pharmacist-in-Charge (or Owner if no PIC) hereon, agrees to the following:

1. The Pharmacist-in-Charge (or Owner if no PIC) has the right to seek advice of counsel prior to signing this document;
2. The Pharmacist-in-Charge (or Owner if no PIC) acknowledges that without his consent, no legal action can be taken against the Pharmacy except pursuant to the Virginia Administrative Process Act, § 2.2-4000 *et seq.* of the Code of Virginia;
3. The Pharmacist-in-Charge (or Owner if no PIC) acknowledges that he has the following rights, among others: the right to an informal fact finding conference before the Board, the right to reasonable notice of said hearing, the right to representation by counsel, and the right to cross-examine witnesses;
4. The Pharmacist-in-Charge (or Owner if no PIC) waives all such right to an informal conference;
5. The Pharmacist-in-Charge (or Owner if no PIC) admits to the violations cited herein and waives his right to contest such violations in any subsequent proceeding before the Board;
6. The Pharmacist-in-Charge (or Owner if no PIC) consents to the entry of the following Order affecting the permit of the Pharmacy in Virginia.

WHEREFORE, on the basis of the foregoing, the Board, effective upon entry of this Order, and in lieu of further proceedings, hereby ORDERS as follows:

1. Pharmacy shall pay a monetary penalty of $250.00 to the Board within 30 days of the date of the Notice.

2. Pharmacy shall submit documentation of immediate action taken to correct all violations.

3. Any violation of the terms and conditions of this Order or of any law or regulation affecting the conduct of Pharmacy in the Commonwealth of Virginia shall constitute grounds for the suspension or revocation of the permit of Pharmacy, and an administrative proceeding shall be convened to determine whether such permit shall be suspended or revoked.

Pursuant to § 2.2-4023 and § 54.1-2400.2 of the Code of Virginia, the signed original of this Notice and Consent Order shall remain in the custody of the Department of Health Professions as public record and shall be made available for public inspection or copying upon request.

	07/24/2023
Signature of PIC or Owner	Date
Stephanie L. Spencer	Pharmacist-in-charge
Printed Name of Person Signing	Position/Title

FOR THE BOARD:

	8/8/2023
Caroline D. Juran, Executive Director	Entered

This completed application must be submitted along with the following:

1. **$625 application fee (made payable to DHHS Licensure Unit)**
2. **Copies of last two inspection reports from the state in which you are located (If the pharmacy has not had two inspections, please send a memo of explanation.)**
3. **A letter of explanation addressed to the Nebraska Board of Pharmacy and copies of documentation of the action taken against the license(s) – ONLY IF APPLICABLE.**

You must <u>additionally</u> contact your State Board and request that certification of the following be sent <u>DIRECTLY TO OUR OFFICE:</u>

1. **Pharmacy Permit**
2. **Pharmacist License of your Pharmacist in Charge**

Send to:

Nebraska Department of Health & Human Services
Division of Public Health
Licensure Unit
ATTN: Pharmacy Desk
PO Box 94986
Lincoln, NE 68509-4986

<u>PHYSICAL ADDRESS</u>: 301 Centennial Mall South
Lincoln, NE 68508

<u>Please Note</u>: All supporting documentation required to complete your application must be submitted within **<u>150 days</u>** from the date your application is received by the Department. If such documentation is not submitted within this time, your application and supporting documentation will be destroyed and a refund will be processed, less the administrative fee of $25.00.

1/29/2021

Tre Hargett
Secretary of State

Division of Business Services
Department of State
State of Tennessee
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

KESLEY RESHA
525 METROPLEX DRIVE
NASHVILLE, TN 37211

June 27, 2024

Request Type: Certificate of Existence/Authorization Issuance Date: 06/27/2024
Request #: 0589756 Copies Requested: 1

Document Receipt

Receipt # : 009093087 Filing Fee: $20.00

Payment-Credit Card - State Payment Center - CC #: 3876771511 $20.00

Regarding: **RARx II LLC**
Filing Type: Limited Liability Company - Domestic
Formation/Qualification Date: 01/25/2018
Status: Active
Duration Term: Perpetual
Business County: DAVIDSON COUNTY
Control # : 943462
Date Formed: 01/25/2018
Formation Locale: TENNESSEE
Inactive Date:

CERTIFICATE OF EXISTENCE

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

RARx II LLC

* is a Limited Liability Company duly formed under the law of this State with a date of incorporation and duration as given above;
* has paid all fees, interest, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;
* has filed the most recent annual report required with this office;
* has appointed a registered agent and registered office in this State;
* has not filed Articles of Dissolution or Articles of Termination. A decree of judicial dissolution has not been filed.

Tre Hargett
Secretary of State

Processed By: Cert Web User **Verification #: 068342429**

DEPARTMENT OF HEALTH
TENNESSEE BOARD OF PHARMACY
COMMUNITY INSPECTION
COMPLIANCE INSPECTION

PHARMACY: Kalx II LLC	
STREET: 525 Metroplex Dr Ste 206	
CITY: Nashville	ZIP: 37211
DATE OPENED:	TELEPHONE NO.: (800) 610 2164
LICENSE NO.: 6240	EXPIRY DATE: 12/31/2025
DEA NO.: FR7458400	EXPIRY DATE: 4/30/2027
PHARMACIST IN CHARGE/Duly: Douglas Courtland Paul	LIC NO.: 33507 / EXPIRY DATE: 3/31/2025

Inspected by: Andrea Miller — Date: 10/9/2024

This inspection Satisfactory: Yes ☒ No ☐

☐ Opening ☐ Relocation
☐ New Ownership ☐ Follow-up
☐ Counseling Compliance
☐ Periodic ☐ Remodeling

Compliance Yes	Compliance No	PERSONNEL
✓		1. Appropriate identification/Name Tags
✓		2. D. Ph./Tech ration
✓		3. Personnel/apparel clean
✓		4. Tech registry & Affidavit

Compliance Yes	Compliance No	PHYSICAL REQUIREMENTS
✓		5. Certificates Displayed
✓		6. RX Dept. – Sufficient Space/Counseling
✓		7. Fully enclosed when applicable
✓		8. Key Lockable/Key Control

Compliance Yes	Compliance No	DRUGS AND EQUIPMENT
✓		9. Dispensing area clean, orderly, well lighted
✓		10. Sink, hot and cold water
✓		11. Refrigeration
✓		12. References, periodicals
✓		13. Vials and closures (child-proof)
✓		14. Shelves and drug stock clean
✓		15. Drugs in-date
✓		16. Labels correct on repackaging
✓		17. Legend drugs stored in RX Dept.
✓		18. Syringes/insulin, restricted products non-accessible

	Compliance Yes	Compliance No	
✓			19. RXs numerically filed
			☐ All C's together ☐ C-11's separate ☐ Multiple file method
✓			20. Patients identifiable
✓			21. Prescribers identifiable
✓			22. New verbal RXs initialed by appropriate personnel
✓			23. Date of original dispensing
✓			24. Initials of dispensing D.Ph.
✓			25. Quantity dispensed indicated
N/A			26. Appropriate Emergency C-11 RXs
✓			27. Computer labels applied appropriately to RXs
✓			28. Pharmacist Signature Log
N/A			29. Daily Print Out

Compliance Yes	Compliance No	DRUG PRODUCT SUBSTITUTION
✓		30. Authorization documented on Rx
✓		31. Manufacturer indicated on Rx or System
✓		32. Approved products used.

Compliance Yes	Compliance No	PATIENT COUNSELING
✓		33. Patient profiles
✓		34. Drug Utilization Review
✓		35. Patient Counseling

Compliance Yes	Compliance No	CONTROLLED SUBSTANCE RECORDS
✓		36. Readily retrievable
N/A		37. All C-11 records separate
N/A		38. DEA Form 222 Copy 3 on hand & completed
✓		39. Drug Receipt date on invoices
✓		40. Record of drug transfers
RX		41. ☐ Schedule V sales record book ☐ Methamphetamine Sales Log
✓		42. Last DEA Inventory (date) 6/30/2024
✓		42. Last Theft/loss report (date) None
✓		43. Access to Control Substance Monitoring Database

Pharmacy Hours: M-F 8-430

ITEMS TO BE CORRECTED: **RESPONSE REQUIRED** **YES ☐** **NO ☒**

Immediately
Needs Improvement
Within 30 Days

Remarks or Recommendations: No CIIs, No compounding, reviewed DSCSA

I [signature] hereby acknowledge and understand all notations made on this report; and confirm that
Pharmacist Signature
I will notify the Board of Pharmacy within 30 days, in writing, of the correction of all deficiencies. (If noted.)

PH-4031 REV 01/18 RDA SW-30

1366738

56633

State of Tennessee
Department of Health

BOARD OF PHARMACY

PHARMACY

RARX 11 LLC

525 METROPLEX DR STE 206

NASHVILLE TN 37211

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000006240

EXPIRATION DATE: 12/31/2025

Jennifer L. Putnam, Esq

ASSISTANT COMMISSIONER, HEALTH LICENSURE & REGULATION

CONTROLLED SUBSTANCE REGISTRATION

COMMISSIONER, DEPARTMENT OF HEALTH

DCF171

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
DIVISION OF HEALTH LICENSURE AND REGULATION
OFFICE OF HEALTH RELATED BOARDS
665 Mainstream Drive, Second Floor
Nashville, TN 37243
http://www.tn.gov/health

Board of Pharmacy
Pharmacy
1-800-778-4123

October 1, 2024

Rx Partners
Attn: Kesley Resha
525 Metroplex Dr
Nashville, TN 37211

TO WHOM IT MAY CONCERN:

This verification can be considered primary source. To expedite the verification process, this is the standard format used by the Tennessee Board of Pharmacy. We are pleased to furnish the following information from our files:

PROFESSION:	Pharmacy
NAME:	RARx II LLC
ADDRESS:	525 Metroplex Dr., Ste. 206 Nashville, TN 37211
LICENSE NUMBER:	6240
ISSUE DATE:	February 27, 2018
EXPIRATION DATE:	December 31, 2025
CURRENT STATUS:	Licensed
STATUS DATE:	February 27, 2018
SPECIAL ENDORSEMENT:	Controlled Substance Registration

COMMENTS: There is no derogatory information in our files concerning this facilty.

Sincerely,

Sheila W Bush

Tennessee Board of Pharmacy

VERFFACLTY

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FR7458400	04-30-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	03-05-2024

RARX II, LLC
525 METROPLEX DR
STE 206
NASHVILLE, TN 372113140

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FR7458400	04-30-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	03-05-2024

RARX II, LLC
525 METROPLEX DR
STE 206
NASHVILLE, TN 372113140

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

RARX II, LLC
82-4159113
525 Metroplex Drive, Ste 206
Nashville, TN 37211



Medipak Holdings LLC Owner of RARX II, LLC (100%)
[redacted]
525 Metroplex Drive
Nashville, TN 37211

Medipak, LLC Owner of Medipak Holdings, LLC (50%)
[redacted]
525 Metroplex Drive
Nashville, TN 37211

Economedical, Inc Owner of Medipak Holdings, LLC (50%)
[redacted]
5012 Fleming Crossroads LN
Kents Store, VA 23084

Will Weimer II, CFO, Owner of Economedical, Inc. (100%)
[redacted]
[redacted]Fleming Crossroads LN
Kents Store, VA 23084

Grace Jackson, Owner of Medipak, LLC (51%)
[redacted]
[redacted]Deer Meadow Ct
Reisterstown, MD 21136

Vincent Jackson, PharmD, CEO Owner of Medipak, LLC (49%)
[redacted]
[redacted]Deer Meadow Ct
Reisterstown, MD 21136

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site RARX II LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 525 METROPLEX DRIVE, STE 206

City NASHVILLE State TN Zip 37211

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-610-2164 Website _____

Licensing Company Email _____

Section 2: Personal Information

First WILLIAM Middle MILTON Last WEIMER II

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] Fleming Crossroads LN

City Kents Store State VA Zip 23084

Telephone _____ Email _____

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
VIRGINIA COMMONWEALTH UNIVERSITY			09/2012 – 05/2014
Address	**City**	**State**	**Zip**
907 FLOYD AVE	RICHMOND	VA	23284
Diploma/Degree obtained, if any			
MASTERS OF SCIENCE IN HEALTH ADMINISTRATION			

School Name			From - To (MM/YY – MM/YY)
UNIVERSITY OF VIRGINIA			09/1993 – 06/1997
Address	**City**	**State**	**Zip**
1827 UNIVERSITY AVE	CHARLOTTESVILLE	VA	22903
Diploma/Degree obtained, if any			
BACHELORS OF SCIENCE IN COMMERCE			

School Name			From - To (MM/YY – MM/YY)
LEE-DAVIS HIGH SCHOOL			09/90 – 06/93
Address	**City**	**State**	**Zip**
7052 MECHANICSVILLE TPKE	MECHANICSVILLE	VA	23111
Diploma/Degree obtained, if any			
ADVANCED HIGH SCHOOL DIPLOMA			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2007 – CURRENT	[redacted] FLEMING CROSSROADS LN	KENTS STORE	VA	23084
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: MEDIPAK HOLDINGS LLC			From - To (MM/YY – MM/YY): 08/24 - PRESENT
Business Address: 525 METROPLEX DR	City: NASHVILLE	State: TN	Zip: 37211
Phone: 615-734-0321	Title: CFO		
Description of Duties: FINANCIAL MANAGEMENT			

Business Name: ECONOMEDICAL, INC.			From - To (MM/YY – MM/YY): 01/09 - PRESENT
Business Address: 5012 FLEMING CROSSROADS LN	City: KENTS STORE	State: VA	Zip: 23084
Phone: 804-908-6245	Title: PRESIDENT & CEO		
Description of Duties: OWNER			

Business Name: COMMONSHARE, INC			From - To (MM/YY – MM/YY): 07/19 - PRESENT
Business Address: 1602 SKIPWITH RD #201	City: HENRICO	State: VA	Zip: 23229
Phone: 804-416-6255	Title: EXECUTIVE DIRECTOR		
Description of Duties: EXECUTIVE MANAGEMENT & OVERSIGHT			

Business Name: HOME RECOVERY HOME AID, INC			From - To (MM/YY – MM/YY): 5/19 - 8/24
Business Address: 816 E. THIRD ST.	City: FARMVILLE	State: VA	Zip: 23901
Phone: 434-392-7336	Title: CONTROLLER		
Description of Duties: FINANCIAL MANAGEMENT & HEATHCARE ADMINISTRATION			

Business Name: BON SECOURS HEALTH SYSTEM			From - To (MM/YY – MM/YY): 12/06 - 2/19
Business Address: 8580 MAGELLAN PKWY	City: RICHMOND	State: VA	Zip: 23227
Phone:	Title:		
Description of Duties: FINANCIAL MANAGEMENT & HEALTHCARE ADMINISTRATION			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	X	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1997	1997	VA	CHARLOTTESVILLE	CITY OF

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
DON'T REMEMBER	CITY OF CHARLOTTESVILLE POLICE

Reason/Charge
DESTRUCTION OF PROPERTY / ASSAULT & BATTERY

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
SELF	MISDEMEANOR CRIMINAL

Name of Business/Industry/Entity
UNIVERSITY OF VIRGINIA MEDICAL CENTER

Provide explanation below:

TRIED TO LEAVE ER AGAINST MEDICAL ADVICE AND WAS STOPPED BY SECURITY AT WHICH POINT I ASSAULTED OFFICERS DESTROYING PROPERTY AND WAS DETAINED)

6 MONTHS SUSPEND SENTENCE COMPLETED

Original Signature (electronic, copies or stamps not accepted)

10/16/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1999	1999	DC	WASHINGTON DC	CITY OF

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
DON'T REMEMBER	WASHINGTON DC POLICE

Reason/Charge
ASSAULT & BATTERY (2)

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
SELF	MISDEMEANOR

Name of Business/Industry/Entity
DC ATTORNEY

Provide explanation below:

I WAS IN A PHYSICAL ALTERCATION WITH MY WIFE OF THE TIME. AT WHICH POINT OFFICER IN THE AREA TRIED TO DETAIN ME AND I RESISTED THEN FLEYED THE SCENE.
1 MONTH JAILTIME & 11 MONTHS SUSPEND SENTENCE WITH COURT ORDERED GROUP THERAPY & PROBATION.

Original Signature (electronic, copies or stamps not accepted)

10/16/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2000	2000	VA	RICHMOND	CITY OF

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
DONT REMEMBER	RICHMOND POLICE DEPARTMENT

Reason/Charge
DRUNK IN PUBLIC

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
SELF	MISDEMEANOR

Name of Business/Industry/Entity
CITY OF RICHMOND

Provide explanation below:

I CONSUMED MORE ALCHOL THAN THE LEGAL LIMIT AND WAS INCARCERATED OVERNIGHT. PAID FINE & WAS RELEASED.

Original Signature (electronic, copies or stamps not accepted)

10/16/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

WILLIAM WEIMER

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/14/24

Date

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Davidson

I, William Weimer, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/14/24

Date

Subscribed and Sworn to before me this 14th day of October 2024.

Notary Public Signature

LINDA MENDOZA
STATE OF TENNESSEE
NOTARY PUBLIC
My Commission Expires on 09/05/2028
DAVIDSON COUNTY

(Seal)

NEVADA STATE BOARD OF PHARMACY

85 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site RARX II

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH03913

Physical Address 525 Metroplex Suite 206

City Nashville State TN Zip 37211

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Vincent Middle Eugene Last Jackson

Alias(es, nicknames, name changes, etc. _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Deer Meadow Ct

City Reistertown State MD Zip 21136

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)
Massachusetts College of Pharmacy	08/88 to 06/94

Address	City	State	Zip
179 Longwood Dr.	Boston	MA	02115

Diploma/Degree obtained, if any: BS/Pharm D

School Name	From - To (MM/YY – MM/YY)
Boston University	08/86 to 06/88

Address	City	State	Zip
Commonwealth Ave	Boston	MA	02215

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY)
Paint Branch High School	08/84 to 06/86

Address	City	State	Zip
14121 Old Columbia Pike	Burtonsville	MD	20866

Diploma/Degree obtained, if any: HS Diploma

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/21 to Current	[redacted] Deer Meadow Ct	Resistertown	MD	21136
04/18 to 08/21	[redacted] old Club Ct	Nashville	TN	37215
08/16 to 04/18	[redacted] Burland Crescent	Brentwood	TN	37027
06/10 to 08/16	[redacted] Riverdowns South Dr.	Midlothian	VA	23113
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
Advocate Health		02/23 to Present	
Business Address	**City**	**State**	**Zip**
1000 Blythe Blvd	Charlotte	NC	28203
Phone	**Title**		
847-713-2215	Chief Pharmacy Officer		
Description of Duties			
Oversee all pharmacy services			

Business Name		From - To (MM/YY – MM/YY)	
Advocate Aurora Health		04/21 to 02/23	
Business Address	**City**	**State**	**Zip**
2025 Windsor Dr.	Oak Brook	IL	60523
Phone	**Title**		
847-713-2215	Chief Pharmacy Officer		
Description of Duties			
Oversee all pharmacy services			

Business Name		From - To (MM/YY – MM/YY)	
Healthtrust		06/16 to 03/21	
Business Address	**City**	**State**	**Zip**
1100 MLK Blvd suite 1100	Nashville	TN	37203
Phone	**Title**		
615-344-3000	VP of Pharmacy		
Description of Duties			
Oversee all pharmacy services			

Business Name		From - To (MM/YY – MM/YY)	
Bon Secours Health		02/09 to 05/16	
Business Address	**City**	**State**	**Zip**
1525 Marriottsville	Marriotsville	MD	21104
Phone	**Title**		
410-442-1333	VP of Pharmacy		
Description of Duties			
Oversee all pharmacy services			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed

Section 8: Arrests. Detentions. Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court orde		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedin before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorce		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Vincent Jackson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10-9-24

Date

Please have this section completed in the presence of a Notary Public.

State of 10/9/24 MD. ss. County of Baltimore

I, Vincent Jackson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof: that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10-9-24

Date

Subscribed and Sworn to before me this 9th day of October 2024

Notary Public Signature

BRANDI M LANE
Notary Public
Baltimore County, Maryland
My Commission Expires 08/17/2027

BRANDI M LANE Notary Public BALTIMORE COUNTY MD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler RARX II, LLC

Pharmacy/Wholesaler License # (if applicable) PH03761

Physical Address 525 METROPLEX DRIVE, STE 206

City NASHVILLE State TN Zip 37211

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-610-2164 Website N/A

Licensing Company Email COMPLIANCE@MEDIPAKRX.COM

Section 2: Personal Information

First DOUGLAS Middle KIRKLAND Last RAWL

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Addre[redacted] WELLSFORD LN

City COLLEGE GROVE State TN Zip 37046

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
LEXINGTON HIGH SCHOOL		8/83-07/86	
Address	**City**	**State**	**Zip**
2463 AUGUSTA HWY	LEXINGTON	SC	29072
Diploma/Degree obtained, if any			
H.S. DIPLOPA			

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF SOUTH CAROLINA		08/86-12/90	
Address	**City**	**State**	**Zip**
101 SUMTER ST	COLUMBIA	SC	29208
Diploma/Degree obtained, if any			
B.S. PHARMACY			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
4/22- PRESENT	[redacted]WELLSFORD LANE	COLLEGE GROVE	TN	37046
08/18-04/22	[redacted]NASHBORO BLVD	NASHVILLE	TN	37217
10/14-08/18	[redacted]SWAWHOLEA DR	MURFREESBORO	TN	37128

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
RARX II			09/23 - PRESENT	
Business Address		**City**	**State**	**Zip**
525 METROPLEX DRIVE		NASHVILLE	TN	37211
Phone	**Title**		**Number of Employed Hours**	
800-610-2164	PIC		40 hrs weekly	
Description of Duties				
PIC, SPECIALTY PHARMACY				

Business Name			From - To (MM/YY – MM/YY)	
CLA RX BIG COUNTRY DERMATOLOGY PHARMACY			09/21-8/23	
Business Address		**City**	**State**	**Zip**
1229 RESERVE BLVD		SPRING HILL	TN	37174
Phone	**Title**		**Number of Employed Hours**	
931-487-1700	PHARMACIST		40 hrs weekly	
Description of Duties				
FULL TIME PHARMACIST				

Business Name			From - To (MM/YY – MM/YY)	
GENOA PHARMACY			11/19-9/21	
Business Address		**City**	**State**	**Zip**
940 S OCOE ST		CLEVELAND	TN	37311
Phone	**Title**		**Number of Employed Hours**	
423-790-1347	PHARMACIST		40 hrs weekly	
Description of Duties				
RETAIL PHARMACIST				

Business Name			From - To (MM/YY – MM/YY)	
LIFE POINT PHARMACY			10/14-10/18	
Business Address		**City**	**State**	**Zip**
3163 S CHURCH ST		MURFREESBORO	TN	37127
Phone	**Title**		**Number of Employed Hours**	
615-225-8870	PIC		40 hrs weekly	
Description of Duties				
RETAIL PHARMACIST				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, DOUGLAS RAWL, **certify that as the designated representative for**

RARX II, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. DR I am at least 21 years of age;
3. DR I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DR I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DR I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DR I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DR I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

DOUGLAS RAWL
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/19/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Douglas Kirkland Rawl

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/14/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Davidson

I, Douglas Rawl, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/14/2024

Date

Subscribed and Sworn to before me this 14th day of October 2024

Notary Public Signature

LINDA MENDOZA
STATE OF TENNESSEE
NOTARY PUBLIC
My Commission Expires on 09/05/2028
DAVIDSON COUNTY

(Seal)

Designated Representative (Applicant's Initials DR) 7 of 7

4BBB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH_____		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Roman Health Pharmacy LLC

Physical Address: 1560-1564 Barclay Blvd.

City: Buffalo Grove State: IL Zip: 60089

Mailing Address (if different from physical address): 3602 Quantum Blvd.

City: Boynton Beach State: FL Zip: 33426

Telephone: 888-798-8686 Toll Free # (NAC 639.708, NRS 639.23286): 888-798-8686

Fax: 866-312-4306 Contact Email: rxlicensing@ro.com

Website: www.romanhealthpharmacy.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Adam Niemeyer

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24189

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Adam Niemeyer	NV Pharmacist Registration #: 24189
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials: N/A	%: N/A
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Roman Health Ventures Inc

Corporation/Organization Name: Roman Health Pharmacy LLC

Mailing Address: 625 Avenue if the Americas, 4th Floor

City: New York State: NY Zip: 10011

Telephone: 888-798-8686 Email: RxLicensing@ro.co

Contact Person Name: Kimberly Sorrentino

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ■ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacist-In-Charge (title) for Roman Health Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Adam Niemeyer

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

7.25.2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Adam Niemeyer hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist-In-Charge (title) for Roman Health Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 26 day of July, 2024

Notary Public

"OFFICIAL SEAL"
MARLA SHAPIRO-GILLEN
Notary Public State of Illinois
My Commission Expires March 8, 2025

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Zachariah Reitano

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

7/25/2024

Date

Board Use Only	Date Received: 9/12/24	Amount: $500-4

Corporate Ownership Organizational Chart and Details

Parent Company:
Roman Health Ventures Inc.
FEIN 82-1285516
State of Incorporation: DE
Business Address:
625 Avenue of the Americas, 4th Floor,
New York, NY 10011
(888) 798-8686



Wholly Owned Subsidiary:
Roman Health Pharmacy LLC
FEIN 82-1743496
State of Incorporation: DE
Business Address:
625 Avenue of the Americas, 4th Floor,
New York, NY 10011
(888) 798-8686

Ownership: Roman Health Ventures Inc. owns 100% of Roman Health Pharmacy LLC.

File Number 0644844-5

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

I, **Alexi Giannoulias,** *Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that*

ROMAN HEALTH PHARMACY LLC, A NEW YORK LIMITED LIABILITY COMPANY HAVING OBTAINED ADMISSION TO TRANSACT BUSINESS IN ILLINOIS ON NOVEMBER 27, 2017, APPEARS TO HAVE COMPLIED WITH ALL PROVISIONS OF THE LIMITED LIABILITY COMPANY ACT OF THIS STATE, AND AS OF THIS DATE IS IN GOOD STANDING AS A FOREIGN LIMITED LIABILITY COMPANY ADMITTED TO TRANSACT BUSINESS IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 11TH *day of* MARCH *A.D.* 2024 .

Authentication #: 2407103118 verifiable until 03/11/2025
Authenticate at: https://www.ilsos.gov

Alexi Giannoulias
SECRETARY OF STATE

STATE OF ILLINOIS
DEPARTMENT OF FINANCIAL AND
PROFESSIONAL REGULATION
DIVISION OF PROFESSIONAL REGULATION
Drug Compliance Unit
9511 Harrison Street, Suite 300
Des Plaines, IL 60016-1563
PHONE NUMBER: 847-294-4900
FAX NUMBER: 847-294-4904

New Pharmacy Inspection

COMMUNITY PHARMACY

BUSINESS NAME	HOURS		DEA LICENSE	EXPIRES	DATE OF INSPECTION
ROMAN HEALTH PHARMACY LLC	M	9a-5p	N/A	N/A	12/7/21
	T	9a-5p			
	W	9a-5p			
ADDRESS	T	9a-5p	**ICSA LICENSE**	**EXPIRES**	**LICENSE NUMBER**
	F	9a-5p			
1560-1562 Barclay Blvd	SAT	Closed	N/A	3/31/22	**054.022004**
	SUN	Closed			
CITY / **ZIP CODE**	OTHER HOURS EXCEP		**TELEPHONE**		
Buffalo Grove 60089		On-Call on Sat 7am to 1pm	(888) 798-8686		

OWNERSHIP	OWNERS	TELEPHONE AFTER HOURS	E-MAIL ADDRESS
☐ Individual pharmacist ☐ Individual Non-pharmacist ☐ Partnership ☐ Corporation ☒ LLC		798-(888) 8686	adam.niemeyer@ro.co
	PERSON IN CHARGE	**FAX NUMBER**	**COUNTY**
	Adam Niemeyer	(—)—	Cook

NAME OF LICENSEE OR REGISTRANTS	LICENSE/REGISTRATION NO.
R Ph IN CHARGE Adam Niemeyer	051.292527
	051.
	049.
	049.
	049.
	049.
*** = Present during inspection**	

PIC ALSO PHARMACIST-IN-CHARGE AT THE FOLLOWING PHARMACIES:

	NAME	ADDRESS	PHONE NUMBER
1.	N/A		( )
2.			( )

SECTION	COMPLIANCE REQUIREMENT	YES	NO
225 ILCS 85/15 (5)	All required current licenses are posted in a conspicuous location. By patient entrance and within pharmacy space.	☑	☐
225 ILCS 85/22	When a drug, medicine or poison is sold pursuant to a prescription a label must be affixed containing the following:		
	a) Pharmacy name and address	☑	☐
	b) Name, initials, and unique identification of the person authorized to dispense	☑	☐
	c) Date on which such prescription was filled	☑	☐
	d) The name of the patient	☑	☐
	e) Serial number of such prescription	☑	☐
	f) Last name of the prescriber who prescribed the same	☑	☐
	g) Directions for use	☑	☐
	h) Name of patient and name(s) of drug(s) and quantity, unless otherwise directed by practitioner	☑	☐
1330.30(k)	Registrants must wear identification bearing his or her name and designation.	☑	☐
1330.500(b)	Whenever the hours of the pharmacy differ from those of the establishment in which the pharmacy is located, the schedule during which pharmacy services are provided shall be conspicuously displayed.	☑	☐
	Whenever a pharmacy is open and a pharmacist is not present and available to provide pharmacy services, a sign stating that situation shall be conspicuously displayed.	☑	☐
225 ILCS 85/3(e)	A prescription for medication other than controlled substances shall be valid for up to 15 months from the date issued for the purpose of refills, unless the prescription states otherwise. **Computer Software:** Pharmacy App (Internal Software)	☑	☐
225 ILCS 85/15	Security provisions must be provided for all drugs and devices during the absence of a pharmacist. **Alarm System: ADT (See ~~Ex.~~ N. Inspection Narrative)**	☑	☐
1330.610	All dispensing and drug storage areas of the pharmacy must be contiguous.	☑	☐
	The pharmacy area and all storerooms shall be well-lighted and properly ventilated.	☑	☐
	Refrigerators shall be for the exclusive use of prescription drugs. **1 Fridge for Drugs with Temperature Gauge**	☑	☐

SECTION	COMPLIANCE REQUIREMENT	YES	NO
1330.610	The pharmacy area shall not be used for storage of merchandise that interferes with the practice of pharmacy.	☑	☐
	Current reference books and copy of laws and rules in hard copy or readily available electronic data format. **Online: Lexi-Comp, Pharmacy Acts/Rules**	☑	☐
410 ILCS 620/14(b)	Expired medications are stored separately from active medication stock. Discussed	☑	☐
1330.630	Pharmacy must be clean and sanitary.	☑	☐
	Pharmacy must have a sink with hot and cold water. (Please see narrative)	☑	☐
	Food and/or beverages shall be placed in designated area away from dispensing activities. There is a separate breakroom. Place a sign for food/beverage only if designated area is made within pharmacy. Discussed	☑	☐
1330.700	An offer to counsel shall be made on all REFILL prescriptions. Verbal counseling by a registered pharmacist or a student pharmacist under the direct supervision of a registered pharmacist is **REQUIRED for all NEW prescriptions.** Discussed	☑	☐
	Counseling sign printed in COLOR or displayed electronically in COLOR, measuring at least 8½ x 11 inches, & posted so the sign is clearly visible to patients.	☑	☐
1330.730(b)	Any prepackaged drugs must have a label affixed that contains the name and strength of the drug, the name of the manufacturer or distributor, beyond use date and lot number on each container. **(Remove Patient's Name off the label on Return to Stock Vials prior to placing back in active stock.)** Discussed	☑	☐
1330.50(c)	Vaccination/immunization records are properly maintained for a minimum of 5 years. N/A	☐	☐
1330.800	Every licensed pharmacy shall conduct an annual self-inspection using forms provided by the Division. Discussed	☑	☐
	Last community self-inspection date: / Last non-sterile self-inspection date:		
225 ILCS 85/15.1	A pharmacist who works 6 continuous hours or longer per day shall be allowed to take at least one 30-minute uninterrupted meal break & one 15-minute break during that 6-hour period. Discussed	☑	☐
	A pharmacy shall maintain a complete & accurate record showing its pharmacists' daily break periods.	☑	☐

NARRATIVE

This is a New Community Pharmacy Inspection by DCI Aarti Parikh on 12/7/21. Present for Inspection is PIC Adam Niemeyer. Pharmacy is located within a business park unit. (Suites 1560 & 1562) Pharmacy will not stock or dispense controlled substances nor pseudoephedrine products. This pharmacy will not compound sterile or nonsterile preparations. The pharmacy will be dispensing ED drugs, finasteride, naltrex, etc (about 25-30 different drugs.)

- Opening Date: 12/23/21
- Non-resident licensing: will be seeking Non-resident licensing
- Vendors: Greenstone, Auburn
- Reverse Distributor: Stericycle
- Pharmacy delivers prescriptions thru UPS.
- Immunizations: Not at this time.
- Per Section 1330.400(d): Any reduction in hours of operation shall be reported to the Division within 30 days.

Compounding Equipment:

- For Non-Sterile Compounding, must meet USP standards including, but not limited to USP 795. R/I discussed with PIC the importance of meeting USP standards in recordkeeping, personnel training, and preparation of Non-Sterile Compounds.
- Per PIC, pharmacy will not compound any non-sterile preparations.

- Equipment: SEMMI Labs - analytical balance. Graduated cylinders, mortar/pestle, spatulas, ointment slab, pipettes
- Sink: Stainless sink located within Suite 1562 is approved as the pharmacy sink Not the portable sink.
- Only licensed pharmacy staff (pharmacists/pharmacy technicians) are permitted within Suites 1560 and 1562 (licensed pharmacy space).
- Licensed released on 12-21-21 once DCI Parikh received all documents/photos requested regarding door sealed between Suites 1562 and 1564 and pharmacy sink.

Sample Label:

John Smith

1663 N Buffalo Grove Rd, Buffalo Grove IL 60089

Dr. Alex Goldmember
Quantity: 90 Refills: 3
ORANGE ROUND SHAPE F1
Filled by: Adam Niemeyer, RPh
Filled on: 08/24/2021
Refill before: 08/23/2022
Discard 1 year after dispensed

Finasteride 1mg Tablets
Generic For: Propecia
MFG: Ascend

Take one tablet by mouth daily

Roman Health Pharmacy LLC
1560-1562 Barclay Blvd
Buffalo Grove, IL 60089
(888) 758-8686
www.getroman.com

Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed

PRE-0000000264228

INVESTIGATOR'S SIGNATURE AND DATE		LICENSEE OR REPRESENTATIVE'S SIGNATURE AND DATE		ILDFPR SUPERVISOR REVIEW AND DATE	
		X	X		

NARRATIVE

Security:

- Alarm System: ADT
  - Keypad located
  - Individual Alarm code with PIC Adam Niemeyer, James Clampett (Sr. Tech Security), and Tommy Krug (Facilities Dir.)
  - If there is unauthorized access, PIC Adam Niemeyer, James Clampett (Sr. Tech Security), and Tommy Krug (Facilities Dir.) are contacted.
- Keys/Badge access for pharmacy are with only licensed pharmacy staff (pharmacists/pharmacy technicians)
- Security Cameras: 15
- Motion Detectors: 7
- Glass Break Sensor: 0
- Pharmacy will NOT have a controlled substance license.
- Entry points into Pharmacy:

(Please see attached layout)

-Suite 1560 & 1562 = Licensed pharmacy.

-PIC Niemeyer does not anticipate walk-in patients as all prescriptions will be delivered to patients.

-However, 2 entrances have been created if for any reason a patient were to come to the pharmacy.

→ Employee Entrance (Suite 1560) - Door signage indicates employee entrance and refers patients to Suite 1562 (patient entrance). This is a commercial glass window door with badge access, dead-bolt lock, & alarm sensor.

→ Patient Entrance (Suite 1562) - Door signage indicates patient entrance. This is a commercial glass window door with badge access & alarm sensor & locked from inside. Unable to use key to enter from this door. This has a camera/intercom that patients can use to communicate to pharmacy staff. Upon entry, one is within a locked vestibule and unable to access pharmacy.

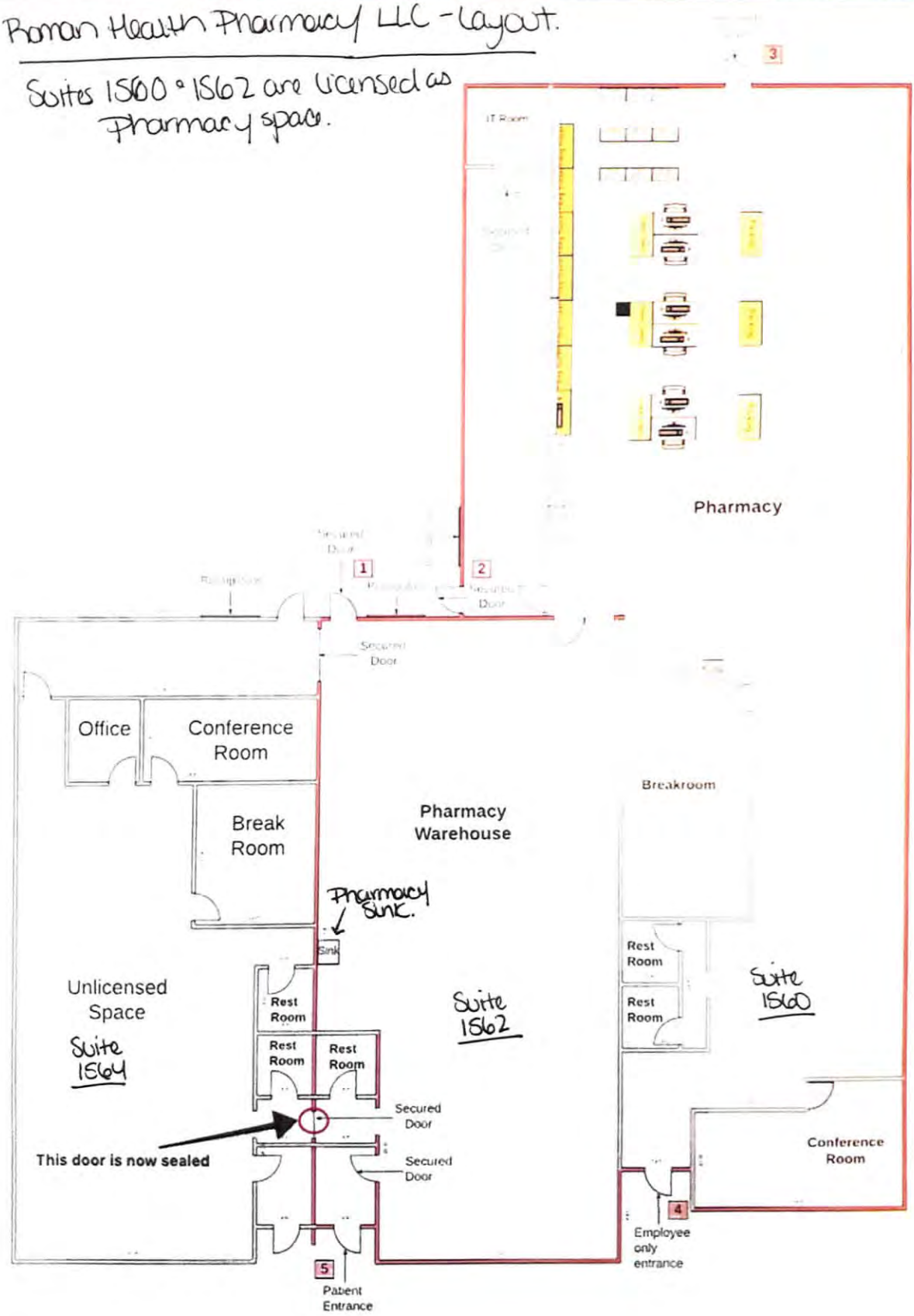
-All doors (exterior & interior) have alarm sensors entering into Suites 1560 & 1562 and require badge or key access.

-Door between Suite 1562 & 1564 has been caulked & sealed using steel & drywall. Please see photos emailed to DCI Parish on 12-21-21. Suite 1564 is currently under their ownership, but is unlicensed space and not to be used for practice of pharmacy.

INVESTIGATOR'S SIGNATURE AND DATE		LICENSEE OR REPRESENTATIVE'S SIGNATURE AND DATE		ILDFPR SUPERVISOR REVIEW AND DATE	
		X	X		

Roman Health Pharmacy LLC - Layout.

Suites 1560 & 1562 are licensed as Pharmacy space.





State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

LICENSE NO
054 022004
051 292527

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below:

EXPIRES
03/31/2026

LICENSED PHARMACY

COMMUNITY

ROMAN HEALTH PHARMACY LLC
ADAM NIEMEYER
1560-1564 BARCLAY BLVD
BUFFALO GROVE, IL 60089

MARIO TRETO JR
SECRETARY

CAMILE LINDSAY
ACTING DIRECTOR

The official status of this license can be verified at IDFPR.Illinois.gov

19609780

ro

Kimberly Sorrentino <kimberly.sorrentino@ro.co>

IDFPR Official Certification of Licensure

2 messages

'IL Department of Financial/Professional Regulation' via Pharmacy Licensing <rxlicensing@ro.co> Mon, Jul 29, 2024 at 10:15 AM
Reply-To: IL Department of Financial/Professional Regulation <donotreply@illinois.gov>
To: ROMAN HEALTH PHARMACY <rxlicensing@ro.co>

To whom it may concern,

Attached to this email is the Illinois Department of Financial and Professional Regulation's Official ***Certification of Licensure*** for:

Board: Illinois Pharmacy Board

Profession: LICENSED PHARMACY

Licensee Name: ROMAN HEALTH PHARMACY

License Number: 054.022004

As of: 07/29/2024

Thank you and please contact the Department if any questions may arise.

Illinois Department of Financial and Professional Regulation

Phone: 1 (800) 560-6420

https://idfpr.illinois.gov/

License Certificate Print - 054.022004.pdf
784K

'IL Department of Financial/Professional Regulation' via Pharmacy Licensing <rxlicensing@ro.co> Mon, Jul 29, 2024 at 10:30 AM
Reply-To: IL Department of Financial/Professional Regulation <donotreply@illinois.gov>
To: ROMAN HEALTH PHARMACY <rxlicensing@ro.co>, Board <ST-PHARMACY@pa.gov>

To whom it may concern,

Attached to this email is the Illinois Department of Financial and Professional Regulation's Official ***Certification of Licensure*** for:

Board: Illinois Pharmacy Board

Profession: LICENSED PHARMACY

Licensee Name: ROMAN HEALTH PHARMACY

License Number: 054.022004

As of: 07/29/2024

Thank you and please contact the Department if any questions may arise.

Illinois Department of Financial and Professional Regulation

Phone: 1 (800) 560-6420

https://idfpr.illinois.gov/

License Certificate Print - 054.022004.pdf
784K

Officer List (Roman Health Ventures Inc.)

- **Zachariah Reitano - Co-Founder, Chief Executive Officer**
- **Saman Rahmanian - Co-Founder, Secretary & Treasurer**

Officer List (Roman Health Pharmacy LLC)

- **Zachariah Reitano - President, Manager**
- **Saman Rahmanian- Secretary & Treasurer, Manager**

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Roman Health Pharmacy LLC

Pharmacy/Wholesaler License # (if applicable) Pending

Physical Address 1560-1562 Barclay Blvd.

City Buffalo Grove State IL Zip 60089

Mailing Address (if different from physical address) 3602 Quantum Blvd.

City Boynton Beach State FL Zip 33426

Telephone 888-798-8686 Website www.romanhealthpharmacy.com

Licensing Company Email RXLicensing@ro.com

Section 2: Personal Information

First Adam Middle Charles Last Niemeyer

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted] S Charlotte St

City Lombard State IL Zip 60148

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)
Midwestern University - Chicago College of Pharmacy	8/4 - 2/08

Address	City	State	Zip
555 31st St	Downers Grove	IL	60515

Diploma/Degree obtained, if any: PharmD

School Name	From - To (MM/YY – MM/YY)
University of Wisconsin - Madison	8/01 - 5/04

Address	City	State	Zip
	Madison	WI	53706

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY)
Deerfield High School	8/97 - 5/01

Address	City	State	Zip
300 Simonson BLVD	Deerfield	WI	53531

Diploma/Degree obtained, if any: High School Diploma

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY

Address	City	State	Zip

Diploma/Degree obtained, if any:

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
8/20 - current	[redacted] S Charlotte St	Lombard	IL	60148
10/19 - 8/20	[redacted] E Maple St #B	Lombard	IL	60148
4/10 - 10/19	[redacted] Martha St	Lombard	IL	60148
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Roman Health Pharmacy			6/21 - Current
Business Address	**City**	**State**	**Zip**
1560-1562 Barclay BLVD	Buffalo Grove	IL	60089
Phone	**Title**		**Number of Employed Hours**
888-798-8686	Pharmacist-in-Charge		>6,240 hours
Description of Duties	Manage the day to day operations of the pharmacy, including supervising staff, prescription processing and ensuring compliance with state and federal regulations.		

Business Name			From - To (MM/YY – MM/YY)
Meijer Pharmacy			7/12 - 6/21
Business Address	**City**	**State**	**Zip**
755 E Boughton Rd	Bolingbrook	IL	60440
Phone	**Title**		**Number of Employed Hours**
630-783-5310	Pharmacist-in-Charge		>18,720 hours
Description of Duties	Managed the day to day operations of the pharmacy, including supervising staff, prescription processing and ensuring compliance with state and federal regulations		

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Adam Niemeyer, **certify that as the designated representative for**

_____,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AN I am at least 21 years of age;
3. AN I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AN I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AN I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AN I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AN I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Adam Niemeyer
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7-25-2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Adam Niemeyer

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7-26-2024

Date

Please have this section completed in the presence of a Notary Public.

State of Illinois, ss. County of Lake

I, Adam Niemeyer, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7-26-2024

Date

Subscribed and Sworn to before me this 26 day of July, 2024

Notary Public Signature

"OFFICIAL SEAL"
MARLA SHAPIRO-GILLEN
Notary Public State of Illinois
My Commission Expires March 8, 2025
(Seal)

4CCC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: pending
	☒ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.)	■ Other: Veterinary	■ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 04067		☐ Hospital
			■ Other: Veterinary

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	■ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Strive Pharmacy Missouri, LLC

Physical Address: 2058 Fenton Logistics Park

City: Fenton State: MO Zip: 63026

Mailing Address (if different from physical address): 325 N. Ash St., Ste 203

City: Gilbert State: AZ Zip: 85233

Telephone: 877-273-1777 Toll Free # (NAC 639.708, NRS 639.23286): 877-273-1777

Fax: 724-213-1907 Contact Email: licensingMO@strivepharmacy.com

Website: strivepharmacy.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Sara Rumpel

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21523

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Michael Spinner	NV Pharmacist Registration #: 21507
Name: Ralph Bonofiglio II	NV Pharmacist Registration #: 21511
Name: Allison Davis	NV Pharmacist Registration #: 21454
Name: Kathy Hahn	NV Pharmacist Registration #: 21686
Name: LeeAnn Hart	NV Pharmacist Registration #: 21482
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: Strive Pharmacy Missouri, LLC

Mailing Address: 325 N. Ash St., Ste 203

City: Gilbert State: AZ Zip: 85233

Telephone: 480-626-4366 Email: licensing@strivepharmacy.com

Contact Person Name: Michael Walker

Please check type of partnership (NAC 639.214) ☐ General ☒ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☒ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

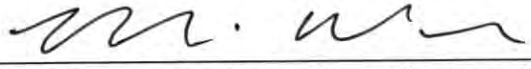
Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Member (title) for Strive Pharmacy Missouri, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Michael Walker

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

8/19/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Sara Rumpel hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist-in-charge (title) for Strive Pharmacy Missouri, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 15th day of August, 2024

Notary Public

CHARISE M GEORGE
Comm. Exp. 08/21/2026
NOTARY PUBLIC NOTARY SEAL #91446172
Jefferson County
STATE OF MISSOURI

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Walker

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

8/19/24

Date

Board Use Only	Date Received: 9/18/24	Amount: $550-cc

STATE OF WYOMING
Office of the Secretary of State

I, CHUCK GRAY, Secretary of State of the State of Wyoming, do hereby certify that according to the records of this office,

Strive Pharmacy Missouri LLC

is a

Limited Liability Company

formed or qualified under the laws of Wyoming did on **June 27, 2024**, comply with all applicable requirements of this office. Its period of duration is Perpetual. This entity has been assigned entity identification number **2024-001481606.**

This entity is in existence and in good standing in this office and has filed all annual reports and paid all annual license taxes to date, or is not yet required to file such annual reports; and has not filed Articles of Dissolution.

I have affixed hereto the Great Seal of the State of Wyoming and duly generated, executed, authenticated, issued, delivered and communicated this official certificate at Cheyenne, Wyoming on this 30th day of July, 2024 at 12:24 PM. This certificate is assigned ID Number 074819632.

Chuck Gray

Secretary of State

Notice: A certificate issued electronically from the Wyoming Secretary of State's web site is immediately valid and effective. The validity of a certificate may be established by viewing the Certificate Confirmation screen of the Secretary of State's website https://wyobiz.wyo.gov and following the instructions displayed under Validate Certificate.

The Division of Professional Registration and its boards are open during the regular business hours of 8:00a.m. to 5:00p.m. Monday through Friday, excluding state holidays (https://oa.mo.gov/commissioner/state-holidays).

Did you know that there is a drop box located in the front of the Professional Registration building? Individuals may leave items for the division and its boards any time. We do ask that all items be placed in a sealed envelope labeled with the board name or name of the individual if not located in a board.

Board of Pharmacy

Pharmacy Detail

Pharmacy Primary Source Verification

The licensee search function of this website provides data extracted from our database and constitutes a Primary Source Verification.

Licensee Name:	Skin Specialty Solutions, Inc.
Profession Name:	Pharmacy
Licensee Number:	2019007736
Expiration Date:	10/31/2025
Original Issue Date:	3/6/2019
Address:	Sara Rumpel, PIC
Address Con't:	2058 Fenton Logistics Park
City, State Zip:	Fenton, MO 63026
County:	St. Louis County
Practitioner DBA Name:	Skin Specialty Solutions, Inc.
Classification:	Class D

Current Discipline Status:	None

Board of Pharmacy (https://pr.mo.gov/pharmacists)
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625
573.751.0091 Telephone
573.526.3464 Fax
800.735.2966 TTY
800.735.2466 Voice Relay

2058 FENTON LOGISTICS PARK
FENTON, MO 63026

Officers:

STRIVE PHARMACY MISSOURI, LLC
325 North Ash, Suite 203
Gilbert, Arizona 85233

NAME & TITLE
Nathan Hill, Member
Michael Walker, Member

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Strive Pharmacy Missouri LLC

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 2058 Fenton Logistics Park

City: Fenton State: MO Zip: 63010

Mailing Address (if different from physical address): 325 North Ash Street, Suite 203

City: Gilbert State: AZ Zip: 85233

Telephone: (877)273-1777 Website: strivepharmacy.com

Licensing Company Email: licensingMO@strivepharmacy.com

Section 2: Personal Information

First: Sara Middle: Kamalay Last: Rumpel

Alias(es, nicknames, name changes, etc.): Sara Kamalay

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Address: 2058 Fenton Logistics Park

City: Fenton State: MO Zip: 63010

Telephone: (877)273-1777 Email: licensingMO@strivepharmacy.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Ohio State University		09/2007 - 06/2011	
Address: 281 West Lane Avenue	City: Columbus	State: OH	Zip: 43210
Diploma/Degree obtained, if any: Doctor of Pharmacy, Cum Laude			

School Name		From - To (MM/YY – MM/YY)	
Ohio State University		01/2003 - 06/2005	
Address: 281 West Lane Avenue	City: Columbus	State: OH	Zip: 43210
Diploma/Degree obtained, if any: Bachelor of Science in Microbiology, with honors in the Arts and Sciences			

School Name		From - To (MM/YY – MM/YY)	
Hilliard Davidson High School		09/1997 - 06-2001	
Address: 5100 Davidson Road	City: Hilliard	State: OH	Zip: 43026
Diploma/Degree obtained, if any: High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2017 - Present	[redacted]Carriage Trace Drive	St. Louis	MO	63128
2014 - 2017	[redacted] Arsenal	St. Louis	MO	63139
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Skin Specialty Solutions, Inc.			From - To (MM/YY – MM/YY): 05/2020 - 09/30/2024
Business Address: 2058 Fenton Logistics Park	City: Fenton	State: MO	Zip: 63010
Phone: (877)273-1777	Title: PIC		Number of Employed Hours: 10,916 hours
Description of Duties: Began as Staff Pharmacists and promoted to PIC in May 2023. Resume attached.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Sara Kamalay Rumpel, **certify that as the designated representative for**

Strive Pharmacy Missouri LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SR I am at least 21 years of age;
3. SR I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SR I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SR I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SR I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SR I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Sara Rumpel

Print Name (First, Last)

Sara R

Original Signature (electronic, copies or stamps not accepted)

9/10/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sara Rumpel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/10/24

Date

Please have this section completed in the presence of a Notary Public.

State of Missouri, ss. County of Jefferson

I, Sara Rumpel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/10/24

Date

Subscribed and Sworn to before me this 10th day of September 2024.

Notary Public Signature

NOTARY PUBLIC SEAL #91446172 Jefferson County STATE OF MISSOURI Comm. Exp. 08/21/2026 CHARISSE M. GEORGE

(Seal)

Sara K. Rumpel, PharmD

[redacted]

Experienced pharmacy leader with background in a variety of practice settings. Skilled at building high performing, highly accountable teams and developing talent. Strong organizational skills and attention to detail. Thrives in fast paced, high pressure environments.

Work Experience

MAY 2023 - PRESENT

Skin Specialty Solutions, Fenton, Missouri - *Director of Fulfillment, Pharmacist-in-Charge*

- Responsible for creating operational workflow processes for new product and brand launches; partners with cross-functional partners at Curology in medical, engineering, and customer support teams to optimize experiences for patients and team members
- Manages inventory team; works closely and collaboratively with supply chain team and contracted logistics partner facility to develop inventory forecasting needs
- Ensures facility and staff remain up to date with all legal and regulatory requirements
- Works with Quality Assurance team to create and update relevant SOPs and compliance training documentation; ensures preparedness in meeting standards for ACHC accreditation and VPP inspection recertifications
- Works with Licensing Coordinator to ensure all licensure requirements are up to date
- Partners with Director of Compounding to create staff schedules and operational plans
- Creates and establishes follow up measures for Employee Engagement Survey action planning; accomplishing ~20% increase in engagement score since taking over as PIC
- Collaborates with strategic finance partners to create budgets and determine accurate standards for CPU benchmarks
- Proficient in use of Tableau, G Suite, Slack, Linear, Netsuite, Workday, Softeon WMS

MAY 2020 - MAY 2023

Skin Specialty Solutions, Fenton, Missouri - *Fulfillment Pharmacist Manager*

- Planned and oversaw daily Fulfillment workflow and production to meet specifications and schedules of the organization
- Worked cross-functionally to develop and implement a customized Softeon Warehouse Management System to optimize inventory accuracy
- Partnered with People and Culture team to lead orientation groups and established processes to improve onboarding for fulfillment new hires

MAY 2019 - MAY 2020

Skin Specialty Solutions, Fenton, Missouri - *Compounding Staff Pharmacist*

- Performed non-sterile compounding of selected formulations based on business needs
- Collaborated with associates to reformat Master Formulation Records to comply with laws and standards based on ACHC accreditation recommendations
- Created and implemented training program for technicians to ensure compliance

DECEMBER 2015 - MAY 2019

CVS Health-Target Channel, Arnold, Missouri - *Pharmacy Manager*

- Managed daily operations of a growing community pharmacy as Pharmacist-In-Charge
- Provided patient counseling, outreach, and education to ensure proper medication use and compliance to improve health outcomes
- Oversaw all human resources and financials activity at store level, including technician scheduling and payroll records maintenance
- Advised and evaluated PharmD students as Pharmacy Practice Experience preceptor
- Mentored staff pharmacist for promotion through emerging leaders program

OCTOBER 2012 - DECEMBER 2015

Target Pharmacy, Arnold, Missouri - *Pharmacy Manager*

- Managed daily retail operations of one of the highest prescription volume stores in region
- Conducted complete medication reviews for Medicare patients identified as candidates for medication therapy management via Outcomes
- Collaborated with Group Compliance Manager to plan and perform outreach to local prescribers of specialty medications

JUNE 2011 - OCTOBER 2012

Target Pharmacy, Saint Louis, Missouri - *Float Pharmacist*

SEPTEMBER 2007 - SEPTEMBER 2010

CVS/Pharmacy, Columbus, Ohio - *Pharmacy Intern*

MAY 2006 - AUGUST 2007

Ohio State University Wexner Medical Center, Columbus, Ohio - *Pharmacy Technician*

JUNE 2005 - MAY 2006

Nestle Quality Assurance Center, Dublin, Ohio - *Microbiologist*

Education

SEPTEMBER 2007 - JUNE 2011

The Ohio State University, Columbus, Ohio - *Doctor of Pharmacy, Cum Laude*

JANUARY 2003 - JUNE 2005

The Ohio State University, Columbus, Ohio - *Bachelor of Science in Microbiology, with honors in the Arts and Sciences*

Licenses and Certifications

Active Pharmacist Licenses in good standing in following states:

Alabama, Alaska, Arkansas, Illinois, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, MIchigan, Mississippi, Missouri, Nebraska, Nevada, Ohio, Oklahoma, Oregon, Pennsylvania, Tennessee, Texas, Virginia, West Virginia

Delivering Medication Therapy Management Services in the Community
American Pharmacists Association, Issued June 2011

Pharmacy-Based Immunization Delivery
American Pharmacists Association, Issued September 2009

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Strive Pharmacy Missouri, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): pending

Physical Address: 2058 Fenton Logistics Park

City: Fenton State: MO Zip: 63026

Mailing Address (if different from physical address): 325 N. Ash St., STE 203

City: Gilbert State: AZ Zip: 85233

Telephone: 877-273-1777 Website: strivepharmacy.com

Licensing Company Email: licensingMO@strivepharmacy.com

Section 2: Personal Information

First: Michael Middle: Last: Walker

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]N. Ash St., Ste 203

City: Gilbert State: AZ Zip: 85233

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Midwestern University- Glendale		06/12-06/15	
Address	**City**	**State**	**Zip**
19555 N. 59th Ave.	Glendale	AZ	85308
Diploma/Degree obtained, if any			
Doctor of Pharmacy			
School Name		From - To (MM/YY – MM/YY)	
University of Utah		01/08-05/12	
Address	City	State	Zip
201 Presidents Circle	Salt Lake City	UT	84112
Diploma/Degree obtained, if any			
Exercise Physiology			
School Name		From - To (MM/YY – MM/YY)	
Viewmont High School		08/02-05/05	
Address	City	State	Zip
120 W 1000 North	Bountiful	UT	84010
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/21-present	[redacted]E. Campbell Ct.	Gilbert	AZ	85234
From - To (MM/YY – MM/YY)		City	State	Zip
11/17-10/21	[redacted]E. Vaughn Ave.	Gilbert	AZ	85234
From - To (MM/YY – MM/YY)		City	State	Zip
07/15-10/17	[redacted]S. Martingale Rd.	Gilbert	AZ	85295
From - To (MM/YY – MM/YY)		City	State	Zip
06/12-06/15	[redacted]W. Behrend Dr. Apt. 1135	Glendale	AZ	85308
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Strive Pharmacy			07/18-present	
Business Address		**City**	**State**	**Zip**
1275 E. Baseline Rd., Ste 104		Gilbert	AZ	85233
Phone	**Title**			
480-626-4366	Owner/Pharmacist/President			
Description of Duties				
Pharmacist duties of running a pharmacy				

Business Name			From - To (MM/YY – MM/YY)	
Sarovja Gilbert Pharmacy			10/15-03/18	
Business Address		**City**	**State**	**Zip**
3570 S. Val Vista Dr. #108		Gilbert	AZ	85297
Phone	**Title**			
480-887-0244	Pharmacist			
Description of Duties				
Pharmacy Manager				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Walker

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/13/2024

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

09/13/2024

Date

Subscribed and Sworn to before me this 13th day of Sept. 2024.

Notary Public Signature

CHARISE M GEORGE
Comm. Exp. 08/21/2026
NOTARY PUBLIC NOTARY SEAL #91446172
Jefferson County
STATE OF MISSOURI

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Strive Pharmacy Missouri, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): pending

Physical Address: 2058 Fenton Logistics Park

City: Fenton State: MO Zip: 63026

Mailing Address (if different from physical address): 325 N. Ash St., STE 203

City: Gilbert State: AZ Zip: 85233

Telephone: 877-273-1777 Website: strivepharmacy.com

Licensing Company Email: licensingMO@strivepharmacy.com

Section 2: Personal Information

First: Nathan Middle: Last: Hill

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]N. Ash St., Ste 203

City: Gilbert State: AZ Zip: 85233

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Utah		08/11-05/13	
Address	**City**	**State**	**Zip**
201 Presidents Circle	Salt Lake City	UT	84112
Diploma/Degree obtained, if any			
Bachelor of Science Business Administration			
School Name		**From - To (MM/YY – MM/YY)**	
Ensign College		01/08-05/11	
Address	**City**	**State**	**Zip**
95 N. 300 West	Salt Lake City	UT	84101
Diploma/Degree obtained, if any			
Associates Degree			
School Name		**From - To (MM/YY – MM/YY)**	
Viewmont High School		08/07-05/05	
Address	**City**	**State**	**Zip**
120 W. 1000 North	Bountiful	UT	84010
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/23-present	[redacted]E. Mesquite St.	Gilbert	AZ	85296
10/17-06/23	[redacted]S. Annie Lane	Gilbert	AZ	85296
10/16-10/17	[redacted]S. Colt Drive	Gilbert	AZ	85296
04/15-10/16	[redacted]W. Willow Green Way	Farmington	UT	8Centeri4025
08/14-04/15	[redacted]N. 200 West	Centerville	UT	84014
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Strive Specialties Inc./Strive Pharmacy			07/18-present	
Business Address		**City**	**State**	**Zip**
1275 E. Baseline Rd., Ste 104		Gilbert	AZ	85233
Phone	**Title**			
480-626-4366	CEO			
Description of Duties				
Founder & CEO, All things related to company				

Business Name			From - To (MM/YY – MM/YY)	
Daiichi Sankyo Inc.			09/16-05/18	
Business Address		**City**	**State**	**Zip**
211 Mt. Airy Road		Basking Ridge	NJ	07920
Phone	**Title**			
973-944-2600	Specialty Sales Rep			
Description of Duties				
Pharmaceutical Sales				

Business Name			From - To (MM/YY – MM/YY)	
Scoreboard Sports			11/15-05/16	
Business Address		**City**	**State**	**Zip**
509 W. 2600 South		Bountiful	UT	84010
Phone	**Title**			
N/A	Sales Representative			
Description of Duties				
Sold corporate and team gear to Schools, Corporations, Teams, etc.				

Business Name			From - To (MM/YY – MM/YY)	
Vivint			05/10-11/15	
Business Address		**City**	**State**	**Zip**
4931 N. 300 West		Provo	UT	84604
Phone	**Title**			
801-377-9111	Sales Representative			
Description of Duties				
Door to door sales. Sold home security and home automation.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nathan Hill

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/13/2024

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/13/2024

Date

Subscribed and Sworn to before me this 13th day of Sept 2024

Notary Public Signature

CHARISE M GEORGE
Comm. Exp. 08/21/2026
NOTARY PUBLIC NOTARY SEAL #91446172
Jefferson County
STATE OF MISSOURI

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.
Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
81.00	Areas, other than the work surface of the C PEC, where contamination can build up (such as areas under the work tray), are deactivated, decontaminated, and cleaned at least monthly.	Yes	
82.00	Additional PPE (eg, respirator) is used in accordance with SOPs, to protect the worker if containment airflows are compromised by opening the cabinets to get to these areas.	Yes	
	Spill Control		
83.00	Spills are contained and cleaned immediately.	Yes	
84.00	Trained/qualified personnel are always available during operation with HDs to handle spills.	Yes	
85.00	Only trained/qualified personnel engage in spill containment and cleanup.	Yes	
86.00	There are signs available to restrict access to spill areas.	Yes	
87.00	Spill kits, containing all ingredients necessary to clean HD spills, are readily available in all areas where HDs are routinely handled.	Yes	
88.00	Spill materials are disposed of as hazardous waste.	Yes	
89.00	The circumstances and management of all spills are documented. ***Review documentation for spills for the last year and list the most recent date.***	Yes	There have been no spills within the last year.

2548

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
	Deactivating and Decontaminating (Cleaning and Disinfecting are performed in accordance with Chapters <795> and <797>)		
77.00	The pharmacy has chosen appropriate oxidizing agent(s) for deactivation and decontamination and proven effective by testing.	Yes	Peridox RTU is used.
78.00	Wipes or other appropriate delivery mechanisms (eg, not a spray bottle) are used for deactivation and decontamination.	Yes	
79.00	The C-PEC must be decontaminated. *All of the following must be done to be compliant:*	Yes	
79.01	Between compounding of different HDs	Yes	
79.02	At least daily when used	Yes	
79.03	Any time a spill occurs	Yes	
79.04	Before and after certification	Yes	
79.05	Any time voluntary interruption occurs	Yes	
79.06	If the ventilation tool is moved	Yes	
80.00	HD containers are wiped down prior to placing them in the C PEC and the solution used does not alter the product label.	Yes	

2549

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.
Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
	Dispensing, Packaging, and Compounding Processes		
74.00	Counting of antineoplastics is done by hand (eg, not placed into automated counting devices).	N/A	There is no counting performed.
75.00	Clean, dedicated (not used for non HD purposes), or disposable equipment is used for counting, packaging, and compounding of HDs.	Yes	
75.01	**Recommendation**: Equipment is decontaminated after every use.	Yes	
75.02	**Recommendation**: When compounding, a plastic backed preparation mat is placed on the C PEC work surface and changed and discarded appropriately as HD waste. All of the following should apply in order to make this a Yes.	No	
75.02.01	Immediately if a spill occurs	No	
75.02.02	Regularly during use	No	
75.02.03	At the end of a shift	No	
76.00	APIs or other powdered HDs are handled in a C PEC during particle generating activities, such as crushing, opening capsules, and weighing powders.	Yes	

2550

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
	Labeling, Packaging, Transport, and Disposal		
69.00	HDs requiring special HD handling are always clearly labeled as hazardous during transport and in accordance with any laws related to labeling of HDs.	Yes	
70.00	Labeling processes do not introduce contamination into non HD handling areas.	Yes	
71.00	Packaging materials are chosen that protect the HD and healthcare worker against damage, leakage, contamination, and degradation during transport, but also maintains the physical integrity, stability, and sterility of the HD.	Yes	
72.00	Pneumatic tubes are not used for transporting any liquid HDs or antineoplastic HDs.	Yes	
73.00	Labeling on HDs shipped outside the pharmacy meets all of the following requirements:		
73.01	Labeling specified in SDS for transport;	Yes	
73.02	Storage and disposal instructions; and	Yes	
73.03	Labeled with HD category.	No	Because the dispensed compounds contain only trace amounts of HDs, labels on shipped HDs are not labeled with the HD category.

2551

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
66.00	Containers are visually examined for signs of damage or breakage prior to opening.	Yes	
67.00	If a shipping container appears damaged and does not need to be opened, it is sealed, enclosed in an impervious container, labeled "hazardous" on the outside, and returned to the supplier after contact or disposed of as hazardous waste.	Yes	
67.01	If a damaged shipping container must be opened, it is done so according to SOPs, to include sealing the container in plastic or an impervious container, transporting it to the C PEC for unpacking, removing, and wiping the outside of the undamaged items with disposable wipes, resealing the damaged items in an impervious container and marking it "hazardous," returning it to the supplier after contact or disposing as hazardous waste, and deactivating, decontaminating, and cleaning the C PEC.\	Yes	
68.00	Damaged packages are considered spills and reported to the designated person. ***List last date of damaged package receipt.***	Yes	There have been no damaged packages received.

2552

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
	Environmental Quality and Control - Surface wipe sampling		
62.00	**Recommendation**: **Surface wipe sampling** is performed routinely (initially and at least every six months) to monitor HD containment processes and trends, which includes all of the following:	No	
62.01	Interior of C-PEC and equipment within the C-PEC	No	
62.02	Pass-through chambers	No	
62.03	Surfaces in staging or work areas near the C-PEC	No	
62.04	Areas adjacent to the C-PEC (eg,. floors directly under, staging, and dispensing areas)	No	
62.05	Areas immediately outside the HD buffer room or the C-SCA	N/A	
	Receiving		
63.00	**Recommendation**: HDs are packaged by the supplier in impervious plastic to segregate them from other drugs and decrease possibility of exposure during unpacking and internal transfer.	Yes	All packages of APIs are double bagged when received.
64.00	HDs are delivered to the HD storage area immediately after unpacking.	Yes	
65.00	A spill kit is readily accessible in the receiving area.	Yes	

2553

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
60.09	The handwashing sink is located in the anteroom at least 1 meter or more away from the door to the buffer room to prevent contamination into the negative pressure buffer room.	N/A	
61.00	If the negative pressure HD buffer room is entered through a positive pressure non HD buffer room, there is a line of demarcation within the buffer room for donning and doffing PPE.	N/A	
61.01	There is a design and method to contain and minimize HD contamination when **transporting** HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room:	N/A	
61.02	Indicate how HD contamination is minimized:		
61.02.01	Pass-through chamber between negative pressure buffer room and adjacent space included in the facility's certification not compromising air quality in the buffer room *(verified in the facility's semi-annual certification report that pass through has not compromised air quality in the buffer room).*	N/A	
61.02.02	Use of sealed containers	N/A	
61.02.03	Other, *describe*	N/A	

2554

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
59.02	A handwashing sink is at least one meter or more away from the C-PEC	N/A	
59.02.01	Describe whether the sink is inside the C-SCA or directly outside the C-SCA		
60.00	If BUDs are longer than the Category 1 BUDs specified in <797>, the PEC is located in a C SEC, which is an ISO Class 7 buffer room adjacent to an ISO Class 7 anteroom.	N/A	
60.01	The buffer room has fixed walls.	N/A	
60.02	The buffer room is externally vented.	N/A	
60.03	The buffer room has HEPA filtered supply air.	N/A	
60.04	The buffer room has at least 30 ACPH.	N/A	
60.05	The buffer room has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to the anteroom.	N/A	
60.06	The anteroom has fixed walls.	N/A	
60.07	The ante room has a minimum of 30 ACPH of HEPA filtered supply air.	N/A	
60.08	The ante room maintains positive pressure of at least 0.02 inches water column relative to any adjacent unclassified areas.	N/A	

2555

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
55.01.07	LAFW (not for antineoplastics)	N/A	
55.01.08	CAI (not for antineoplastics)	N/A	
56.00	The C PEC maintains ISO Class 5 or better air quality and is under continuous operation, unless power loss or repair occurs.	N/A	
57.00	Is the C-PEC used for **sterile HD compounding** externally vented?	N/A	
58.00	If a BSC or CACI that is used for **sterile HD compounding** is also used for non HD preparations, is the non HD preparation placed into a protective outer wrapper during removal from the C PEC?	N/A	
58.01	If used for both, is the non HD preparation labeled to require PPE handling precautions?	N/A	
59.00	If the C SEC is an unclassified containment segregated HD compounding area (C SCA: enclosed separate room with fixed walls, but not ISO classified), beyond-use dates (BUDs) are limited in accordance with <797> as Category 1 compounded sterile preparations.	N/A	
59.01	The C SEC (C-SCA) has at least 12 ACPH. *Verify documentation and monitoring.*	N/A	

2556

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.
Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
52.03	Is the C PEC decontaminated, cleaned, and disinfected prior to resuming sterile compounding?	N/A	
53.00	The C SEC has at least 12 ACPH. *Verify documentation and monitoring.*	Yes	
54.00	The ceilings, walls, floors, fixtures, shelving, counters, and cabinets are smooth, impervious, free from cracks and crevices, and non shedding. *If non-compliant describe.*	Yes	
55.00	Does the pharmacy engage in **sterile HD compounding**? If yes, complete 55.01 61.02.03. If no, skip to 62.	No	
55.01	Select the type(s) of containment primary engineering control(s) used for **sterile HD compounding**:		
55.01.01	CACI	N/A	
55.01.02	Class II BSC, Type A1 (formerly Type A and not suitable for volatile toxic chemicals and volatile radionuclides)	N/A	
55.01.03	Class II BSC, Type A2 (formerly Type B3)	N/A	
55.01.04	Class II BSC, Type B1	N/A	
55.01.05	Class II BSC, Type B2 (total exhaust for volatile components)	N/A	
55.01.06	Class III BSC	N/A	

2557

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
50.02	Select the type(s) of containment primary engineering control(s) used for **nonsterile HD compounding**:		
50.02.01	Class I biological safety cabinet (BSC)	Yes	
50.02.02	Class II BSC	No	
50.02.03	Containment ventilated enclosure (CVE)	No	
50.02.04	Compounding aseptic containment isolator (CACI)	No	
50.02.05	Other, describe	No	
51.00	Indicate if the C-PEC used for **nonsterile HD compounding** (must be one of two below in order to be compliant):		
51.01	Is externally vented *(preferred)* ; **and/or**	Yes	
51.02	Has redundant High Efficiency Particulate Air (HEPA) filters in series	No	
52.00	Does the pharmacy use the same C PEC (Class II BSC or CACI) used for sterile HD compounding and nonsterile HD compounding?	No	
52.01	Is **nonsterile HD compounding** only "occasional"? *If yes, please describe frequency and quantity.*	N/A	
52.02	Is the **nonsterile HD compounding** activity only occurring when sterile HD compounding is not being performed?	N/A	

2558

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
47.01.03	Is able to meet (12) or exceed ACPH requirements;	Yes	
47.01.04	Is physically separated (ie, a different room) from other preparation areas; and	Yes	
47.01.05	Has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to all adjacent areas.	Yes	
48.00	The C PEC operates continuously if it supplies some or all of the negative pressure in the C SEC or if it is used for sterile compounding.	Yes	
49.00	There is a sink readily available for handwashing on the hazardous side.	Yes	
49.01	There is an eyewash station readily available.	Yes	
49.02	Water sources and drains are a minimum of 1 meter away from the C PEC.	Yes	
50.00	Does the pharmacy engage in **nonsterile HD compounding**? If yes, complete 50.01 54. If no, skip to 55:	Yes	
50.01	Select the location where **nonsterile HD compounding** is performed type(s):		
50.01.01	C-PECs used for sterile HD compounding are located in a different room than C-PECs used for nonsterile HD compounding	N/A	
50.01.02	C-PECs used for sterile HD compounding are located in the same room as C-PECs used for nonsterile HD compounding.	N/A	

2559

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
44.03	Refrigerated antineoplastic HDs are stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH (eg, storage room, buffer room, or containment segregated compounding area [C SCA]).	N/A	
44.04	**Recommendation**: *If the refrigerator is located in a buffer room, is an exhaust located adjacent to the refrigerator's compressor and behind the refrigerator?*	N/A	
45.00	If non antineoplastic, reproductive risk only, and final dosage forms of antineoplastics are stored with other non HD inventory, there is a written policy/SOP addressing it.	N/A	
46.00	**Compounding**: There are appropriate engineering controls to protect the HD preparation from cross contamination, and if sterile compounding, from microbial contamination, during all phases of the compounding process.	Yes	
47.00	All HD compounding are performed within a C PEC located in a C-SEC room.	Yes	
47.01	The C SEC for both sterile and nonsterile HD compounding has all of the following:		There is no sterile compounding.
47.01.01	Has fixed walls;	Yes	
47.01.02	Is externally vented;	Yes	

2560

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
42.00	HDs are not unpacked in a sterile compounding area (eg, no external containers are brought into C SEC).	N/A	
43.00	**Storage**: Are HDs stored in a manner to minimize accidental exposure? *Describe.*	Yes	HDs are stored inside a tote, with separated inside containers, on the bottom shelves of a stainless steel table, in a negative pressure room.
43.01	HDs are not stored on the floor.	Yes	
43.02	HDs are stored in a manner to minimize breakage and spillage.	Yes	
43.03	If facility is in an area prone to specific types of natural disasters, appropriate precautions are taken (eg, raised front lips on shelving in earthquake prone areas).	N/A	
44.00	Antineoplastic HDs that require manipulation (other than counting and repackaging final dosage forms) and HD API are stored separately from non HDs.	N/A	
44.01	These HDs are stored in an externally ventilated, negative pressure room.	N/A	
44.02	The HD storage room has at least 12 air changes per hour (ACPH).	N/A	

2561

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
39.02	Storage of HDs	Yes	
39.03	Nonsterile HD compounding (if performed by the pharmacy)	Yes	
39.04	Sterile HD compounding (if performed by the pharmacy)	N/A	
40.00	***Recommendation**: If there is a requirement for certain designated areas to have negative pressure from surrounding areas, is there an uninterrupted power source (UPS) to the ventilation systems in order to maintain negative pressure in the case of power loss?*	No	
41.00	**Receipt**: Are HDs received and unpacked (removed from external shipping containers) in an appropriate environment? *Describe.*	Yes	Drugs received and marked as HD are moved immediately to the HD PEC for opening. Shipments received but not marked as HD are opened and moved to the HD PEC immediately when HDs are included in the shipment.
41.01	Antineoplastics and HD APIs are unpacked in an area with air pressure relative to surrounding areas that is either neutral or negative pressure. *Indicate the type of environment. If the environment is positive pressure, it is non-compliant.*	Yes	All drugs are received in a neutral air pressure area. They are unpacked in a negative pressure PEC when determined to be hazardous.
41.01.01	Neutral	Yes	
41.01.02	Negative	No	

2562

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
37.02	The HD waste container is located in reasonable proximity to HD PPE doffing activities.	Yes	
37.03	Chemotherapy gloves, and sleeve covers if worn, are carefully removed and discarded immediately into an approved HD trace waste container inside the C PEC or contained in a sealable bag for discarding outside the C PEC.	Yes	
	Facilities and Engineering Controls		
38.00	There are signs prominently displayed before the entrance to all HD handling areas designating the hazard.	Yes	
38.01	Access to these areas are restricted to authorized personnel who have been appropriately trained.	Yes	
38.02	HD areas are located away from breakrooms/refreshment areas for personnel, patients, and/or visitors.	Yes	
39.00	There are designated HD areas for any of the following:		
39.01	Receiving and unpacking of HDs	Yes	Drugs received and marked as HD are moved immediately to the HD PEC for opening. Shipments received but not marked as HD are opened and moved to the HD PEC immediately when HDs are included in the shipment.

2563

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
35.00	The pharmacy uses an appropriate respiratory PPE for large HD spills; deactivating, decontaminating, and cleaning underneath the work surface of the C-PEC; and when there is known or suspected airborne exposure to powders or vapors. *Indicate what type of PPE which is available to employees (and is fit-tested, when required).*	Yes	
35.01	Fit-tested NIOSH-certified N95 respirator;	Yes	
35.02	Elastomeric half-mask with a multi-gas cartridge and P100-filter;	No	
35.03	Full-facepiece, chemical cartridge-type respirator;	No	
35.04	PAPR; and/or	No	
35.05	Other (describe in notes).	No	
36.00	Surgical masks are **not** used as PPE when respiratory protection is needed.	Yes	
37.00	**Disposal of Used PPE**: Is all PPE worn during handling of HDs considered contaminated with at least trace quantities?	Yes	
37.01	Worn PPE is placed in an appropriate HD waste container.	Yes	

2564

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
33.00	**Respiratory Protection**: The pharmacy is using appropriate respiratory PPE protection for the activities conducted (receiving, transport, compounding, administration, and waste disposal) based on assessment of risk based on type of HD and type of activity, if required. *Indicate what type of PPE which is available to employees (and is fit tested, when required).*	Yes	
33.01	Fit-tested NIOSH-certified N95 respirator;	Yes	
33.02	Elastomeric half-mask with a multi-gas cartridge and P100-filter;	No	
33.03	Full-face piece, chemical cartridge-type respirator;	No	
33.04	PAPR; and/or	No	
33.05	Other (describe in notes).	No	
34.00	Surgical masks are **not** used as PPE when respiratory protection is needed.	Yes	

2565

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
31.00	**Head, hair** (beard and moustache, if appropriate), **and shoe and sleeve covers.** The pharmacy is using appropriate head, hair, and shoe and sleeve covers for the type of compounding based on standards or assessment of risk to provide protection from contact with HD residue, if required.	Yes	
31.01	When HD compounding, a second pair of shoe covers are donned before entering the C SEC and doffed when exiting the C SEC.	Yes	
31.02	Shoe covers worn in HD areas are not worn into other areas of the facility.	Yes	
32.00	**Eye and Face Protection**: The pharmacy is using appropriate eye and face PPE protection for the activities conducted (based on assessment of risk that HDs are irritating to the eyes and mucous membranes, where there is risk of spills or splashes when working outside of a C PEC), if required.	Yes	
32.01	If a risk to eyes, goggles (or a full face respirator) are worn. *Eyeglasses or safety glasses with side shields are not substituted for goggles.*	N/A	All HD compounding is performed inside of a BSC.
32.02	If a risk to face and eyes, goggles plus a face shield (or a full face respirator) are worn.	N/A	All HD compounding is performed inside of a BSC.

2566

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
30.00	**Gowns**: The pharmacy is using appropriate gowns for the activities conducted (if required for type of compounding based on standards or assessment of risk).	Yes	
30.01	Gowns are disposable.	Yes	
30.02	Gowns resist permeability of HDs and are not laboratory coats, surgical scrubs, or isolation gowns (selected based on HDs handled).	Yes	
30.03	Gowns close in the back, are long sleeved, and have closed cuffs that are elastic or knit.	Yes	
30.04	Gowns do not have seams or closures that will allow HDs to pass through.	Yes	
30.05	Gowns are changed in accordance with the manufacturer's instructions, or if no permeation information is available, they are changed every two to three hours or immediately after a spill or splash.	Yes	
30.06	Gowns worn in HD areas are not worn to other areas.	Yes	

2567

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
29.00	**Gloves**: The pharmacy is using appropriate gloves for the activities conducted (chemotherapy gloves meet ASTM standard D6978 -- or its successor -- and are resistant to cleaning agents used) and are resistant to cleaning agents used.	Yes	
29.01	**Recommendation**: Are *chemotherapy gloves worn for handling all HDs including non antineoplastics and for reproductive risk only HDs?*	Yes	
29.02	Chemotherapy gloves are powder free.	Yes	
29.03	Chemotherapy gloves are inspected for physical defects before use and defective gloves (eg, pin holes, tears, weak spots) are discarded.	Yes	
29.04	For sterile compounding, the outer chemotherapy gloves are sterile.	N/A	There is no sterile compounding performed.
29.05	Chemotherapy gloves are changed when torn, punctured, or contaminated.	Yes	
29.06	**Recommendation**: Are *chemotherapy gloves changed every 30 minutes (unless otherwise recommended by the manufacturer)?*	No	
29.07	Hands are washed with soap and water after removing chemotherapy gloves.	Yes	

2568

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
26.02	Storage;	Yes	
26.03	Transport;	Yes	
26.04	Nonsterile Compounding (if performed by the pharmacy);	Yes	
26.05	Sterile Compounding (if performed by the pharmacy);	Yes	
26.06	Administration, if applicable;	N/A	
26.07	Deactivation/decontamination, cleaning, and disinfecting (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted/addressed in SOPs);	Yes	
26.08	Spill control;	Yes	
26.09	Waste disposal; and	Yes	
26.10	If administering injectable antineoplastics, two pairs of chemotherapy gloves and permeability resistant gowns are worn.	N/A	
27.00	Disposable PPE is not reused.	Yes	
28.00	Reusable PPE is decontaminated and cleaned after each use.	Yes	The only reusable PPE used is goggles.

2569

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
23.05	Appropriate procedures for deactivation, decontamination, cleaning, and disinfection (if applicable);	Yes	
23.06	Response to known or suspected HD exposure;	Yes	
23.07	Spill management;	Yes	
23.08	Proper disposal of HDs and trace-contaminated materials; and	Yes	
23.09	New HD drug/new equipment or prior to any significant change in process or SOP.	Yes	
24.00	If respiratory protection is needed for any HDs handled, personnel are fit tested and trained in the proper use of the respirator.	Yes	
	Personal Protective Equipment		
25.00	For sterile and nonsterile compounding with HDs, personnel wear gowns; head, hair, and shoe covers; and two pairs of chemotherapy gloves.	Yes	There is no sterile compounding performed.
26.00	Appropriate PPE is readily accessible where HD is handled, include all of the following:		
26.01	Receipt (PPE appropriate to HD as set forth in SOPs, and at a minimum, chemotherapy gloves worn);	Yes	

2570

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
19.00	For sterile HD compounding, personnel competency is observed and assessed at least annually for proper sterile compounding aseptic technique, with no concerns identified.	Yes	
20.00	After initial HD training, personnel are trained prior to introduction of any new HD or new equipment, or prior to any significant change in process or SOP.	Yes	
21.00	All HD training and assessments are documented for each employee who transports, compounds, or administers HDs, and meets Occupational Safety and Health Administration Standard 1910.120 and any other requirements of law or regulation.	Yes	
22.00	All personnel who perform custodial HD waste removal and cleaning in HD handling areas are trained in appropriate procedures to protect themselves and the environment.	Yes	
23.00	HD training, based on employee file review, all of the following are present:		
23.01	Overview of pharmacy's HD list and their risks;	Yes	
23.02	Review of the SOPs related to HDs;	Yes	
23.03	Proper use of PPE;	Yes	
23.04	Proper use of equipment and devices (eg, engineering controls);	Yes	

2571

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
15.03	SDSs are maintained for each hazardous chemical they use (29 CFR 1910.1200);	Yes	
15.04	How SDSs are readily accessible to personnel during each work shift and when they are in their work areas;	Yes	
15.05	Information and training provided to personnel prior to initial assignment to work with a hazardous chemical and whenever the hazard changes; and	Yes	
15.06	Personnel of reproductive capability confirm in writing that they understand the risks of handling HDs.	Yes	
	Personnel Training --*Check four employee files for documentation*		
16.00	All personnel handling HDs are trained based on their job function prior to independently handling HDs.	Yes	
17.00	Personnel file contains the employee's acknowledgement of the risk of handling HD (as part of the hazardous communication program).	Yes	
18.00	For non sterile HD compounding, personnel competency is observed and assessed at least annually for proper compounding technique, with no concerns identified.	Yes	

2572

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
13.22.07	Use of appropriate full-face, chemical cartridge-type respirator or powered air-purifying respirators (PAPR) if capacity of spill kit is exceeded or known or suspected airborne exposure to vapors/gases; and	No	
13.22.08	Medical evaluation/incident reporting/documentation/other handling of persons potentially exposed or with direct skin/eye contact to the HD.	Yes	
13.23	***Recommendation:*** *Does the pharmacy have a medical surveillance program? (a comprehensive control program to monitor and identify potential worker health care issues from HD exposure.)*	No	
14.00	The **hazard communication program** SOP has policies and procedures that ensure worker safety in all aspects of HD handling relevant to the pharmacy and ensure effective personnel training in proper labeling, transport, storage, and disposal of HDs, use of Safety Data Sheets (SDSs), based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).	Yes	
15.00	The pharmacy's hazard communication program includes, at a minimum, all of the following:		
15.01	A written plan that describes how the standard will be implemented;	Yes	
15.02	How containers of HDs/hazardous chemicals will be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings;	Yes	

2573

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
13.19	Administering SOPs, if applicable	N/A	
13.20	***Recommendation: Environmental monitoring (eg, wipe sampling) SOPs***	No	
13.21	HD waste segregation and disposal (including reference to following local, state, and federal regulations) SOPs	Yes	
13.22	Spill prevention and direction of spill cleanup and control SOPs must address the following:		
13.22.01	Size and scope of spill;	Yes	
13.22.02	Responsible person for handling spills;	Yes	
13.22.03	Location of spill kits and clean-up materials;	Yes	
13.22.04	Capacity of the spill kits;	Yes	Spill kits are capable of handling large spills and multiple kits are available in all areas.
13.22.05	PPE to be worn during spills;	Yes	
13.22.06	Handling of worn PPE and any exposed clothing under PPE;	Yes	

2574

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
13.14.02	It is transported to the C-PEC before opening, preferably nonsterile compounding C-PEC, if available;	Yes	
13.14.03	container is placed on a plastic-backed preparation mat;	No	There is no plastic-backed preparation mat used.
13.14.04	It is opened and undamaged items are removed and wiped down with a disposable wipe;	Yes	
13.14.05	Damaged item is enclosed in an impervious container and labeled "hazardous";	Yes	
13.14.06	Damaged item is returned to the supplier or disposed of as hazardous waste;	Yes	
13.14.07	Deactivate, decontaminate, and clean the C-PEC in accordance with SOPs; and	Yes	
13.14.08	If a sterile compounding C-PEC must be used, it is also disinfected after cleaning prior to resuming any sterile compounding activities.	N/A	
13.15	Safe work Practices SOPs	Yes	
13.16	Dispensing SOPs	Yes	
13.17	Packaging and labeling SOPs	Yes	
13.18	Transport SOPs	Yes	

2575

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
13.11.04	PPE to be worn (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted--addressed in SOPs)	Yes	
13.11.05	Documentation requirements	Yes	
13.12	Receiving SOPs to include communications with suppliers about packaging and visual/other inspection of shipping containers for signs of damage and how to handle damaged containers.	Yes	
13.13	If a shipping container appears damaged and **does not need to be opened**:		
13.13.01	It is sealed without opening and wrapped in impervious plastic;	Yes	
13.13.02	Labeled as "hazardous"; and	Yes	
13.13.03	Returned to the supplier after contacting the supplier or disposed of as hazardous waste if supplier declines return.	Yes	
13.14	If a damaged shipping container **must be opened**:		
13.14.01	Container is sealed in plastic or an impervious container;	Yes	

2576

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
13.09	Use and maintenance of proper engineering controls (eg, containment primary engineering control [C PECs], containment secondary engineering control [C SECs], and closed system drug transfer device [CSTDs]) to include SOPs for repairs, loss of power, moving, etc.	Yes	
13.10	Hand hygiene and proper use of appropriate PPE based on activity (eg, receipt, transport, compounding, administration, spill, disposal).	Yes	
13.11	Deactivation, decontamination, cleaning, disinfection SOPs include all of the following:		
13.11.01	Agents used	Yes	
13.11.02	Dilutions, if used	N/A	All agents used are RTU.
13.11.03	Frequency	Yes	

2577

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
13.00	SOPs address at a minimum: *If no, document "missing" in Inspector Notes for each SOP topic*		**Please note NABP did not review each SOP for alignment on USP <800>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**
13.01	Hazard communication program plan	Yes	
13.02	Competent personnel	Yes	
13.03	Occupational safety program	Yes	
13.04	Designation of HD areas	Yes	
13.05	Receiving HDs, including handling of damaged shipping containers/breakages	Yes	
13.06	A list of HDs	Yes	
13.07	Storage of HDs	Yes	
13.08	Compounding of HDs	Yes	

2578

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
10.02	**Dispensing**: Counting or packaging tablets and capsules	N/A	
10.03	**Compounding/other manipulations**: Crushing/splitting tablets, opening capsules, pouring liquids, weighing or mixing, constituting/reconstituting powdered/lyophilized HDs, expelling air from HD syringes, HD residue on personal protective equipment (PPE), cleaning activities of HD areas, and HD equipment maintenance.	Yes	
10.04	**Administration and other patient care activities** (if applicable).	N/A	
10.05	**Spills**: Spill generation, management, and disposal.	Yes	
10.06	**Transport**	Yes	
10.07	**Waste**: Collection and disposal of HD waste and trace contaminated waste	Yes	
11.00	SOPs are reviewed at least every 12 months by the designated person, and the review is documented.	Yes	
12.00	SOPs are readily available to all who may need to handle HD or respond to a spill (pharmacy employees, housekeeping, nursing personnel, delivery personnel, etc). *Describe whether P&Ps are available electronically, by paper, or both.*	Yes	

2579

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
8.06	If applicable, Table II and III drugs have alternative containment strategies and/or work practices to minimize occupational exposure.	N/A	
8.07	The assessment of risk is reviewed at least every 12 months, and the review is documented. *Enter date of last review in the notes.*	N/A	
	Personnel Responsibilities		
9.00	The pharmacy has a designated person(s) to oversee the handling of HDs who is qualified and trained for development of standard operating procedures (SOPs); overseeing compliance with standards, laws, and rules; ensuring competency of personnel; and ensuring environmental control.	Yes	
9.01	The designated person oversees the monitoring of the facility, including testing/sampling programs, maintaining, and documentation, and acting on results.	Yes	
	Documentation and Standard Operating Procedures (SOPs)		
10.00	The assessment of risk and SOPs for handling HDs addresses all potential types of exposure, including all activities occurring within the operation that present an opportunity for exposure:		There is no assessment of risk as the pharmacy is not handling any HDs not using all containment requirements of USP <800>.
10.01	**Receiving**: Contacting HD residues on packaging, work surfaces, floors	Yes	

2580

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
6.02	In the absence of information, the pharmacy treats any new drug as an HD.	Yes	
7.00	If the pharmacy handles any HDs not using all containment requirements of <800>, an assessment of risk was performed for each drug and dosage form individually to determine alternative containment strategies, if needed, and work practices for each. *Review documentation of assessment and SOPs related to work practices/alternative containment.*	N/A	All HDs (APIs) are handled using all containment requirements of USP Chapter <800>.
8.00	The assessment of risk evaluation performed by the pharmacy's organization includes all required information, for each drug and dosage form. *The first five (5) items below must be included in the evaluation in order to be compliant.*	N/A	There is no assessment of risk as the pharmacy is not handling any HDs not using all containment requirements of USP <800>.
8.01	Type of HD (eg, antineoplastic, non-antineoplastic, reproductive risk only);	N/A	
8.02	Dosage form;	N/A	
8.03	Risk of exposure;	N/A	
8.04	Packaging;	N/A	
8.05	Manipulation; and	N/A	

2581

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
2.02	Does the pharmacy handle any dosage forms of other HDs **that are handled in full compliance** with containment requirements of <800>? *If yes, please list.*	No	
2.03	Does the pharmacy handle any dosage forms of other HDs **that are not handled** using all containment requirements of <800>? *If yes, please list.*	No	
	List of Hazardous Drugs		
3.00	The pharmacy maintains a list of any items it handles that are included on the current NIOSH list of antineoplastic and other HDs. ***Review and attach list.*** *Verify that pharmacy has access to a copy of current NIOSH list.*	Yes	Tretinoin, spironolactone and finasteride are handled. The pharmacy maintains a current NIOSH list.
4.00	The pharmacy reviews this list at least every 12 months for additions, deletions, or other changes and documents the review. *Verify documentation and* ***list date*** *of last change/review.*	Yes	
5.00	The pharmacy reviews this list whenever the pharmacy adds a new agent or dosage form to the items it handles.	Yes	
6.00	The pharmacy has a system in place for the evaluation of new drugs (purchased, stored, handled, and/or dispensed) to determine whether they are considered HD.	Yes	There are no drugs. Only APIs are used.
6.01	Pharmacy evaluates the drugs against the current version of the NIOSH list.	Yes	

2582

Copyright ® March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observatio	Notes
	General Information and Scope:		
1.00	Does the pharmacy handle any drugs on the National Institute for Occupational Safety and Health (NIOSH) list that **require** all the containment requirements of USP <800>?	No	
1.01	Does the pharmacy handle any ***hazardous drug*** active pharmaceutical ingredients (HD API)? *If yes, please list.*	Yes	Spironolactone, finasteride, and tretinoin are handled.
1.02	Does the pharmacy handle any antineoplastic requiring manipulations (which can produce particles, aerosols, or gasses)? *If yes, please list.*	No	
2.00	Does the pharmacy handle any drugs on the NIOSH list that **do not** require all containment requirements of <800>?	No	
2.01	Does the pharmacy handle any final dosage forms of HDs (either compounded or manufactured unless required by the manufacturer) that do not require further manipulation other than counting and repackaging? *If yes, please list.*	No	

2583

Copyright © December 2023 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Glossary & References	USP <795>
Master formulation record (MFR)	A detailed record of procedures that describes how the CNSP is to be prepared.
Monograph	A quality documentary standard within USP–NF that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Oversight	The review, monitoring, and supervision of actions taken by personnel; bearing responsibility for those actions; and being available if and when needed for consultation, even if not physically present.
Preservative	A substance added to inhibit microbial growth.
Purified water	The minimal quality of source water for the production of Purified Water is drinking water whose attributes are prescribed by the US Environmental Protection Agency (EPA), the European Union, Japan, or the World Health Organization (WHO). This source water may be purified using unit operations that include deionization, distillation, ion exchange, reverse osmosis, filtration, or other suitable purification procedures. (See <1231>, 3.1.1 Purified Water.)
Quality Assurance (QA)	A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.
Quality Control (QC)	The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met for the CNSP.
Reconstitution	The process of adding a diluent to a conventionally manufactured product to prepare a solution or suspension.
Release inspection and testing	Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
Sanitizing agent	An agent for reducing, on inanimate surfaces, the number of microorganisms (eg, 70% isopropyl alcohol).
SDS	Safety data sheet.
SOP	Standard operating procedure.
Specification	The tests, analytical methods, and acceptance criteria to which any components, CNSP, container closure system, equipment, or other material used in the compounding of CNSPs must conform to be considered acceptable for its intended use.
Stability	The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
Verify	To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Water activity (a_w)	A measure of the fraction of total water that is unbound and freely available to participate in chemical, biochemical, or physicochemical reactions or provide an environment that can support microbial growth. Note that a_w is not water content.

Copyright © December 2023 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Glossary & References	USP <795>
Component	Any ingredient used in the compounding of a preparation, including any API, added substance, or conventionally manufactured product.
Compounded nonsterile preparation (CNSP)	A preparation not intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance.
Compounding	The process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.
Compounding area	An area that is specifically designated for nonsterile compounding.
Compounding personnel	Personnel trained to compound or oversee compounding of preparations.
Compounding record (CR)	Documents the compounding of each CNSP.
Container closure system	Packaging system components that together contain and protect the dosage form. This includes primary packaging system components and secondary packaging system components if the latter are intended to provide additional protection.
Containment glove bag	A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE)	A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.
Conventionally manufactured product	A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Designated person(s)	One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CNSPs.
FDA	US Food and Drug Administration
Formulation	The specific qualitative and quantitative composition of the final CNSP.
Hazardous Drug (HD)	Any drug identified by at least one of the following criteria: carcinogenicity, teratogenicity or developmental toxicity; reproductive toxicity in humans; organ toxicity at low dose in humans or animals; genotoxicity or new drugs that mimic existing HDs in structure or toxicity. See <800>.
Label	The part of the labeling on the immediate container.
Labeling	All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container.

Copyright © December 2023 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Glossary & References	USP <795>
Active Pharmaceutical Ingredient (API)	Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body. Also referred to as a bulk drug substance. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added Substance	An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with inactive ingredient, excipient, and pharmaceutical ingredient.
Administration	The preparation of a nonsterile pharmacologic or other therapeutic agent for ingesting, inserting, applying, or otherwise providing a nonsterile medication in its final form to a single patient. This includes crushing a tablet(s) or opening a capsule(s) to mix with food or liquids to facilitate patient dosing.
Alcohol-based hand rub	An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Assigned trainer	One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CNSPs.
Beyond-use date (BUD)	The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded.
Biological Safety Cabinet (BSC)	A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
Bulk drug substance	See the entry for Active Pharmaceutical Ingredient.
Certificate of analysis (COA)	A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
Cleaning	The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleaning agent	An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Closed-system processing device	A device designed to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples include CVEs, BSCs, or single-use containment glove bags.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

	Employee Title	PIC	Designated Person	Pharmacist	Compounding Technician	Compounding Technician	Notes
2.5	The annual competency assessment for cleaning and sanitizing is complete.	Yes	Yes	Yes	Yes	Yes	
2.6	The annual competency assessment for handling and transporting components and CNSPs is complete.	Yes	Yes	Yes	Yes	Yes	
2.7	The annual competency assessment for measuring and mixing is complete.	Yes	Yes	Yes	Yes	Yes	
2.8	The annual competency assessment for proper use of equipment is complete.	Yes	Yes	Yes	Yes	Yes	
2.9	The annual competency assessment for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Yes	Yes	Yes	Yes	Yes	
2.10	The annual competency assessment for interpreting a COA is complete.	Yes	Yes	Yes	Yes	Yes	
2.11	The annual competency assessment for how to read/interpret a SDS is complete.	Yes	Yes	Yes	Yes	Yes	
2.12	The annual competency assessment for spill management is complete.	Yes	Yes	Yes	Yes	Yes	
3.0	The designated person(s) has documented a (periodic) evaluation of their direct observations for compounding activities and documented any deficiencies in the record. *Inspector note: if there are not observations documented, the inspector should answer this question as N/A. Per USP, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*	N/A	Missing	N/A	N/A	N/A	The designated person reviews a synopsis of compounding competency evaluations performed by a Senior Compounding Technician responsible for evaluation of compounding activities. There is no documentation of direct observation by the designated person.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

	Employee Title	PIC	Designated Person	Pharmacist	Compounding Technician	Compounding Technician	Notes
1.7	The training record for measuring and mixing is complete.	Yes	Yes	Yes	Yes	Yes	
1.8	The training record for proper use of equipment is complete.	Yes	Yes	Yes	Yes	Yes	
1.9	The training record for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Yes	Yes	Yes	Yes	Yes	
1.10	The training record for interpreting a Certification of Analysis (COA) is complete.	Yes	Yes	Yes	Yes	Yes	
1.11	The training record for how to read/interpret a Safety Data Sheet (SDS) is complete.	Yes	Yes	Yes	Yes	Yes	
1.12	The training record for spill management is complete.	Yes	Yes	Yes	Yes	Yes	
2.0	The annual competency assessment was evaluated and documented on the following topics:						
2.1	Compounding personnel are re-trained on facility SOPs.	Yes	Yes	Yes	Yes	Yes	
2.2	Compounding personnel are re-trained on USP <795> standards.	Yes	Yes	Yes	Yes	Yes	
2.3	The annual competency assessment for hand hygiene is complete.	Yes	Yes	Yes	Yes	Yes	
2.4	The annual competency assessment for garbing is complete.	Yes	Yes	Yes	Yes	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Nonsterile <795> Employee File Records Review

Select the PIC, designated person, a staff pharmacist that checks compounded preparations, and two to three compounding pharmacy technicians. *Do not record the employee name, list only their title or position.
From the drop-down List:
*Mark as "Yes" if the document is present in the records and the competency evaluation was conducted in compliance with USP <795> requirements.
*Mark as "No" if the document is present in the records but is not in compliance with USP <795> requirements.
*Mark as "Missing" if any part of the record is missing and explain in Notes column.
*Mark as "N/A" if the training does not apply (eg, long-term employee may not have initial training available). Document further in the Notes column.

		Employee Records #1	Employee Records #2	Employee Records #3	Employee Records #4	Employee Records #5	
	Employee Title	**PIC**	**Designated Person**	**Pharmacist**	**Compounding Technician**	**Compounding Technician**	**Notes**
1.0	The training program provides initial training, evaluation, and documentation on the core competencies listed below:						Major training and retraining records are maintained in Simplify.
1.1	Compounding personnel are trained on facility SOPs.	Yes	Yes	Yes	Yes	Yes	
1.2	Compounding personnel are trained on USP <795> standards.	Yes	Yes	Yes	Yes	Yes	
1.3	The training record for hand hygiene is complete.	Yes	Yes	Yes	Yes	Yes	
1.4	The training record for garbing is complete.	Yes	Yes	Yes	Yes	Yes	
1.5	The training record for cleaning and sanitizing is complete.	Yes	Yes	Yes	Yes	Yes	
1.6	The training record for handling and transporting components and CNSPs is complete.	Yes	Yes	Yes	Yes	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
61.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and sanitizing activities in the compounding area in compliance with USP <795> standards? ***Document observations while pharmacy staff are performing live compounding activities in Inspector Notes.*** ***If no, go to compliance statements.***	Yes		5
61.1	Pharmacy staff starts with a clean and sanitized work surface prior to compounding a CNSP.	Yes		5 Table 1
61.2	Pharmacy staff perform cleaning and sanitizing between compounding CNSPs with different components. ***Inspector note: Per USP, "If cleaning and sanitizing are performed as separate steps, cleaning must be performed first."***	Yes		5 Table 1
61.3	Pharmacy staff ensure equipment and devices used in compounding activities are clean and sanitized after use (to prevent cross contamination of the next preparation).	Yes		6.1 Table 2
61.4	Pharmacy staff perform cleaning and sanitizing on work surfaces when visibly soiled, after spills, and/or when surface contamination is known or suspected.	Yes		5 Table 1

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
59.6	If a CNSP will not be released or dispensed on the day the preparation was made, a visual inspection was conducted immediately before it is released or dispensed to make sure the CNSP did not develop any defects during storage.	Yes		8, 8.1
59.7	All checks and inspection that are performed are properly documented.	Yes		8.1, 14
59.8	CNSP that do not meet requirements, are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before disposal	Yes		8.1
60.0	Inspect several different finished compounded nonsterile preparations. Are all the finished compounded preparations free from any evidence of signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately.*** ***Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, particulates, dirt/debris/(suspected) mold within container closure); number of preparations affected (eg, two of the five containers on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes		12

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
58.16	The compounding personnel labeled the CNSP. ***Inspector note: Storage requirements must be included on the label if refrigerated or frozen (so patient can identify the storage temperature requirements).***	Yes		9
58.17	The compounding personnel completed any documentation on the CR. ***If no, describe observations of what was missing or omitted in Inspector Notes.***	Yes		7.2, 8, 14 Box 3
58.18	The compounding personnel cleaned and sanitized the compounding area before the next CNSP (with differing ingredients) is prepared.	Yes		5
59.0	**Final CNSP check observation**: Does the visual inspection of the CNSP by the pharmacist confirm all USP <795> requirements? ***Observe a pharmacist check several CNSP prescriptions. List the name of CNSPs release inspection observed in the Inspector Notes.*** ***If no, go to compliance statements.***	Yes	Hydroquinone 4%, kojic acid 4%, azelaic acid 3% and hydrocortisone 2.5% in a cream base 18 gm, and azelaic acid 4%, clindamycin 1% and niacinamide 4% in a cream base 24 gm were observed.	8, 8.1, 9
59.1	CNSP was visually inspected to determine the physical appearance of the CNSP is as expected (eg, color, texture, physical uniformity), including any special characteristics listed in the MFR (eg, emulsions must be checked for phase separation).	Yes		8, 8.1
59.2	Visual inspection included checking for container closure integrity (eg, leakage, cracks, improper seals).	Yes		8, 8.1
59.3	CNSP label was verified against the prescription or medication order.	Yes		8, 8.1, 9
59.4	CNSP label was verified against the MFR.	Yes		8, 8.1, 9
59.5	CNSP label was verified against the CR.	Yes		8, 8.1, 9

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
58.8	The compounding personnel have knowledge of and access to any SDS.	Yes		6.2
58.9	The compounding personnel only compound one CNSP at a time (to proactively prevent mix-ups, errors, and cross contamination).	Yes		1.1.3
58.10	The compounding personnel compound the CNSP according to the MFR. ***If no, inspector needs to describe in detail their observations in the Inspector Notes and collect a copy of the MFR and CR (no PHI or PII to be collected).***	Yes		7.1, 7.2 Box 2
58.11	The compounding personnel document any required steps listed in the MFR on the CR. ***Inspector note: This would include any weights, volume, and any in-process checks needed.***	Yes		7.2, 14 Box 3
58.12	Documentation in the CR is legible. ***If no, collect copy of record that is illegible. Redact any PHI on record.***	Yes		14
58.13	The compounding personnel verify the correct BUD in accordance with the MFR requirements in USP <795>.	Yes		10 Table 3, Table 4
58.14	The compounding personnel performed any quality control steps specified in the MFR. ***Inspector note: Examples of this include, but are not limited to: testing of pH for a suspension, weighing of capsules, and visual inspection against product description specifications.*** ***If no, describe observations in Inspector Notes.***	Yes		7.2, 8, 8.1, 12 Box 3
58.15	The compounding personnel placed the CNSP into the proper container closure system.	Yes		8.1 Box 2

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
58.0	**Compounding Observation:** Are compounding personnel using appropriate nonsterile compounding techniques for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		2 Box 3
58.1	The compounding personnel enter the nonsterile compounding area in accordance with the SOPs.	Yes		3.1, 4.1
58.2	The compounding personnel started with a clean compounding area for CNSPs.	Yes		4.1, 4.3, 5 Table 1
58.3	The compounding personnel selected the correct MFR for the CNSP to be prepared.	Yes		7, 7.1 Box 2
58.4	The compounding personnel performed hand hygiene. ***Inspector note: Per USP <795>, Box 1, personnel are to: wash hands with soap and water for at least 30 seconds, dry hands completely with disposable towels or wipers, and then don gloves.***	Yes		3.2 Box 1
58.5	The compounding personnel are appropriately garbed for the type of CNSP prepared.	Yes		3.3
58.6	The compounding personnel obtained the proper ingredients (APIs and/or components). ***Inspector note: All ingredients must be within date and match what is listed in the MFR. If the ingredient is an API, the COA must have already been reviewed and approved for use.***	Yes		6.2 (6.2.1 - 6.2.5)
58.7	The compounding personnel gathered all necessary materials, equipment, and supplies necessary and/or specified in the MFR and is in good working order prior to use for the CNSP. ***Inspector note: All items must be clean prior to use. If equipment requires calibration and/or certification, compounder must ensure the equipment or device is within proper specifications (eg, tare scales and/or balances).***	Yes		6.1 Table 2

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
54.1	All personnel who enter the compounding area to compound performed hand hygiene.	Yes		3.2 Box 1
54.2	Personnel wash hands with soap and water for at least 30 seconds.	Yes		3.2
54.3	Personnel dry their hands completely with disposable towels or wipers.	Yes		3.2
54.4	Personnel do not solely rely on the use of alcohol hand sanitizers.	Yes		3.2
55.0	***Garbing Observation:*** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3 Box 1
55.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3 Box 1
55.2	All personnel who perform compounding activities don gloves. ***Inspector note: Per USP, "Gloves must be worn for all compounding activities."***	Yes		3.2, 3.3 Box 1
55.3	Gloves are inspected periodically for holes, punctures, or tears and replaced immediately if a defect is detected.	Yes		3.3 Box 1
56.0	Are gloves wiped or replaced before beginning compounding a CNSP with a different component or when other objects were touched (eg, pens, keyboards) to minimize risk of cross contamination with other CNSPs? ***Inspector note: This is a USP recommendation.***	Yes		3.3
57.0	List the name(s) of the CNSPs observed by the inspector as part of live compounding demonstration.	[redacted]	Compounding of azelaic acid 4%, niacinamide 4%, and clindamycin phosphate 1%, in propylene glycol and cream base was observed.	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
	Compounding Personnel Observations - *Inspector must observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. It is acceptable for pharmacy staff to perform mock compounding activities (with two creams or other drugs) as long as all observations can be viewed.*			
53.0	**Personal Preparation Observation:** Before entering the compounding area, do personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		
53.1	Personnel removed all outer garments (eg, hats, scarves, bandanas, vests, coats, and jackets).	Yes		3.1
53.2	Personnel removed all items that are not easily cleanable and that might interfere with garbing.	Yes		3.1
53.3	Personnel removed all hand, wrist, and other exposed jewelry, including piercings, that could interfere with the effectiveness of garbing and hand hygiene (eg, watches, rings that may tear gloves).	Yes		3.1
53.4	Personnel removed earbuds or headphones.	Yes		3.1
53.5	Any accommodations permitted by the designated person(s) should be documented. ***Inspector note: Per USP <795>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	N/A	There are no accommodations made.	3.1
54.0	**Hand Hygiene Observation:** Were personnel who enter the compounding area to compound observed performing the appropriate hand washing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.2, Box 1

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
49.1	The pharmacy has procedures to determine when recalls must be initiated.	Yes		12.1
49.2	The pharmacy documented the implementation of the recall.	Yes		12.1
49.3	Pharmacy reports recalled CNSPs to the appropriate regulatory bodies (as required by laws and regulations of the applicable regulatory jurisdiction).	Yes		1.1.3, 12.1
49.4	Investigations into an adverse event that reveals a quality problem with a CNSP that is likely to affect other patients are reported to both patients and their prescribers.	Yes		12.3
50.0	Does the pharmacy procedures include a step to immediately notify the prescriber of a failure of specifications with potential to cause harm (eg, strength, purity, or other quality attributes)? ***Inspector note: This is a USP recommendation.***	Yes		12.1
	CNSP Packaging			
51.0	Does the pharmacy's packaging processes and materials meet the requirements in USP <795>? ***If no, go to compliance statements.***	Yes		13.1
51.1	The packaging materials protect CNSPs from damage, leakage, contamination, and degradation.	Yes		13.1
51.2	The packaging materials used protects personnel from exposure (from the packaged CNSP).	Yes		13.1
52.0	The packaging materials selected by the pharmacy maintain the physical and chemical integrity and stability needed for CNSPs (eg, protect from light).	Yes		13.1

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
47.3	Complaints are reviewed to determine whether it indicates a potential quality problem with the CNSP.	Yes		12.2
47.4	Complaints are fully investigated.	Yes		12.2
47.5	Complaint investigations consider whether the quality problem extends to other CNSPs.	Yes		12.2
47.6	Corrective action, if necessary, is implemented for all potentially affected CNSPs. ***Inspector note: Per USP, the pharmacy is to, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected."***	Yes		12, 14
47.7	A CNSP that is returned in connection with a complaint is quarantined until it is destroyed after the completion of the investigation and in accordance with the laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 12.2
48.0	Has the pharmacy initiated any recalls of CNSPs within the past two years? ***Inspector note: Per USP <795> requires all records to be readily retrievable for two years, including recalls; However, the state/jurisdictional regulator may require records to be kept for a longer period of time.*** ***Review most recent recall and describe in the Inspector Notes.*** ***If the pharmacy has not had any recalls within the past two years, inspector should answer the question as No.***	No		12.1, 14
49.0	Does the pharmacy follow recall and adverse event procedures for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.1, 12.2, 12.3

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
45.3	The QA/QC programs address prevention and detection of errors and other quality problems.	Yes		12
45.4	The QA/QC programs address evaluation of complaints and adverse events. ***Review at least one complaint and one adverse event. If there are no complaints or adverse events, review the process that the pharmacy would follow in the event of a complaint or adverse event.***	Yes	Two complaints were reviewed which were appropriately addressed. There were no adverse events on file.	12
45.5	The QA/QC programs address appropriate investigations and corrective actions.	Yes		12
46.0	Has the pharmacy received any complaints related to CNSPs within the past year?	Yes		12
47.0	Does the pharmacy follow complaint handling requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.2
47.1	The pharmacy has a complete written or electronic record of each complaint made. ***Inspector note: Per USP, "The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint. In addition, to the extent that the information is known, the following should be recorded: the name and strength of the CNSP and the assigned internal identification number (e.g., prescription, order, or lot number). The record must also include the findings of any investigation and any follow-up. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained."***	Yes		12.2
47.2	Complaints are reviewed in accordance with SOPs by the designated person for the QA program.	Yes		12.2

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
44.7	Aqueous CNSPs whose labeled BUDs are extended beyond Table 4, have: - been tested for antimicrobial effectiveness at least once for each formulation in the type of (with the same material composition of the) container closure system that will be used; - received study results from an FDA-registered facility (for the same CNSP formulation using the same material composition of the container closure system); or - a study published from peer-reviewed literature (for the same CNSP formulation using the same material composition of the container closure system). ***Inspector note: Pharmacy may rely on a bracketed study from the above options as long as the bracketed study information includes the low and high concentration of each active ingredient in the formulation. Per USP, this is "to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must fall within the bracketed range.***	Yes	A bracketed study using the low and high concentration of each active ingredient in the formulation is used.	10.5
	Quality Assurance (QA), Quality Control (QC), and Quality Management (QM) Inspector to review at least one complaint, one adverse event, and one recall (if applicable).			
45.0	Does the pharmacy have a QA/QC program to ensure that CNSPs are prepared per the requirements in USP <795> standards and any applicable regulatory requirements? ***If no, go to compliance statements.***	Yes		1.1.3, 12
45.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (<795>) and the laws and regulations of the applicable regulatory jurisdiction."***	Yes		12
45.2	The QA/QC programs address adherence to procedures.	Yes		12

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
44.4	The pharmacy has a copy of the cited stability study, which used a stability-indicating analytical method, for extending BUDs. ***Per USP, any stability study that meets the requirements of a stability-indicating assay method can be used (whether it is published or unpublished, such as a study provided by a chemical supplier) to extend BUDs up to 180 days for a CNSP.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	Yes		10.5
44.5	The cited stability study (which uses a stability-indicating analytical method for extending BUDs) describes the API(s), CNSP formulation, and material composition of the container closure used. ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	Yes		10.5
44.6	If the cited stability study (which uses a stability-indicating analytical method for extending BUDs) is bracketed, the pharmacy's CNSP formulation is at or within the low and high concentration of each active ingredient within the stability study. ***If no, describe the concentrations cited in the stability study and the concentration of the CNSP compounded by the pharmacy.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.***	Yes		10.5

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
43.0	Does the pharmacy label any CNSPs with BUDs that extend beyond the maximum limits in Table 4 USP <795>?	Yes		10.5 Table 4
44.0	Does the pharmacy follow the requirements for labeling a CNSP with a BUD that exceeds Table 4 in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		10.5
44.1	The labeled BUD for an aqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	Yes		10.5
44.2	The labeled BUD for a nonaqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	Yes		10.5
44.3	Pharmacy is following the results of their own stability study. ***If the pharmacy only follows cited stability studies (does not conduct their own stability studies) for extending BUDs, answer this question as N/A.*** ***If pharmacy is following a bracketed study, inspector may mark this statement as yes if concentrations of CNSPs are at or within the concentrations specified within the study.*** ***If pharmacy is following a bracketed study and is using a concentration outside the study, answer this question as a no and describe observations.***	N/A		10.5

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
42.3	**Nonaqueous, Oral Liquid Dosage Forms:** The nonaqueous, oral liquid dosage form CNSP is labeled with a BUD that does not exceed 90 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous oral liquid dosage forms are ones that have a A_w < 0.6. Some examples of oral liquids that are nonaqueous include: oil-based oral solution or suspension.*** ***If pharmacy does not compound nonaqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>
42.4	**Nonaqueous Dosage Forms:** The nonaqueous dosage form CNSP is labeled with a BUD that does not exceed 180 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous (Solid) dosage forms are ones that have a A_w < 0.6. Some examples include capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.*** ***If pharmacy does not compound other nonaqueous solid dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes	The maximum BUD is 120 days.	10.4 Table 4 USP <659>

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
42.1	**Non-preserved, Aqueous Dosage Forms**: The non-preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 14 days with refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound non-preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	No	All of the non-preserved, aqueous dosage forms compounded are given BUDs of 120 days. The BUDs are developed from a validated Stability Indicating Assay, established by Compounder's International Analytical Laboratory, Castle Rock, CO. An example is provided in Doc02_NS42.1.	10.4 Table 4 USP <659>
42.2	**Preserved, Aqueous Dosage Forms:** The preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 35 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
40.3	Components used by the compounder match those listed in the monograph. ***If no, describe the source of the component in monograph and the source that the pharmacy used.***	N/A		10.5
40.4	The maximum BUD specified in the USP monograph is not exceeded. ***If no, identify the drug, monograph-stated BUD, and the BUD used by the pharmacy.***	N/A		10.5
41.0	Does the pharmacy compound CNSPs that are not available from a USP monograph?	Yes		10.4
42.0	Does the pharmacy adhere to the BUD (maximum) limits established in Table 4 for CNSPs in compliance with USP <795> standards? ***Inspector note: This question is for the CNSPs compounded that are <u>not</u> following a USP monograph or those CNSPs where extending BUD requirements were applied (where pharmacy has completed or has access to CNSP-Specific Stability Information). Per USP, the pharmacy is not required to measure water activity (A_w) for a CNSP.*** ***If no, go to compliance statements.*** ***If <u>all</u> CNSPs compounded at the pharmacy are following a USP monograph or the pharmacy is following a stability study that used a stability-indicating assay analytical method for the API, CNSP formulation, and material of composition of the container closure system, then the inspector should answer this question as N/A.***	No		10.4

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
37.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest BUD of any individual compounded components? ***Inspector note: Per USP, "For CNSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CNSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CNSP must not be negatively impacted." Another example of these "acceptable instances" (similar to pH-altering components mentioned above) inspectors may see are stock solutions (and other formulas within a formula) such as methocel 1%.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		10.4
38.0	Does the designated person(s) evaluate a CNSP formulation to establish the maximum BUD? ***If no, who establishes the maximum BUD for a MFR?***	Yes		7.1, 10.2, 10.3
39.0	Does the pharmacy compound CNSPs with a USP monograph?	No		10.5
40.0	Does the pharmacy compound CNSPs following the USP monograph precisely? ***If no, go to compliance statements.***	N/A		10.5
40.1	Pharmacy staff have access to the USP monograph for reference.	N/A		10.5
40.2	CNSPs are prepared in accordance with the USP monographs. ***If no, inspector to collect a copy of the compounding record, label; and describe what specific steps of the monograph were not followed.***	N/A		10.5

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
	Establishing Beyond Use Dating (BUDs)			
36.0	Is each CNSP assigned and labeled with a BUD in compliance with USP <795> standards? ***Inspector note: Per USP, the BUD is defined as, "The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded." This is not the same term as "expiration date." If no, go to compliance statements.***	Yes		10 USP <7>
36.1	CNSP label has a BUD that specifies the date, or the hour and date, beyond which the preparation cannot be used and must be discarded.	Yes		10.1
36.2	CNSP labels do not list an "expiration date" or equivalent language.	Yes		10.1
36.3	BUDs are assigned from the date (and time) of preparation.	Yes		10.1
36.4	BUDs are assigned based on dispensing in tight, light resistant containers/overpacks. ***Inspector note: Per USP, the Table 4 maximum limits for BUD are, "based on the ability of the CNSP to maintain chemical and physical stability and to suppress microbial growth. These BUDs represent the limit for CNSPs that are packaged in tight, light-resistant containers unless conditions in 10.4 CNSPs Requiring Shorter BUDs or 10.5 Extending BUDs for CNSPs apply."***	Yes		10.3
36.5	The BUD assigned to the CNSP does not exceed the shortest remaining expiration date of any of the commercially available starting components.	Yes		10.4

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
31.5	The label on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		9
31.6	The label on the immediate container includes the BUD. ***If no, please describe whether the pharmacy instead used the term "expiration date" or similar language or if this information was not included on the label.***	Yes		9
31.7	The label on the immediate container includes the dosage form.	Yes		9
31.8	The label on the immediate container includes the total amount or volume, if it is not obvious from the container.	Yes		9
32.0	Does the labeling on the dispensed CNSP include the route of administration? ***Inspector note: This is a USP recommendation.***	Yes		9
33.0	Does the labeling contain information identifying the CNSP as a compounded preparation? ***Inspector note: Per USP, this is a recommendation.***	Yes		9 USP <7>
34.0	Does the labeling on the dispensed CNSP display any applicable special handling instructions or warning statements? ***Inspector note: This is a USP recommendation.***	Yes		9
35.0	Does the labeling on the dispensed CNSP display the name of the compounding facility and contact information if the CNSP was to be sent outside of the facility or health care system? ***Inspector note: This is a USP recommendation.*** ***If the pharmacy only compounds CNSPs for patient use onsite (eg, a health care facility), inspector should answer this question as N/A .***	Yes		9

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
29.16	The CR shows traceability of all components in the case of a recall or known quality issue.	Yes		7.2, 12.1, 14
30.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes. These checks indicate that appropriate procedures for measuring/mixing are followed for each step, including pharmacist verification of steps performed by non-pharmacists and visual inspection of preparation.*** ***Inspector should describe their observations in the Inspector Notes.***	Yes	All measurements are confirmed by the weights of the components measured, using the specific gravity for the measurement of liquids. Measurements are communicated electronically to the CR and checked by a pharmacist. An electronic ElectricLab system manages the compounding process and retains all weights and measures, internal checks and technician and pharmacist confirmations.	2, 7.2, 8
	Labeling			
31.0	Are the pharmacy's labels for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		9
31.1	Information on the label is prominently and legibly displayed. ***Inspector note: Per USP, labeling includes other accompanying materials along with the CSP, which is defined as "All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container."***	Yes		9
31.2	The labeling meets any state or federal regulatory requirements.	Yes		1.1.3, 9
31.3	The label on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		9
31.4	The label on the immediate container includes the active ingredients and their amount(s), activity(ies), or concentration(s).	Yes		9

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
29.6	The CR has a method to identify the individual who completed the review and verified the final CNSP.	Yes		7.2, 14
29.7	The CR includes: name, vendor or manufacturer, lot number, and expiration date of each component.	Yes		7.2, 14
29.8	The CR includes the weight or measurement of each component.	Yes		7.2, 14
29.9	The CR identifies the total quantity compounded.	Yes		7.2, 14
29.10	The CR lists the assigned BUD and storage requirements.	Yes		7.2, 14
29.11	If applicable, the CR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of API.	Yes		7.2, 14
29.12	The CR has a physical description of the final CNSP.	Yes		7.2, 14
29.13	The CR includes the results of quality control procedures (eg, pH testing, visual inspection).	Yes		7.2, 14
29.14	The CR contains a MFR reference for the CNSP.	Yes		7.2, 14
29.15	Each CR is reviewed for completeness before the CNSP is released.	Yes		7.2, 8

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
28.8	Labeling requirements (eg, shake well) are described on the MFR.	Yes	There are no labeling requirements such as "shake well", or "external use only" on the printed MFR (printed MFRs are not used by the facility, only the electronic version is used). Labeling requirements do appear on the electronic version of the MFR which is what is used by the pharmacy.	7.1
28.9	If applicable, the MFR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of APIs.	Yes		7.1
28.10	An MFR has QC procedures (eg, pH testing, visual inspection) and expected results.	Yes		7.1
29.0	Does the pharmacy complete a Compounding Record (CR) for all CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and the CR (no PHI or PII is to be collected).***	Yes		7.2, 14
29.1	A CR is completed for each CNSP prepared.	Yes		7.2, 14
29.2	The CR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.2, 14
29.3	The CR includes the date (or date and time) the CNSP was prepared.	Yes		7.2, 14
29.4	The CR includes the assigned internal identification number (eg, prescription, order, or lot number).	Yes		7.2, 14
29.5	The CR has a method to identify the individuals involved in the compounding process of the CNSP.	Yes		7.2, 14

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
28.0	Does the pharmacy's MFRs contain all requirements in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and include as an attachment.***	Yes		7.1
28.1	MFR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.1
28.2	MFR identifies the identities and amounts of all components and, if applicable, relevant characteristics of components (eg, particle size, salt form, purity grade, solubility).	Yes		7.1
28.3	MFR includes the type of container–closure system(s).	Yes		7.1
28.4	MFR has complete instructions for preparing the CNSP, including equipment, supplies, and a description of the compounding steps. ***Inspector note: Per USP, the MFR will also include, "Other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature)." MFRs will include the detailed instructions necessary for an experienced compounder. Some examples of other details to ensure repeatability include, but are not limited to: speed duration, settings on equipment, and specific order of mixing (if applicable).*** ***Inspector should review several MFRs for completeness of instructions.***	Yes		7.1
28.5	MFR has a physical description of the final CNSP.	Yes		7.1
28.6	MFR includes the assigned beyond-use date (BUD) and storage requirements.	Yes		7.1
28.7	MFR contains the reference source to support the assigned BUD.	Yes		7.1

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
	Master Formulation Records (MFR) and Compounding Records (CR) **Inspector should review a minimum of five (5) MFRs and five (5) CRs.**			
27.0	Is an MFR created for each unique formulation of a CNSP in compliance with USP <795> standards? ***Inspector note: Per USP, an MFR is a detailed record of procedures that describes how the CNSP is to be prepared.*** ***If no, go to compliance statements.***	Yes		7.1
27.1	An MFR is created for each unique formulation.	Yes		7.1 Box2
27.2	Any changes or alterations to the MFR are approved and documented.	Yes		7.1
27.3	Does the designated person(s) or designee evaluate CNSP's characteristics when considering the assigned BUD for an MFR? ***Inspector note: Per USP, "When establishing a BUD for a CNSP, compounders must consider parameters that may affect quality, including but not limited to the following:*** ***- Chemical and physical stability properties of the API and any added substances in the preparation (e.g., if the API and added substances in the preparation are known to rapidly degrade over time and/or under certain storage conditions, reduce the strength of the preparation, or produce harmful impurities)*** ***- Compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, adsorption, and storage conditions)*** ***- Degradation of the container closure system, which can lead to a reduction in integrity of the CNSP*** ***- Potential for microbial proliferation in the CNSP (and)*** ***- Significant deviations from essential compounding steps and procedures; changes to essential compounding steps may have an impact on the stability of the formulation."***	Yes		7.1, 10.2 Table 4

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
25.0	When components are removed from the original container and not used in compounding (eg, excess after weighing), are they discarded and not returned to the original container (to minimize risk of contamination of the original component container)? ***Inspector note: This is a USP recommendation.***	Yes		6.2.4
26.0	Does the pharmacy maintain a chemical hazard, spill management, and disposal information program in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.5
26.1	Pharmacy staff have access to safety data sheets (SDS).	Yes		6.2.5
26.2	Pharmacy staff have documented, annual training for those who might have to clean up a spill.	Yes		6.2.5, 14
26.3	The pharmacy has a readily accessible spill kit in the compounding area.	Yes		6.2.5
26.4	The pharmacy has a process to manage and document any nonhazardous spills and disposal.	Yes		6.2.5
26.5	Waste of any component is disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.5

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
23.5	Any other lots of that (rejected) component from that vendor are examined to determine whether other lots have the same defect.	Yes		6.2.2
24.0	Does the pharmacy re-inspect all components before use and handle them in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.3, 6.2.4
24.1	Compounding personnel visually re-inspect each component, including packaging system (any evidence of container breakage, looseness of cap or closure) and deviation from the expected appearance or texture of the contents (that might have changed during storage).	Yes		6.2.3
24.2	Compounding personnel ascertain before use that components are the correct identity based on labeling, that they have been stored under required conditions, and there is no evidence of deterioration or other aspects of unacceptable quality before use of component.	Yes		6.2.3
24.3	Components where correct identity, strength, purity, and quality cannot be confirmed (eg, containers with damaged or incomplete labeling), are immediately rejected and if not immediately discarded, labeled as rejected and segregated from active stock.	Yes		6.2.3
24.4	Compounding personnel handle all components following facility SOPs, manufacturer's instructions/labeling, and laws/regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.4
24.5	All components are handled in a manner that minimizes the risk of contamination, mix-ups, and deterioration.	Yes		6.2.4

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
23.1	For non-conventionally manufactured components, the COA is reviewed upon receipt. ***Inspector note: Per USP, "the COA must be reviewed to ensure that the component has met the acceptance criteria in an appropriate USP–NF monograph, if one exists." Pharmacy's review should be documented. Alternatively, the pharmacy can demonstrate how it's been reviewed (for example, there are notes to show a water content calculation back to 100% based on the specific COA). Inspector can verify the COA is retrievable.***	Yes		6.2.2
23.2	The pharmacy documents specific information according to the facility's SOP, including: receipt date, quantity received, supplier name, lot number, expiration date, and the results of any testing performed (whether performed in-house or through a third-party).	Yes		6.2.2, 14
23.3	For all components that lack a vendor expiration date, the pharmacy clearly and indelibly marks on each packaging system received the date the component must no longer be used by the pharmacy. ***Inspector note: Per USP, "Packaging systems of components (i.e., API and added substances) that lack a vendor's expiration date must not be used by the compounding facility after 3 years from the date of receipt. A shorter expiration date must be assigned according to Pharmaceutical Compounding—Sterile Preparations 797 , 9.3.2 Component receipt if the same component container is also used in sterile compounding or if the ingredient is known to be susceptible to degradation."***	Yes		6.2.2
23.4	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		6.2.2

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
20.2	All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that the test results for the component show the API meets expected quality. ***Inspector note: Per USP, the API should be checked to ensure it is pharmaceutical grade and meets the requirements in the chemical monograph. COA will report an assay has been performed and will include water content (so any corrections/calculations can be performed).***	Yes		6.2.1
20.3	All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Food, Drug, and Cosmetic Act, Section 503A, requirement as well. If the API comes from a repackager, the pharmacy must be able to confirm the manufacturer of the API was registered as an Establishment with FDA.***	Yes		6.2.1
21.0	When formulations indicate the inclusion of water, is purified water or better quality (eg, sterile water for irrigation) used in compliance with USP <795> standards?	Yes		6.2.1
22.0	What type(s) of water is used for compounding CNSP? ***List the type(s) in the Inspector Notes.***	[redacted]	Purified water is used.	6.2.1
23.0	Do the pharmacy's component receipt processes comply with the requirements in USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.2

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
18.5	Equipment and devices are verified for accuracy as recommended by the manufacturer (at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent). ***If the pharmacy does not compound CNSPs that require equipment or devices that must be calibrated for accuracy (such as ones needed for weighing or measuring), the inspector should answer this statement as N/A.***	Yes		6.1
18.6	If a CVE or BSC is used by the pharmacy, it is certified at least every 12 months, according to the manufacturer specifications or regulations of the applicable regulatory jurisdiction. ***If the pharmacy does not have the record or documentation of the certification and maintenance of the CVE/BSC, the inspector should answer this statement as no. If the pharmacy does not have a CVE or BSC, the inspector should answer this statement as N/A.***	Yes		6.1
19.0	Does the pharmacy compounding CNSPs use APIs?	Yes		6.2
20.0	Does the pharmacy select APIs that comply with the requirements in USP <795> standards? ***Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.*** ***If no, go to compliance statements.***	Yes		6.2.1
20.1	APIs comply with criteria in the USP-NF monograph, if one exists. ***If the pharmacy does not compound any CSPs that have an available USP monograph, the inspector should answer this statement as N/A.***	Yes		6.2.1

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
18.2	Pharmacy has evaluated and documented the nonsterile compounding pharmacy activities for weighing, measuring, and otherwise manipulating for an assessment of risk. ***Inspector note: Per USP, "components that could generate airborne chemical particles (eg, active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs."*** ***If no, inspector should describe observations.***	Yes		6.1
18.3	The equipment and devices used for compounding CNSPs are clean and stored in a manner and frequency that minimizes the risk of contamination. ***Inspector note: Per USP <795>, "After compounding, the equipment must be cleaned to prevent cross contamination of the next preparation." Additionally, per Table 2:*** ***- CVE/BSC are cleaned and sanitized at the beginning and end of each shift when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected;*** ***- CVE/BSC horizontal surfaces are cleaned and sanitized between compounding of different components;*** ***- Under the work surface of a BSC is cleaned and sanitized at least monthly; and*** ***- Other devices and equipment used in compounding are cleaned before initial use, in between compounding CNSPs with different components, and following manufacturer recommendations.*** ***If no, inspector should describe observations.***	Yes		6.1 Table 2
18.4	Equipment and devices used in compounding or testing of CNSPs are inspected prior to use (to ensure they are in good working order). ***Inspector note: For example, the pharmacy may need to tare a scale and/or balance prior to use.***	Yes		6.1

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
	Equipment and Components			
17.0	Does the pharmacy use a closed-system processing device (eg, CVE, BSC, and single-use containment glove bags)? ***Inspector note: Per USP, examples of closed-system processing devices include: containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags.*** ***If yes, list the type(s) in the Inspector Notes.***	Yes	There are 8 CVEs for nonhazardous compounding and 2 BSCs for hazardous compounding.	6.1
18.0	Does the pharmacy select, store, clean, and maintain equipment in compliance with USP <795> standards? ***Inspector note: Per USP <795>, "Equipment surfaces that contact components are not reactive, additive, or sorptive, and must not alter the quality of CNSPs."*** ***Review certification reports, calibration records, and cleaning logs.*** ***If no, go to compliance statements.***	Yes		6.1
18.1	Equipment and supplies are readily available at the pharmacy for the types of CNSPs prepared. ***Inspector note: For example, if the pharmacy compounds with API as a component, which must be weighed, a scale or balance would be expected.***	Yes		6.1

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
15.3	All work surfaces are cleaned and sanitized **between compounding CNSPs with different components**.	Yes		5 Table 1
15.4	Floors are cleaned and sanitized daily on days when compounding occurs.	Yes		5 Table 1
15.5	Walls and ceilings are cleaned and sanitized when visibly soiled. ***Inspector note: No specific frequency is specified by USP. View compounding area walls and ceilings. If inspector observes soiled walls or ceilings, inspector should answer statement as no.***	Yes		5 Table 1
15.6	All work surfaces, floors, walls, ceilings and storage shelving are cleaned and sanitized when surface contamination (eg, splashes) or spills are known or suspected.	Yes		5 Table 1
15.7	Storage shelving is cleaned and sanitized at least every three months.	Yes		5 Table 1
16.0	Are floors in the compounding area easily cleanable, non-porous, and non-particle generating? ***Inspector note: This is a USP recommendation. Per USP, "Surfaces should be resistant to damage by cleaning and sanitizing agents."***	Yes		5

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
12.3	The sink is emptied of all items unrelated to compounding and before being used to clean any equipment used in nonsterile compounding.	Yes		4.3
12.4	The sink is cleaned when visibly soiled (before being used to clean equipment used in nonsterile compounding).	Yes		4.3
12.5	The plumbing system is free of any defects that may contribute to contamination of CNSPs.	Yes		4.3
13.0	Is purified water, distilled water, or reverse osmosis water used for rinsing equipment and utensils used in nonsterile compounding? ***Inspector note: This is a USP recommendation.***	Yes	Tap water is used.	4.3 USP <1231>
	Cleaning and Sanitizing			
14.0	What agent(s) are used for cleaning and sanitizing the nonsterile compounding area? ***Inspector note: Per USP <795>, "agents must be selected and used with consideration of compatibilities, effectiveness, and minimal potential to leave residues."*** ***List the agents in the Inspector Notes.***	[redacted]	PREmpt Plus RTU and 70% isopropyl alcohol are used.	5
15.0	Does the pharmacy perform cleaning and sanitizing activities on all surfaces at the minimum frequency per Table 1 and documented in a log or other record in compliance with USP <795> standards? ***Review compounding cleaning logs.*** ***If no, go to compliance statements.***	Yes	Cleaning and sanitizing records are recorded in Simplify.	5 Table 1
15.1	All work surfaces are cleaned and sanitized at the **beginning of each shift** on days when compounding occurs.	Yes		5 Table 1
15.2	All work surfaces are cleaned and sanitized at the **end of each shift** on days when compounding occurs.	Yes		5 Table 1

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
10.4	Pharmacy has a process to evaluate temperature excursions. ***Inspector note: Per USP, "When it is known that a CNSP or component has been exposed to temperatures either below or above the storage temperature limits for the CNSP or component, personnel must determine whether the CNSP or component integrity or quality has been compromised and if so, the CNSP or component must be discarded."***	Yes		4.2
10.5	CNSPs, components, equipment, and containers are stored off the floor.	Yes		4.2
10.6	CNSPs, components, equipment, and containers are stored in a manner that permits inspection and cleaning of the storage area(s).	Yes		4.2
10.7	CNSPs, components, equipment, and containers are stored in a clean environment (free of dirt, dust, and debris, and rodent/pest/insect free) to prevent contamination.	Yes		4.2
11.0	What is the current temperature of the nonsterile compounding storage area? ***Record in the Inspector Notes.***		The current temperature is 71.23 degrees F.	4.2
12.0	Are plumbing fixtures, water sources, and cleanliness of sink in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.3
12.1	The pharmacy staff can easily access a sink within or nearby the nonsterile compounding area.	Yes		4.3
12.2	There is hot and cold running water available at the sink within or nearby the nonsterile compounding area.	Yes		4.3

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
9.0	Is the compounding area free of carpet?	Yes		4.1
10.0	Does the pharmacy's storage area (for CNSPs, components, equipment, and containers) meet requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.2
10.1	The pharmacy records the temperature of the compounding storage area on days when the pharmacy is open. ***Inspector note: Per USP, "Compounding personnel must monitor temperatures in the storage area(s) either manually at least once daily on days that the facility is open, or continuously with a temperature recording device to ensure the temperature remains within the appropriate range for the CNSPs and components."*** ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes	A continuous electronic monitoring system is used with daily manual recording of temperatures.	4.2
10.2	The pharmacy's temperature monitoring records are readily retrievable. ***Inspector note: Per USP, "The results of the temperature readings must be documented on a temperature log or stored in the continuous temperature recording device and must be retrievable."***	Yes		4.2
10.3	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Per USP, "All temperature monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer." USP reports that these devices may be verified against a calibrated device.*** ***Monitoring devices are typically calibrated or replaced.***	Yes	Sensors are sent to the manufacturer's lab, Control Solutions, St. Helens, OR, an accredited calibration lab for Lascar Electronics, Erie, PA, on an annual basis.	4.2

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
8.2	The compounding area is well lit.	Yes		4.1
8.3	The compounding area is clean and sanitary.	Yes		4.1
8.4	The compounding area is orderly (eg, clutter free, no tripping hazards).	Yes		4.1
8.5	The compounding area is in a good state of repair.	Yes		4.1
8.6	The compounding area is designed for orderly placement of equipment and materials to prevent mix- ups among components, containers, labels, in-process materials, and finished CNSPs.	Yes		4.1
8.7	The compounding area is not being used for other activities at the same time that it is used for compounding.	Yes		4.1
8.8	The compounding area is designed, arranged, and used in a manner that minimizes cross contamination from non-compounding areas.	Yes		4.1

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
6.4	Additional garb (shoe covers, hair and facial hair covers, face masks, gowns) is worn as needed for protection of the personnel/CNSPs. ***If no, please list the garb worn for the type of component and compounding activity.***	Yes		3.3
6.5	The garb purchased by the pharmacy is appropriate for the type of compounding being performed.	Yes		3.3
6.6	Garb is stored in manner that minimizes risk of contamination (away from sinks to avoid splashing, etc).	Yes		3.3
6.7	Gowns that are reused do not leave the compounding area.	Yes		3.3
6.8	Visibly soiled garb or garb with tears or punctures are changed immediately (are not reused).	Yes		3.3
6.9	Soiled garb is disposed of or sent for laundering.	Yes		3.3
6.10	Shoe covers, hair and facial hair covers, face masks, and head covers are not reused once personnel have left the compounding area.	Yes		3.3
7.0	Are non-disposable garb such as goggles cleaned then sanitized with 70% isopropyl alcohol before re-use?	Yes		3.3
	Buildings and Facilities			
8.0	Does the compounding area meet the facility requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.1
8.1	The pharmacy has a designated compounding space for nonsterile compounding.	Yes		4.1

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
5.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in the compounding areas before their conditions have resolved.	N/A	There are no accommodations made.	3
5.3	Personnel removes any unnecessary items (outer garments, jewelry that could interfere with garbing, and earbuds/headphones) before entering the compounding area. ***Inspector note: Inspector should also observe compounding area to identify any items stored that do not belong (ie, dirty garments, jackets, or electronics).***	Yes		3.1
5.4	If personnel do not remove an item, the designated person has determined that the quality of the environment and CNSPs are not adversely affected by the accommodation.	Yes		3.1
6.0	Do personnel perform hand hygiene, wear required garb and gloves, and follow requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3
6.1	All personnel entering the compounding area complete hand hygiene procedures.	Yes		3.2 Box 1
6.2	Garb is used for all compounding activities. ***Inspector note: Per USP <795>, gloves are mandatory garb for all compounding activities.***	Yes		3.2, 3.3 Box 1
6.3	Pharmacy uses SDS to determine other garb requirements for the components and compounding activity.	Yes		3.3

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
3.3	All compounding personnel, including those who have direct oversight of compounding personnel, have completed an initial training and at least every 12 months thereafter. ***Inspector note: Per USP, "Other personnel, who do not compound and only perform functions such as in-process checks, final verification, or dispensing of CNSPs must undergo training as required by the facility's SOPs."*** ***If questions 2.0-2.12 in the records review tab for compounding personnel or personnel who have direct oversight over compounding personnel are answered "no" or "missing," this statement should be answered no. For details, see the Records Review module.***	Yes		2, 14
4.0	Does the designated person(s) have a documented (periodic) evaluation of their direct observations for compounding activities and documentation of any deficiencies in the record? ***Inspector note: Per USP, this is a recommendation, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*** ***Inspector should complete the <795> Records Review module question 3.0.***	No	The designated person reviews a synopsis of compounding competency evaluations performed by a Senior Compounding Technician responsible for evaluation of compounding activities. There is no documentation of direct observation by the designated person.	2, 14
	Compounding Personal Hygiene and Garbing			
5.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3
5.1	Compounding personnel are required to report to the designated person(s)conditions that may contaminate the compounding preparation area. ***Inspector note: Per USP <795>, examples of conditions that have a higher risk of contaminating the CNSP include: rashes, recent tattoos, open sores, conjunctivitis, and active respiratory infection.***	Yes		

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
2.7	The designated person(s) is responsible for establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs.	Yes		1.1.4
3.0	Has the pharmacy created and implemented a training program that is in compliance with USP <795> standards? ***Inspector note: Per USP, "Training and competency of personnel must be documented."*** ***Inspector is to review a minimum of five personnel records and document their observations (see <795> Records Review module).*** ***If no, go to compliance statements.***	Yes		2, 14
3.1	All personnel who compound CNSPs have been initially trained and qualified before being allowed to independently compound (eg, perform their job functions). ***Inspector note: Per USP, compounding personnel are defined as "Personnel trained to compound or oversee compounding of preparations."*** ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	Yes		2, 14
3.2	All personnel who have direct oversight, perform in-process checks, final verification of a CNSP, and/or dispense a CNSP have been initially trained and qualified (according to SOPs) being allowed to independently perform their job functions. ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	Yes		2, 14

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
2.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		1.1.4, 12
2.2	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented. ***Inspector note: Per USP, "The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program... The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed."***	Yes		1.1.4, 12
2.3	The designated person(s) is responsible for overseeing a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs.	Yes		1.1.4, 2
2.4	The designated person(s) is responsible for selecting components used by the pharmacy.	Yes		1.1.4, 6.2.1
2.5	The designated person(s) is responsible for monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed.	Yes		1.1.4
2.6	The designated person(s) is responsible for ensuring SOPs are fully implemented and following up if problems, deviations, or errors are identified.	Yes		1.1.4, 11

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
1.14	**Recalls:** The pharmacy has an SOP describing minimum requirements for recalls. ***Inspector note: Per USP, "The facility must have procedures in place to:*** ***- Determine when recalls must be initiated, which should include procedures to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, strength, purity, or other quality attributes)*** ***- Recall any unused dispensed CNSPs and quarantine any stock remaining in the pharmacy*** ***- Investigate if other lots are affected and recall if necessary*** ***An SOP for recall of dispensed CNSPs must contain:*** ***- Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall*** ***- Procedures to determine the distribution of any affected CNSP, including the data and quantity of distribution*** ***- Procedures to identify patients who have received the CNSP*** ***- Procedures for disposal and documentation of the recalled CNSP (and)*** ***- Procedures to investigate and document the reason for recall."***	[redacted]	Recall Procedures 5000-150a. All are effective 3/1/2024.	12.1
	Designated Person(s) and Personnel Training Program **Inspector must complete the <795> Records Review module to complete this section.**			
2.0	Does the pharmacy have a designated person(s) who meets the requirements in USP <795> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CNSPs."*** ***If no, go to compliance statements.***	Yes		1.1.4

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
1.11	**QA/QC Program Complaint Handling and Adverse Event Reporting:** The pharmacy has an SOP for evaluation of complaints and adverse events, including investigations and corrective actions. ***Inspector note: Per USP <795>, the pharmacy, "must develop and implement SOPs for complaint handling." SOPs are to include any state or federal requirements for reporting to government agencies (example adverse event reporting). Further, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease compounding until problems have been identified and corrected."***	[redacted]	Complaint Management 6000-150a; Patient-Reported Adverse Drug Event 6000-140a; Quality Assurance for Compounding 6000-170a. All are effective 3/1/2024.	1.1.3, 11, 12.1, 12.2, 12.3
1.12	**Packaging:** The pharmacy has an SOP describing packaging CNSPs. ***Inspector note: Per USP <795>, "SOPs must describe packaging of CNSPs."***		Compounded Preparation Storage and Dispensing 2000-190a. All are effective 3/1/2024.	11, 13.1
1.13	**Transporting:** The pharmacy has an SOP describing transporting CNSPs. ***Inspector note: Per USP <795>, there must be "written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed."*** ***If the pharmacy does not transport CNSPs, inspector should answer statement as N/A.***		Compounded Preparation Storage and Dispensing 2000-190a. All are effective 3/1/2024.	11, 13.2

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
1.7	**Safety Data Sheet (SDS)/Spill Management:** The pharmacy has an SOP describing spill management and disposal. ***Inspector note: Per USP <795>, "The management and documentation of nonhazardous component spills and disposal must be described in the facility's SOPs."***		Hazardous Drugs - Spills, Breakage and Exposure 8000-200a. All are effective 3/1/2024. (used for all spills)	6.2.5, 11
1.8	**Master Formulation Records (MFR):** The pharmacy has an SOP on the process for MFR creation and content. ***Inspector note: Per USP <795>, "Any changes or alterations to a Master Formulation Record are approved and documented in accordance with the facility's written SOP."***		Master Formulation Record (MFR) 7000-120a. All are effective 3/1/2024.	7.1, 11
1.9	**Labeling:** The pharmacy has an SOP on the processes for labeling, label verification (confirming against the prescription or medication order, the MFR, and the compounding record (CR)) in order to prevent errors and CNSP mix-ups and required displayed information. ***Inspector note: Per USP <795>, "Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups."***		Labeling of Compounded Prescriptions 2000-220a. All are effective 3/1/2024.	9, 11
1.10	**Quality Assurance (QA)/Quality Control (QC) Program:** The pharmacy has an SOP regarding its QA and QC program, including roles of the designated person(s), trainers, compounding personnel; adherence to procedures; and prevention and detection of errors and quality issues. ***Inspector note: Per USP <795>, "QA and QC programs must be formally established and documented in SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with this chapter, and laws and regulations of the applicable regulatory jurisdiction."***		Quality Assurance for Compounding 6000-170a; Finished Preparation Quality Control Program 6000-180a; Quality Related Events 6000-130a; Performance Improvement (PI) Monitoring 6000-120a. All are effective 3/1/2024.	11, 12 USP <1163>

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
1.3	**Personal Hygiene and Garbing:** The pharmacy has an SOP regarding personal hygiene, glove, and garbing requirements consistent with compounding activities. ***Inspector note: Per USP <795>, "Garbing requirements and frequency of changing garb must be determined by the facility and documented in the facility's SOPs."***	[redacted]	Hand Hygiene, Nonsterile Compounding 8000-210a; Respiratory Protection Program 4000-220a. All are effective 3/1/2024.	3.3, 11
1.4	**Components:** The pharmacy has an SOP describing selection, handling, storage, and inventory control of all components used in compounding. ***Inspector note: Per USP <795>, "The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP."***		Selection and Receipt of Bulk Drug Substances 5000-120a; Storage and Monitoring of Materials 5000-130a; Compounding Process 2000-180a. All are effective 3/1/2024.	6.2, 11
1.5	**Temperature Monitoring:** The pharmacy has an SOP regarding temperature monitoring and handling of excursions. ***Inspector note: Per USP <795>, "The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s)."***		Storage and Monitoring of Materials 5000-130a; Compounded Preparation Storage and Dispensing 2000-190a. All are effective 3/1/2024.	4.2, 11
1.6	**Equipment**: The pharmacy has an SOP for assessment of need for closed system processing devices (based on the types of CNSPs prepared). ***Inspector note: Per USP <795>, "Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples of closed-system processing devices include containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags. The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented."***		Nonsterile Compounding Pharmacy Specifications 3000-100a; Compounding Process (Nonhazardous) 2000-180a. All are effective 3/1/2024.	6.1, 11

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions

e-Profile ID: 1470017

Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures for Compounded Nonsterile Preparations (CNSPs)		**Please note NABP did not review each SOP for alignment on USP <795>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**	
1.0	Does the pharmacy have standard operating procedures (SOPs) on all aspects of the compounding operation that cover the minimum topic requirements in USP <795> standards? ***If no, document "missing" in Inspector Notes*** ***If yes, document the name, number, and version of each SOP in the Inspector Notes.***	Yes		11
1.1	**Buildings and Facilities:** The pharmacy has an SOP for the compounding facility. ***Inspector note: Per USP <795>, there is a written SOP for "the method of designation" for the area designated specifically for nonsterile compounding and processes for maintaining, cleaning, and sanitizing the compounding area and equipment.***	[redacted]	Nonsterile Compounding Pharmacy Specifications 3000-100a; Compounding Lab Cleaning and Sanitizing 3000-120a; Compounding Lab Equipment Maintenance and Supplies 3000-130a. All are effective 3/1/2024.	4.1, 5, 11
1.2	**Personnel Training and Evaluation:** The pharmacy has an SOP describing the training program, the frequency of training, and the process for evaluating the competency of personnel. ***Inspector note: Per USP <795>, "Facility SOPs must describe procedures for monitoring and observing of compounding activities and personnel."***	[redacted]	Pharmacy Training 4000-190a; Competency Assessment 4000-250a; Finished Preparation Quality Control Program 6000-180a; All are effective 3/1/2024.	2, 11

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Notes
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	No	
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	N/A	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	These are performed monthly.
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	No	
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Notes
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	Yes	The on site Quality department reviews each event. The Quality team and leadership also review data monthly and quarterly.
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	N/A	
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	N/A	There is no formulary used.
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Notes
	Quality Assurance/Quality Improvement Program **If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	The CQI program is overseen by Ralph Michael Bonofiglio.
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	P & P is both hard copy and electronic.
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	Training is part of the onboarding process with a mix of Power Point and live discussions with the new employee. DocuSign is used to record annual training.
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	Initial documentation is an electronic form.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Notes
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin or Tikosyn).*	N/A	There are no REMS drugs dispensed.
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	Yes	There is electronic documentation that the patient education information was included in the shipment.
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).*	No	The toll free number provides a voice mail which is responded to within 24 hours
85.00	Are processes in place to handle a drug recall?	Yes	
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Notes
76.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	N/A	This is a closed door pharmacy.
77.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	N/A	This is a closed door pharmacy.
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer".*	N/A	This is a closed door pharmacy.
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	N/A	There are no delivered prescriptions.
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	All prescriptions are shipped with printed materials specific to that prescription. A toll-free phone number is on each prescription label and on all printed information shipped with the prescription.
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	N/A	There are no drugs dispensed requiring PPIs.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	N/A	There are no drugs dispensed requiring MedGuides.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Notes
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
	Patient Counseling and Communication **If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all <u>new</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	N/A	This is a closed door pharmacy.
75.01	Is an "offer" to counsel made for all <u>new</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	N/A	This is a closed door pharmacy.
76.00	Does the pharmacist provide counseling for all <u>refilled</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	N/A	This is a closed door pharmacy.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Notes
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	Yes	A progress note in added for the prescription, the prescription is rejected, and steps taken to contact the prescriber are noted.
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	N/A	There are no veterinary prescriptions.
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	At PV2, a pharmacist scans the patient label, and compares the data to the prescription. The batch label is scanned and compared to the prescription. Documentation is electronically maintained in the system using the pharmacist's logon credentials.
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	The pharmacy system prints a label that is unique for each state where required and consistent with all state requirements.
70.00	**Confidentiality**: Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	The system is password protected with access limited by job type. The system used is proprietary and named Admin.
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	There are no vials. The Shred Truck comes on an as needed basis for document shredding.
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Notes
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	DUR occurs at the PV1 station.
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	Yes	There are no other parameters included.
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	Yes	The facility uses a short protocol DUR list for most patient conditions.
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	Pharmacists Letter, Facts and Comparisons and any relevant references are available.
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	Zero reporting is provided to states as required.
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	N/A	There are no controlled substances dispersed.
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	There are no overrides permitted. Should a DUR occur, the pharmacist contacts the prescriber for a change in the mediation prescribed.
67.07	Is the DUR process performed electronically by the computer system? ***Identify integrated drug database used.***	No	All DUR is manual.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Notes
	Prescription Processing **If any part of a question is no, enter "No" and explain the observation.**		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	Patient data is transferred electronically to the pharmacy system by the prescriber system. Data is updated by the prescriber. There is no data entry by staff.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	N/A	There are no veterinary prescriptions.
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	All prescription orders come only from telehealth provider group, and as part of the MSA the facility has access to all licensing and other necessary or appropriate information regarding the prescribers.
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Yes	One of the telehealth provider group supervising providers would be contacted for investigation. All prescriptions are transmitted electronically from telehealth provider group.
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	The MSA agreement between the pharmacy and telehealth provider group requires assurance from telehealth provider group that the patient/prescriber relationship meets the requirements of the prescriber's state, the patient's state of residence, and the facility.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	The system may have controlled substance capabilities, however, none are stocked and none are prescribed by the telehealth provider group source.
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	N/A	
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	Pharmacists perform PV1 analysis of the prescription using the patient's medical condition and data provided by the prescriber, and electronically communicated to the pharmacy system.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Notes
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	All APIs are checked daily by the Inventory team for expiration date. There are no manufactured prescription or OTC drugs stocked.
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	
60.02	How often is active-stock examined for drugs past the expiration date?		APIs are checked daily by the Inventory team for expiration.
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	There are no manufactured drugs stocked.
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	N/A	
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	N/A	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Notes
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	A perpetual inventory is maintained electronically.
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	Incidents may be reported to Board of Pharmacy, and local law enforcement if appropriate.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	N/A	There are no controlled substances.
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	N/A	There are no controlled substances.
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	N/A	There are no controlled substances.
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	N/A	There are no controlled substances.
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Notes
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	None to date.
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	N/A	There are no DSCSA drugs.
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	This procedure is for APIs only.
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	N/A	There are no controlled substances.
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	N/A	There are no controlled substances.
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	N/A	There are no controlled substances.
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	N/A	There are no controlled substances.
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Notes
	Product Receipt and Inventory **If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	N/A	There are no manufactured drugs purchased or used by this pharmacy. All drugs used are APIs and must be purchased from an FDA registered facility.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	N/A	There are no manufactured drugs purchased or used by this pharmacy. All drugs used are APIs and must be purchased from an FDA registered facility.
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	No	
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	N/A	There are no manufactured drugs purchased or used by this pharmacy. All drugs used are APIs and must be purchased from an FDA registered facility. Darmerica, Fagron/Letco, Medisca and Willow Birch are sources of APIs.
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	N/A	There are no manufactured drugs purchased or used by this pharmacy. All drugs used are APIs and must be purchased from an FDA registered facility.
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	N/A	There are no manufactured drugs purchased or used by this pharmacy. All drugs used are APIs and must be purchased from an FDA registered facility.
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	N/A	The facility uses only APIs.
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	N/A	The facility uses only APIs.
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	N/A	There are no manufactured drugs purchased or used by this pharmacy. All APIs are examined upon receipt and moved to quarantine if suspect. The source is contacted for investigation.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Notes
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	N/A	There are no refrigerated or frozen drugs or components.
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	There are no refrigerated or frozen drugs or components.
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	N/A	There are no refrigerated or frozen drugs or components.
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	There are no refrigerated or frozen drugs or components.
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	N/A	There are no refrigerated or frozen drugs or components.
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	There is an on site generator, however, there is no refrigerated or frozen material.
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	Multiple heating and AC units can manage all heated and cooled areas of the facility. Should one unit fail, the other units can manage the facility.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	Manufacturers are contacted for stability studies when necessary.
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	N/A	
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	N/A	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Notes
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	N/A	There are no manufactured prescription drugs and nothing is destroyed onsite.
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	Safety Kleen is the reverse distributor.
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	Yes	Safety Kleen is the hazardous waste manager and picks up as needed.
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	N/A	This is a closed door pharmacy.
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Yes	The temperature is thermostatically controlled by staff. The CRT area is currently 71.23 degrees F.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process.*	Yes	A Lascar EasyLog data logger system is used to continuously and electronically record the temperature. The temperature is also manually recorded once daily.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	COAs are reviewed and manufacturers are contacted for stability studies if studies are available. Per staff interviewed, APIs are never used if there is any question regarding the integrity of the API.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Notes
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	N/A	
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	This is part of P & P.
	Personnel **If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	The Licensing Coordinator reviews all personnel licenses quarterly for all states where licenses are held, using primary source verification. The licensing information is documented in a spreadsheet.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	The Licensing Coordinator reviews all facility licenses quarterly for all states where licenses are held, using primary source verification. The licensing is documented in a spreadsheet.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	N/A	There is no ratio requirement in Missouri.
	Facility and Security **If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	The system is an Avigilon Alta system and consists of magnetic door sensors, electronic badge readers, and cameras. There are no motion detection devices. Access is based on job description and limits access as required. Alarms are sent to the PIC.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	N/A	
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	A pharmacist is required to stay on site until security can be restored.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Notes
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	Yes	ACHC accredited the pharmacy for PCAB from a survey dated 7/27/2022 and for Hazardous Drug Handling, also from a survey dated 7/27/2022.
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	Records are maintained on site infinitely.
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	Yes	Records are maintained on site infinitely.
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronic prescriptions are maintained electronically.
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Dispensing records are maintained electronically.
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Pharmacy records cannot be deleted and are maintained electronically.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Notes
	General Operations and Licensure **If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	No	The pharmacy is closed door, however, all licenses are posted inside the pharmacy.
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	The Missouri Board of Pharmacy inspected the pharmacy on 3/9/2023. The state inspects approximately every 18 months.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	No	No deficiencies were noted.
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	No	Some states require zero reporting for controlled substances, and some states provide waivers for CS reporting.
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Notes
	Types of Practice Additional Questions **If any part of a question is no, enter "No" and explain the observation.**		
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	No	
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Skin Specialty Solutions Inc dba Skin Specialty Solutions
e-Profile ID: 1470017
Inspection Date: 07/02/2024 - 07/03/2024

		Observation	Notes
	General Pharmacy		
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	The PIC is on site approximately 40 hours per week.
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	No	
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	N/A	There are no websites.
4.01	Does the pharmacy hold .pharmacy verification?	No	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	N/A	There are no websites.
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	N/A	There are no websites.
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	N/A	There are no websites.
8.00	Are photographs allowed during the inspection (**no PHI**)?	Yes	
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**		Ralph Michael Bonofiglio, the designated person, played a major role in this inspection. Also, Michael Spinner provided key information for the nonsterile compounding portion of the inspection.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):

Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)	1422	0	June 2024
Nevada (NV)	2346	0	June 2024
New Hampshire (NH)			
New Jersey (NJ)			
New Mexico (NM)	1627	0	June 2024
New York (NY)			
North Carolina (NC)			
North Dakota (ND)			
Ohio (OH)			
Oklahoma (OK)	1992	0	June 2024
Oregon (OR)	2685	0	June 2024
Pennsylvania (PA)			
Rhode Island (RI)			
South Carolina (SC)			
South Dakota (SD)			
Tennessee (TN)			
Texas (TX)	18843	0	June 2024
Utah (UT)	2838	0	June 2024
Vermont (VT)			
Virginia (VA)			
Washington (WA)	6590	0	June 2024
West Virginia (WV)			
Wisconsin (WI)			
Wyoming (WY)	549	0	June 2024
Other:			

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)			
Alaska (AK)	494	0	June 2024
Arizona (AZ)	5288	0	June 2024
Arkansas (AR)	783	0	June 2024
California (CA)	31887	0	June 2024
Colorado (CO)	5660	0	June 2024
Connecticut (CT)			
Delaware (DE)			
District of Columbia (DC)			
Florida (FL)			
Georgia (GA)			
Hawaii (HI)	1238	0	June 2024
Idaho (ID)	1181	0	June 2024
Illinois (IL)	7223	0	June 2024
Indiana (IN)			
Iowa (IA)	1670	0	June 2024
Kansas (KS)	1602	0	June 2024
Kentucky (KY)			
Louisiana (LA)			
Maine (ME)			
Maryland (MD)			
Massachusetts (MA)			
Michigan (MI)			
Minnesota (MN)	4385	0	June 2024
Mississippi (MS)	647	0	June 2024
Missouri (MO)	3940	0	June 2024
Montana (MT)	822	0	June 2024

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample)	N/A
Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason.	N/A

	Volume Dispensed		Volume Distributed
Total Prescriptions Dispensed/day:	4500	Total Orders Distributed/day:	0
% Veterinary Prescriptions	0%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	0%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	100%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	0%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	33%	% Hazardous Drugs (HD) Orders	0%

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Facility Size in Square Feet *(can be approximated)* and Number of PECs		Personnel	
Total Pharmacy size:	48080	Total Pharmacists:	9
Nonsterile Compounding Room size:	7500	Number of Compounding Pharmacists:	9
Nonsterile Compounding powder hoods number:	8	Total Student Interns:	0
Nonsterile Hazardous Drugs (HD) Compounding Room size:	1880	Total Technicians:	46
Nonsterile HD Compounding CVE/BSC/CACI hoods number:	2	Number of Compounding Technicians:	4
Sterile Compounding Ante Room size:	N/A	Of technicians, how many are nationally certified?	1
Sterile Compounding Clean/Buffer Room size:	N/A	Of technicians, how many are techs-in-training?	0
Sterile Compounding Number LAFW hoods/areas:	0	Total Other Unlicensed Personnel:	0
Sterile Compounding Number BSC hoods:	0	Ratio #Technician(s) : #Pharmacist(s) present at time of inspection:	4:1
Sterile Compounding Number CAI/CACI hoods:	0	If multiple compounding suites are present under this licensed location (eg outsourcing facilities or hospital health systems), describe in notes other spaces where compounding occurs (eg location name, approximate size of space, and number and type of PECs:	N/A
Negative Pressure Sterile HD Room size:	N/A		
Sterile HD Compounding Number of BSC hoods:	0		
Sterile HD Compounding Number of CACI hoods:	0		

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Types of CNSPs:		Categories of CSPs:	
Aqueous	X	Category 1 CSPs	
Nonaqueous	X	Category 2 CSPs	
Specific types:		Category 3 CSPs	
Solid oral preparations		Types of CSPs:	
Liquid oral preparations		Allergenic extracts	
Otic preparations		Allergenic extracts in addition to prescription patient sets	
Rectal preparations		Immediate Use	
Vaginal preparations		Proprietary bag and vial systems	
Topical preparations:	X	Blood-derived or other biological material (eg autologous serum)	
Nasal and sinus preparations:		Sterile injections/ sterile infusions	
Other (please list):		Ophthalmic dosage forms	
		Baths and soaks for live organs and tissues	
		Implants/ Pellets	
		Other (please list):	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply		Compounded Sterile Preparations (CSPs) Type "X" for all that apply	
CNSPs with controlled substance(s)		CSPs with controlled substance(s)	
CNSPs with vitamins or nutritional supplements		CSPs with vitamins or nutritional supplements (includes total parenteral nutrition)	
CNSPs sold to other pharmacies - If so, list to whom – instate, out of state, under common ownership/shared services – central fill agreement; and state if patient specific or distributed		CSPs sold to other pharmacies - If so, list to whom - in state, out of state, under common ownership/shared services - central fill agreement; and state if patient specific or distributed	
Patient specific (compounded preparation labeled for an individually identified patient):		**Patient specific** (compounded preparation labeled for an individually identified patient):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients	X	CSPs for human patients	
Distributed (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):		**Distributed** (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
CNSPs to practitioners for office use		CSPs to practitioners for office use	
CNSPs to hospitals, clinics, or surgery centers		CSPs to hospitals, clinics, or surgery centers	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail		Central Fill/Processing/Shared Services	
Open to the Public		Nuclear Pharmacy	
Closed Door	X	Specialty Pharmacy	
Drive-through window		White bagging/ clear bagging	
Mail- in state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	Outsourcing Facility	
Mail- out of state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	FDA Registered Drug Establishment (eg Manufacturer, repackager, relabeler)	
Local Delivery (if out of state describe in note)		Wholesale Distributor	
Veterinary Pharmacy (occasionally dispenses prescriptions for animals)		Provide prescription drugs for "Office Use" (eg distributes)	
Institutional (hospital or correctional facility)		Handles Medical Marijuana	
Long-Term Care (nursing home, residential care)		Nonsterile Compounding	X
Investigational Drugs, Clinical Trials/Research		Nonsterile Hazardous Drug Compounding	X
Telepharmacy		Sterile Compounding	
Internet Pharmacy		Sterile Hazardous Drug Compounding	

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Business Licensure Information for State of Residence and Federal

(board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
Missouri Division of Professional Registration	Skin Specialty Solutions, Inc	Pharmacy	2019007736 - Exp - 10/31/2025

Inspector Notes: Non resident licenses are held in AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MD, ME, MI, MN, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, and WY. This pharmacy is a closed door pharmacy which compounds and dispenses only nonsterile and nonsterile hazardous prescription medications consisting only of topical acne and anti-aging medications. There is no DEA registration as controlled substances are not stocked or dispensed. The pharmacy has an MSA a telehealth provider group operating out of San Francisco, CA. Each patient connects with one of over 100 licensed dermatology providers. The staff was unable to provide significant details regarding the MSA with telehealth provider group other than they stated they can contact telehealth provider group for any licensure or other information regarding a prescriber or a prescription. The staff also stated telehealth provider group was responsible for verification of prescriber licenses and for ensuring that the telehealth interactions between telehealth provider group prescribers and patients meet the requirements of all states involved in the interaction. These providers discuss the medical issue with the patient, review photos and/or live video of the patient's skin and prescribe a personalized topical formula. Of the 46 licensed technicians, two technicians performs HR functions, two technicians perform IT functions, and two technicians are administrative personnel. There is no insulin stocked and there was no ReliOn insulin observed. The PIC stated there are no marketplaces used which are a platform to buy, sell, and bid on overstock and short date prescription drugs. A copy of a COA for one API from each API supplier is attached to this inspection report. Please see Doc01_PI. There are no biologicals compounded and no semaglutide compounded. There is no white bagging performed.

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description
Doc01_PI	A COA for an API from each API supplier
Doc02_NS42.1	MFR, CR, and label for a non-preserved, aqueous dosage forms compounded with a BUDs of 120 days

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	(X)
Sunday			X
Monday	8:00	16:30	
Tuesday	8:00	16:30	
Wednesday	8:00	16:30	
Thursday	8:00	16:30	
Friday	8:00	16:30	
Saturday			X

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	Sara Rumpel	sarapharmd@skinspecialtysolutions.com	295821
Nonsterile Designated person(s)	Ralph Michael Bonofiglio	mike.bonofiglio.rph@skinspecialtysolutions.com	202745
Sterile Designated person(s)	N/A	N/A	N/A
Hazardous Designated person(s)	Ralph Michael Bonofiglio	mike.bonofiglio.rph@skinspecialtysolutions.com	202745

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Ralph Michael Bonofiglio	Designated Person/Pharmacist	Y
2	Sara Rumpel	PIC	Y
3	Alyssa Hanebrink	Pharmacist	Y
4	LeeAnn Hart	Pharmacist	Y
5	Christine Hillis	Pharmacist	Y
6	Jaicy Joseph	Pharmacist	Y
7	Jacob Krebs	Pharmacist	Y
8	Michael Spinner	Pharmacist	Y
9	Paige Alexander	Technician	Y
10	Dawn Aston	Technician	Y

In addition to the above, there were 31 technicians present.

Copyright © March 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Business e-Profile ID:	1470017		**Inspection Information**
Legal Business Name:	Skin Specialty Solutions Inc	**Conference Call Date:**	7/2/2024
Doing Business As (DBA):	Skin Specialty Solutions	**Start Time: 24-hour format (13:00)**	9:20
Address:	2058 Fenton Logistics Park	**End Time: 24-hour format (13:00)**	10:10
City:	Fenton	**Onsite Inspection Date(s):**	7/3/2024
State:	Missouri	**Start Time(s): 24-hour format (13:00)**	8:16
Zip Code:	63026	**End Time(s): 24-hour format (13:00)**	14:22
Telephone number:	877-273-1777	**Inspector Name(s):**	Howard Kramer RPh/ Jason Smith
Toll free number:	877-273-1777	**Inspection performed by (NABP, State, etc):**	NABP
Fax number:	724-213-1905	**Observer Name/Affiliation (if applicable):**	N/A
Website:	N/A	**Observer Name/Affiliation (if applicable):**	N/A

Focused Information

The following, if any, are specific Section(s) and/or Question(s) to which the facility may want to consider further response. The facility is encouraged to read the inspection report in its entirety and carefully. As this Focused Information section is not all inclusive, there may be Section(s) and/or Question(s) not noted below to which the facility may want to consider further response.

General Pharmacy- 91.00 and 93.00
Nonsterile - 4.0, 42.0, and 42.11
Hazardous- 13.14.03, 13.22.07 and 73.03

Additional information on NABP's Inspection website.

NABP Disclaimer: NABP can only verify the authenticity of an Inspection Report if it is transmitted directly from NABP to an intended recipient. NABP cannot verify the authenticity of an Inspection Report transmitted from any other party.

4DDD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 02913	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: FT3066594 ☒ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Triad Rx, Inc.

Physical Address: 26258 Pollard Rd.

City: Daphne State: AL Zip: 36526

Mailing Address (if different from physical address): PO BOX 1530

City: Daphne State: AL Zip: 36526

Telephone: 251-380-7630 Toll Free # (NAC 639.708, NRS 639.23286): 855-288-0135

Fax: 251-621-9914 Contact Email: maria@triadrx.com

Website: https://triadrx.us

Nevada Business License # (if applicable) PH02913

Supervising/Managing Pharmacist Name (NRS 639.220): Robert Reyburn Roberts, III

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21165

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Robert Reyburn Roberts, III	NV Pharmacist Registration #: 21165
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Alabama

Parent Company (if any):

Corporation/Organization Name: Triad Rx, Inc.

Mailing Address: 26258 Pollard Rd.

City: Daphne State: AL Zip: 36526

Telephone: 251-380-7630 Email: maria@triadrx.com

Contact Person Name: Mariia Kostiukova

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President/Owner (title) for Triad Rx, Inc (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

David Edwin Lindsey

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

8/26/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Robert R. Roberts hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist In Charge (title) for Triad Rx, Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Robert R. Roberts III
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this twenty sixth day of August, 2024

Mariia Kostiukova
Notary Public

MARIIA KOSTIUKOVA
NOTARY PUBLIC
ALABAMA - STATE AT LARGE
My Commission Expires April 27, 2027

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Edwin Lindsey

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

8/26/24

Date

Board Use Only	Date Received: 9/17/24	Amount: $500-ck 5695

Wes Allen
Secretary of State

P.O. Box 5616
Montgomery, AL 36103-5616

STATE OF ALABAMA

I, Wes Allen, Secretary of State of Alabama, having custody of the Great and Principal Seal of said State, do hereby certify that

the entity records on file in this office disclose that TRIAD RX, INC. was formed in Baldwin County on January 9, 2012. The Alabama Entity Identification number for this entity is 000-036-902. I further certify that the records do not disclose that said entity has been dissolved, cancelled or terminated.

In Testimony Whereof, I have hereunto set my hand and affixed the Great Seal of the State, at the Capitol, in the city of Montgomery, on this day.

08/21/2024

Date

Wes Allen **Secretary of State**

20240821000003084



DEMOGRAPHICS

☒ Not Licensed

AL License Number	DEA Number	Status
113869	FT3066594	Closed - Compliant
Supervising Pharmacist	**Supervising Pharmacist-License**	**Supervising Pharmacist Email**
ROBERT REYBURN ROBERTS	12683	ROB@TRIADRX.COM
Pharmacist Assisting	**Pharmacist Assisting License**	**Pharmacist Assisting Email**
SARAH WADE SIEFERT	16775	sarah.siefert@gmail.com
Inspection Type	**Inspection Date**	**Inspector Name**
Routine	12/27/2023	cshaw

☒ Case Number

SEE SEPARATE USP 795 NON-STERILE INSPECTION REPORT

ADDRESS INFORMATION

Address 1 : 26258 POLLARD ROAD

Address 2 :

City : DAPHNE

State / Zip : AL 36526

REQUIREMENT

Pharmacy space and layout 16 sq. ft counter space; 24 sq ft if 2 or more pharmacists.	☒ Yes	☐ No	☐ N/A	
Non-sterile compounding pharmacy.				34-23-71
Reference Books or online data: Facts and Comparisons.	☒ Yes	☐ No	☐ N/A	
All required licenses and permits are displayed prominently	☒ Yes	☐ No	☐ N/A	34-23-70(b)
Private consultation area available.	☒ Yes	☐ No	☐ N/A	680-X-2-.27
Is the method used to collect patient signatures to approve or refuse pharmacist counseling HIPAA compliant? (Signatures should not be visible to other customers)	☒ Yes	☐ No	☐ N/A	
Pharmacy Staff makes verbal offer to counsel on each new prescription.	☒ Yes	☐ No	☐ N/A	680-x-2-.21
Access to pharmacy (keys or code) with pharmacist only.	☐ Yes	☒ No	☐ N/A	680-X-2-.11
Designated Key Holder (List Name) (Approval Form must be posted in pharmacy)	☐ Yes	☐ No	☒ N/A	680-X-2-.11
Refrigerator is clean, temperature between 2 – 8 degrees C, or 36-46 degrees F.	☐ Yes	☐ No	☐ N/A	
Continuously monitored. Alerts if out of range.				
Only drug related products stored in refrigerator.	☐ Yes	☐ No	☐ N/A	

Prescription area is clean and orderly. Minimal chance to confuse orders. ☑ Yes ☐ No ☐ N/A

Daily, Weekly, and monthly cleaning log maintained.

Drugs in date; ☑ Yes ☐ No ☐ N/A

34-23-9

Drugs purchased from reputable sources. ☑ Yes ☐ No ☐ N/A

34-23-32-1

Do you provide prescriptions to patients in a Skilled Nursing Facility (SNF) and/or Intermediate Care Facility (ICF)? ☐ Yes ☑ No ☐ N/A

TECHNICIANS

Pharmacy technicians: supervised, registered, have name tag. ☑ Yes ☐ No ☐ N/A

34-23-131

Pharmacist:technician ratio of 1:2, 1:3 if one tech is certified. ☑ Yes ☐ No ☐ N/A

Pharmacy technician manual: may use www//albop.com ☑ Yes ☐ No ☐ N/A

680-X-2-.14(5)

Technicians have been trained in all assigned tasks. ☑ Yes ☐ No ☐ N/A

680-X-2-.14(5)

Are technicians prevented from processing/receiving prescriptions before a pharmacist arrives or after the pharmacist leaves? ☑ Yes ☐ No ☐ N/A

Does a pharmacist verify all work performed by technicians and document this verification? ☑ Yes ☐ No ☐ N/A

CONTROLS/MONITORED MEDICATIONS

Pharmacy connected to NPLEX if selling ephedrine pseudoephedrine products (Those selling by prescription only, do not have to submit to database) ☐ Yes ☐ No ☑ N/A

By prescription only

20-2-190

Pharmacy is reporting to PDMP
(Pharmacies should be uploading every day)
(Should be uploading a zero balance even if no CS filled) ☑ Yes ☐ No ☐ N/A

20-2-213

Controlled Substance Inventory (Date of Last Inventory) ☑ Yes ☐ No ☐ N/A

01/15/2023

680-X-3-.08

PRESCRIPTIONS

refills limited to prescriber's orders. ☑ Yes ☐ No ☐ N/A

Record keeping of prescriptions (initials, number, date, label, notes compounding notes) ☑ Yes ☐ No ☐ N/A

680-X-2-.05 680-X-2-.14

all controlled substance prescriptions shall bear full name and address of the patient along with date, drug, strength, dosage form, quantity, directions for use, and name, address and registration number of practitioner. ☒ Yes ☐ No ☐ N/A

DRUG RETURN

Pharmacy takes back non-controlled medication from patients for destruction. ☐ Yes ☒ No ☐ N/A

Pharmacy takes back controlled medication from patients for destruction. ☐ Yes ☒ No ☐ N/A

Quarantined all out-dated medications (both prescription and OTC)? Note: This includes compounding supplies and items in the refrigerator. ☒ Yes ☐ No ☐ N/A

COMPOUNDING

Have a separate, clean area for any compounding (only compounding equipment, orderly, clean) ☒ Yes ☐ No ☐ N/A

A separate USP 795 inspection was conducted. 34-23-152

Compounding area has washable counter, floors, ceiling, shelves. ☒ Yes ☐ No ☐ N/A

Sink with potable hot and cold water, sink clean, available to hand washing before compounding. ☒ Yes ☐ No ☐ N/A

Prescription Balance/scale and Weights, , Technical Equipment commensurate with its level of practice. ☒ Yes ☐ No ☐ N/A

680-X-2-.04

Purified water used for compounding or reconstitution ☒ Yes ☐ No ☐ N/A

Last time calibrated balance or scale Date: _____ ☐ Yes ☐ No ☐ N/A

34-23-153

Prepares a compounding record with each compound which includes amount of each ingredient, lot number and expiration date. ☐ Yes ☐ No ☐ N/A

34-23-156

Master Formula and compounding instructions available for commonly used formulas. ☐ Yes ☐ No ☐ N/A

Compounding of hazardous drugs follows USP 800. ☒ Yes ☐ No ☐ N/A

Any staff who compound hazardous drugs have been trained and have signed an informed consent. ☐ Yes ☐ No ☐ N/A

AUTOMATED FILLING DEVICES

Are you able to identify brand name, or generic name & manufacturer; strength; lot number; expiration date; or an internal control number which references the manufacturer and lot number used for medications placed into all cells in automated dispensing machines ? ☐ Yes ☐ No ☐ N/A

Pharmacy is not equipped.

Does pharmacist verify technician filling of automated dispensing machines? ☐ Yes ☐ No ☐ N/A

ALABAMA STATE BOARD OF PHARMACY

111 Village Street, Birmingham, AL 35242
www.albop.com Phone: 205-981-2280

License Verification

Name: TRIAD RX INC.
26258 POLLARD ROAD

DAPHNE, AL 36526

Permit/Registration/License Number: 113869

License Type: Community Pharmacy

License Status: Active

Date Issued: 02/16/2012

Expiration Date: 12/31/2024

Disciplinary Action: Yes

Date Prepared: 06/14/2024

Donna C Yeatman

Donna Yeatman, R.Ph.
Executive Secretary



26258 Pollard Rd
Daphne, AL 36526

Triad Rx, Inc. Owners and Officers POST-SALE (08/15/2024)

David Edwin Lindsey-Shareholder (President)
President & Sole (100%) Shareholder
[redacted]

Tara Morris
Vice President – Operations
[redacted]

Stuart Viator
Chief Operating Officer
[redacted]

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Triad Rx, Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 26258 Pollard Rd.

City Daphne State AL Zip 36526

Mailing Address (if different from physical address) PO Box 1530

City Daphne State AL Zip 36526

Telephone 251-580-7630 Website www.triadrx.us

Licensing Company Email maria@triadrx.com

Section 2: Personal Information

First Robert Middle Reyburn Last Roberts, III

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] Derby Lane, Fairhope, AL 36525

City [redacted]ollard Rd, Daphne State AL Zip 36526

Telephone _____ Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
Present	[redacted] Durby Lane	Fairhope	AL	36525
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Triad Rx, Inc.			From - To (MM/YY – MM/YY): 2/12 - current
Business Address: 26258 Pollard Rd	City: Daphne	State: AL	Zip: 36526
Phone: 251.380.7630	Title: PIC	Number of Employed Hours: 40/week ; 10,520 hours total	
Description of Duties: Ensuring compliance & regulations, observing safe and timely prescription filling and dispensing			
Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			
Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			
Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			
Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I, Robert Reyburn Roberts, IV certify that as the designated representative for Triad Rx, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. Yes I am at least 21 years of age;
3. Yes I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. Yes I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. Yes I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. Yes I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. Yes I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Robert Roberts, IV

Print Name (First, Last)

Robert R Roberts III

Original Signature (electronic, copies or stamps not accepted)

8/26/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert, Roberts III

Print Name (First, Last)

Robert R. Roberts III

Original Signature (electronic, copies or stamps not accepted)

8/26/24

Date

Please have this section completed in the presence of a Notary Public.

State of Alabama, ss. County of Baldwin

I, Robert Rayburn Roberts, III, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Robert R. Roberts III

Original Signature

8/26/24

Date

Subscribed and Sworn to before me this 26th day of August.

Mariia Kostiukova

Notary Public Signature

MARIIA KOSTIUKOVA
NOTARY PUBLIC
ALABAMA - STATE AT LARGE
My Commission Expires April 27, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application
Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Triad Rx, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 26250 Pollard Rd

City Daphne State AL Zip 36526

Mailing Address (if different from physical address) PO BOX 1530

City Daphne State AL Zip 36526

Telephone 251-380-7630 Website www.triadrx.us

Licensing Company Email maria@triadrx.com

Section 2: Personal Information

First Stuart Middle James Last Viator

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address (home address) Firestone Dr, Pace, FL

City [redacted] Pollard Rd, Daphne State AL Zip 36526

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)
New Iberia High School	1987 – 1991

Address	City	State	Zip
1301 E Admiral Doyle Dr	New Iberia	LA	70560

Diploma/Degree obtained, if any: N HS

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/22 - present	[redacted] Firestone Dr.	Pace	FL	32571
10/16 - 06/22	[redacted] GreyStone Dr	Pace	FL	32571
02/2005 – 10/2016	[redacted] Indian Hills Dr.	Pace	FL	32571
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Triad Rx, Inc.			From - To (MM/YY – MM/YY): 2021 – present
Business Address: 26258 Pollard Rd.	City: Daphne	State: AL	Zip: 36526
Phone:	Title: COO		
Description of Duties: Responsible for Sale allocation and types of operations			

Business Name: API Solutions, Inc			From - To (MM/YY – MM/YY): 2020 – Present
Business Address: 25309 Friendship Rd	City: Daphne	State: AL	Zip: 36526
Phone: 251·980·7621	Title: COO		
Description of Duties: same as At TRIADRx			

Business Name: PPR, Inc.			From - To (MM/YY – MM/YY): 2014 – 2020
Business Address: 4854 Woodbine Rd	City: Pace	State: FL	Zip: 32571
Phone: 806-236-5040	Title: COO		
Description of Duties: Same as TRIAD Rx			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	X	
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 8. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
5/31/23		MN	Saint Paul	
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A		MN BOP		
Reason/Charge	VOLUNtaRILY surrendering of a license.			
Plaintiff/Defendant/Claimant/Respondent	N/A	**Lawsuit/Arbitration/Bankruptcy**	N/A	
Name of Business/Industry/Entity	API Solutions, Inc License # 461822			

Provide explanation below:

I, Stuart Viator, is (and have been COO of API Solutions, Inc. for the last 5 years. In May of 2023 the company surrendered their license PURELY for financial reasons and NOT due any disciplinary orders. Paperwork is attached for your review

Original Signature (electronic, copies or stamps not accepted)

8/26/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Stuart Viator
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/26/24
Date

Please have this section completed in the presence of a Notary Public.

State of Alabama, ss. County of Baldwin

I, Stuart Viator, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/26/24
Date

Subscribed and Sworn to before me this 26th day of August.

Mariia Kostiukova
Notary Public Signature

MARIIA KOSTIUKOVA
NOTARY PUBLIC
ALABAMA - STATE AT LARGE
My Commission Expires April 27, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Triad Rx, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): AL 113869

Physical Address: 26258 Pollard Road

City: Daphne State: AL Zip: 36526

Mailing Address (if different from physical address): PO Box 1630

City: Daphne State: AL Zip: 36526

Telephone: 251-380-7630 Website: https://www.triadrx.us/

Licensing Company Email: maria@triadrx.com

Section 2: Personal Information

First: Tara Middle: Janelle Last: Morris

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] Belrose Avenue

City: Daphne State: AL Zip: 36526

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Escambia Academy			08/1977-05/1988	
Address		City	State	Zip
268 Cowpen Creek Road		Atmore	AL	36502
Diploma/Degree obtained, if any				
Highschool Diploma				
School Name			From - To (MM/YY – MM/YY)	
Patrick Henry Junior College (known today as Coastal Alabama Community College)			08/1988-05/1990	
Address		City	State	Zip
2800 South Alabama Avenue		Monroeville	AL	36460
Diploma/Degree obtained, if any				
Associates Degree				
School Name			From - To (MM/YY – MM/YY)	
Univeristy of Mobile			08/1990-07/1992	
Address		City	State	Zip
5735 College Parkway		Mobile	AL	36613
Diploma/Degree obtained, if any				
Bachelor of Arts				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/2012-09/2024	[redacted]Belrose Avenue	Daphne	AL	36526
06/2006-03/2012	[redacted]Yacht Club Drive # 108	Daphne	AL	36526
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
TRIAD RX, INC			09/2015-09/2024
Business Address	**City**	**State**	**Zip**
26258 Pollard Road	Daphne	AL	36526
Phone	**Title**		
251-380-7630	VP of Operations		

Description of Duties

Manage and oversee operations and make recommendations to the CEO. Work with managers, discuss any issues and help to ensure we comply with legal and regulatory requirements. I also oversee procurement and resource allocation.

Business Name			From - To (MM/YY – MM/YY)
TOTAL CARE SOLUTIONS, INC			09/2011-09/2015
Business Address	**City**	**State**	**Zip**
26450 Pollard Road	Daphne	AL	36526
Phone	**Title**		
251-380-7336 (Closed)	CEO		

Description of Duties

Developed, implemented business and operational policies. Worked with managers to ensure adherence to legal guidelines and in-house policies. Ensured daily operations were consistent with overall strategy and mission.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tara Morris

Print Name (First, Last)

Tara Morris

Original Signature (electronic, copies or stamps not accepted)

09/03/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Alabama, ss. County of Baldwin

I, Tara Janelle Morris, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Tara Morris

Original Signature

09/03/24

Date

Subscribed and Sworn to before me this Third day of September.

Mariia Kostiukova

Notary Public Signature

MARIIA KOSTIUKOVA
NOTARY PUBLIC
ALABAMA - STATE AT LARGE
My Commission Expires April 27, 2027

MARIIA KOSTIUKOVA NOTARY PUBLIC ALABAMA STATE AT LARGE (Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Triad Rx, Inc

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 26258 Pollard Rd.

City Daphne State AL Zip 36526

Mailing Address (if different from physical address) PO Box 1530

City Daphne State AL Zip 36526

Telephone 251·380·7630 , Website www.triadrx.us

Licensing Company Email maria@triadrx.com

Section 2: Personal Information

First David Middle Edwin Last Lindsey

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒M ☐F ☐X

Mailing Address (Home address) [redacted] Normandy Ave., Dallas, TX 75205

City [redacted] Pollard Rd, Daphne, ~~AL~~ State AL Zip 36526

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒Yes ☐No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Diboll High School			8/1972 – 5/1976
Address	**City**	**State**	**Zip**
708 Booker St	Diboll	Texas	75941
Diploma/Degree obtained, if any			
Degree			

School Name			From - To (MM/YY – MM/YY)
University of Texas of Arlington			1978 1982
Address	**City**	**State**	**Zip**
Arlington Texas	Arlington	TX	76019
Diploma/Degree obtained, if any			
BA Degree in Finance			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2014 – Present	[redacted] Normandy Ave	Dallas	TX	75205
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Lindsey Health Holdings			2013 present	
Business Address		**City**	**State**	**Zip**
4201 Spring Valley		Dallas	TX	75244
Phone	**Title**			
214-417-2399	CEO			
Description of Duties				
CEO				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Edwin Lindsey

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/26/24

Date

Please have this section completed in the presence of a Notary Public.

State of Alabama, ss. County of Baldwin

I, David Edwin Lindsey, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/26/24

Date

MARIIA KOSTIUKOVA
NOTARY PUBLIC
ALABAMA - STATE AT LARGE
My Commission Expires April 27, 2027

Subscribed and Sworn to before me this 26th day of August.

Mariia Kostiukova

Notary Public Signature

(Seal)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FT3066594	11-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	10-03-2023

TRIAD RX INC
26256 POLLARD RD
DAPHNE, AL 36526

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FT3066594	11-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	10-03-2023

TRIAD RX INC
26258 POLLARD RD
DAPHNE, AL 36526

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

MINNESOTA
BOARD OF PHARMACY

License Closure Notification – In-State and Out of State Facilities

Wholesalers, Manufacturers, Medical Gas Distributors

This form should be submitted to the Board of Pharmacy at least **14 days prior** to the date the facility closes and/or ceases operation in the state of Minnesota. For comprehensive information on the reporting requirements for closing a pharmacy, see MN Rule 6800.1010.

Return license to the Board of Pharmacy on the closing date, noting the date of closure on the license.

Closing License Information

Current Facility Name/DBA Name as listed on the License	Reason for Closure		Closing Date	MN License Number
API Solutions, Inc.	Reduced tradeflow		5/31/23	461822
Street Address	**City**	**State**	**Zip**	**Phone Number**
25309 Friendship Rd.	Daphne	AL	36526	855-878-1489

Contact Information at the Facility

Contact Name	Phone Number	Fax Number	Email Address
Joshua Warren	855-878-1489		maria@apisolutions.net

I certify that this facility is closing permanently or ceasing operations in the state of Minnesota and the license is therefore surrendered to the Minnesota board of Pharmacy. I recognize that the facility cannot operate in Minnesota past the date listed above.

Signature of Owner, CEO, or President	Print Name	Date
	Matthew McDonald	5/5/23

Additional Information (Optional)

API Solutions, Inc. is surrendering this license and will cease serving customers in Minnesota on or before the above Closing Date. This is done voluntarily and for purely financial reasons, and specifically not due to any threat of agency action or other regulatory noncompliance issue. The $5,200+ annual licensing fee simply makes doing business in Minnesota unsustainable for a small business like us.

Download this form and use the submit button below to e-mail to the Board of Pharmacy.
This document must be submitted with all requested supporting documents.

Submit Form

Minnesota Board of Pharmacy
335 Randolph Ave, Suite 230 | Saint Paul, MN 55102
E-mail: pharmacy.board@state.mn.us | Fax: (651) 215-0951

Maria Kostiukova

From: MN_HLB_Pharmacy Board <Pharmacy.Board@state.mn.us>
Sent: Tuesday, June 13, 2023 2:51 PM
To: Maria Kostiukova
Subject: RE: license 461822 surrender

Hello,

License 461822 has received a closure notification. This request has been completed.

Thank you,

Minnesota Board of Pharmacy
335 Randolph Ave, Suite 230
St. Paul, MN 55102
O: 651-201-2825
F: 651-215-0951
Protecting the Public Since 1885 | mn.gov/boards/pharmacy

MINNESOTA
BOARD OF PHARMACY

Disclaimer: If this e-mail is in response to a question concerning statutes, rules and guidances, please be advised that it was prepared based solely upon the information presented. This response is not intended to be determinative, nor can it be considered as legal advice. Although references to current laws and regulations may be included in this response, keep in mind those laws and regulations may have, and often do change. To insure that all current applicable Federal and/or State laws have been considered, you may want to consult with your own legal counsel.

From: Maria Kostiukova <maria@apisolutions.net>
Sent: Monday, June 12, 2023 9:49 AM
To: MN_HLB_Pharmacy Board <pharmacy.board@state.mn.us>
Subject: FW: license 461822 surrender
Importance: High

This message may be from an external email source.
Do not select links or open attachments unless verified. Report all suspicious emails to Minnesota IT Services Security Operations Center.

Good morning. Could you please provide a status on this license that we are surrendering and that expires today?
Paper version of the current application has been mailed out 5/8
Thank you

Sincerely,

Maria Kostiukova
Office Manager

A.P.I. Solutions, Inc.
Phone: 855-878-1489
Facsimile: 251-380-7621
maria@apisolutions.net

From: Maria Kostiukova
Sent: Wednesday, May 31, 2023 8:37 AM
To: pharmacy.board@state.mn.us
Subject: RE: license 461822 surrender

Good morning. Could you please provide a status on this license that we are surrendering and that expires today?
Paper version of the current application has been mailed out 5/8
Thank you

From: Maria Kostiukova
Sent: Friday, May 5, 2023 1:15 PM
To: pharmacy.board@state.mn.us
Subject: license 461822 surrender
Importance: High

Good afternoon.
After thorough assessment, API Solutions has decided to voluntarily surrender current license that expires 5/31/23 and no longer intends to maintain presence at the state of MN at this time.
Please see attached signed form for withdrawal and let us know if you need any other paperwork.

Sincerely,

Maria Kostiukova
Office Manager
A.P.I. Solutions, Inc.
Phone: 855-878-1489
Facsimile: 251-380-7621
maria@apisolutions.net

SEARCH

Minnesota Health Licensing Boards

Minnesota Board of Pharmacy

License/Registration Verification as of July 6, 2023 for API Solutions, Inc.

Business Information

Name	API Solutions, Inc.
Address	2S309 Friendship Rd
	Daphne, AL 36256

License Information

License Type	Manufacturer License
Category of Licensure	Humand Legend Controlled Substances, Veterinary Legend Drugs
License Number	461822
License Status	Closed
Original Issue Date	11/20/2020
Effective Date	03/23/2022
Expiration Date	06/13/2023

Disciplinary Action

No

This data is authorized to be used as primary source verification of a Minnesota License.

Disclaimer

While we believe this information to be reliable, human or mechanical error remains a possibility, as does delay in the posting or updating of information. Therefore there is no guarantee as to the accuracy, completeness, timeliness, or currency of the data listed in the individual section. The Board is not responsible for the use, or result obtained from the use, of this information.

New Search Print

Alabama State Board of Pharmacy

2024

This is to certify:

TRIAD RX INC.
26258 POLLARD ROAD
DAPHNE, AL 36526

Permit Number:

113869

Is Duly Licensed as a:

Community Pharmacy

Specialty Services:

Non-Sterile Compounding

Supervising Pharmacist

ROBERT REYBURN ROBERTS

12683

IN COMFORMITY WITH THE PROVISIONS OF ACT #205, GENERAL ACTS OF ALABAMA, 1966 SPECIAL SESSION, AND RULES AND REGULATIONS OF THE BOARD. THIS CERTIFICATE MUST BE CONSPICIOUSLY DISPLAYED AND EXPIRE ON THE LAST DAY OF

December 2024

THIS IS YOUR RECEIPT FOR FEE PAID AS REQUIRED BY LAW
THIS PERMIT IS NOT TRANSFERRABLE

Donna C Yeatman
EXECUTIVE SECRETARY

Alabama State Board of Pharmacy

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE

2024

Controlled Substance Number:

113869

Business Activity:

Community Pharmacy

Schedules:

II,III,IV,V

The Controlled Substance Act of 1971 reads in part as follows:
Section 304 (Revocation and Suspension of the Registration.)

(a) A registration under Section 303 to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the Certifying Boards upon a finding that the registrant:

(1) Has furnished false or fraudulent material information in any application filed under this Act,

(2) Has been convicted of a felony under any State or Federal law relating to any controlled substance or

(3) Has had his Federal registration suspended or revoked to manufacture, distribute, or dispense controlled substances

(4) Has violated the provisions Act 205 (al-a32) Code of Alabama 1940 (Recomp. 1958)

Date Issued: 01/01/2023

Expiration Date: 12/31/2024

TRIAD RX INC.
26258 POLLARD ROAD
DAPHNE, AL 36526

CERTIFICATE MUST BE PROMINENTLY DISPLAYED AT ALL TIMES

THIS REGISTRATION IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY

Business Lookup Online Application

This is primary source verification

Date Printed : 8/15/2024

License Information

Name :TRIAD RX INC.
License # :113869
Supervising Pharmacist:ROBERT REYBURN ROBERTS
Email Address:josie@triadrx.com
License Type : Community Pharmacy
License Status : Active
Issue Date :02/16/2012
Expiration Date :12/31/2024
Discipline :Y
Address :26258 POLLARD ROAD
City :DAPHNE
State :AL
Zip :36526
Designated Representative :
USP 795 : Yes
USP 797 : No

Controlled Substance Information

Status : Active
Issue Date :01/01/2023
Expiration Date :12/31/2024

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	FINAL DECISION AND ORDER
TRIAD RX, INC.	:	
RESPONDENT.	:	ORDER0019890

Division of Legal Services and Compliance Case No. 22 PHM 120

The parties to this action for the purpose of Wis. Stat. § 227.53 are:

Triad Rx, Inc.
Daphne, AL 36526

Wisconsin Pharmacy Examining Board
P.O. Box 8366
Madison, WI 53708-8366

Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 7190
Madison, WI 53707-7190

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final disposition of this matter, subject to the approval of the Pharmacy Examining Board (Board). The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following Findings of Fact, Conclusions of Law, and Order.

FINDINGS OF FACT

1. Triad Rx, Inc. (Respondent), is licensed in the state of Wisconsin as an Out-of-State Pharmacy, having license number 774-43, first issued on May 29, 2012, and current through May 31, 2024. Respondent's most recent address on file with the Wisconsin Department of Safety and Professional Services (Department) is in Daphne, Alabama 36526.

2. At all times relevant to this proceeding, Respondent was an Out-of-State Pharmacy located in Daphne, Alabama (Facility).

3. On August 19, 2022, Respondent notified the Department of a disciplinary action taken against Respondent by the Alabama Board of Pharmacy (Alabama Board).

4. In 2017 the FDA conducted an inspection at Respondent's facility. In 2019, the FDA issued a warning letter to Respondent for using ineligible drug products in compounding. The ineligible products were intended for conditions not amenable to self-diagnosis and treatment by individuals who were not medical practitioners. Respondent did not alert the Board to the warning letter.

5. Some of the medications which were referenced by the FDA in their warning letter as using ineligible products included Sermorelin Acetate 9mg/GHRP-2 9mg Lyophilized, Sermorelin Acetate 3mg/GHRP-2 3mg Lyophilized, L-Carnitine 250 mg/ml, and Chromium Picolinate.

6. Following the FDA inspection, Respondent shipped Sermorelin Acetate 9mg/GHRP-2 9mg Lyophilized to Wisconsin on 11 occasions, and L-Carnitine 250 mg/ml to Wisconsin on five occasions.

7. Respondent did not report the FDA warning letter to the Board because "(i) it was published on FDA's website and does not constitute final agency action, (ii) none of the allegations in the Warning Letter involved or implicated patient harm of any kind; (iii) [Respondent] did not consider the Warning Letter to describe any pharmacy practices constituting a realistic danger to the health, safety, or welfare of a patient or the public."

8. On July 7, 2022, the Alabama Board issued a consent order ordering Respondent to pay a $15,000 fine based upon findings that the Respondent used bulk drug substances which were not the subject of an applicable USP or NF monograph, were not components of an FDA approved human drug, and which did not appears on the 503A bulks list. Further, Respondent violated the FDCA Adulterated Drug Product on at least eleven occasions, compounded unapproved new drug products, and misbranded the unapproved compounded drug products.

9. In resolution of this matter, Respondent consents to the entry of the following Conclusions of Law and Order.

CONCLUSIONS OF LAW

1. The Board has jurisdiction to act in this matter pursuant to Wis. Stat. § 450.10(1) and is authorized to enter into the attached Stipulation pursuant to Wis. Stat. § 227.44(5).

2. By the conduct described in the Findings of Fact, Respondent committed unprofessional conduct by engaging in an any pharmacy practice which constitutes a danger to the health, welfare, or safety of patient or public including but not limited to, practicing in a manner which substantially departs from the standard of care ordinarily exercised by a pharmacist which harmed or could have harmed a patient pursuant to Wis. Admin. Code § Phar 10.03(2).

3. By the conduct described in the Findings of Fact, Respondent committed unprofessional conduct by failing to report to the Pharmacy Examining Board any pharmacy practice which constitutes a danger to the health, safety or welfare of patient or public pursuant to Wis. Admin. Code § Phar 10.03(7).

4. As a result of the above violations, Respondent is subject to discipline pursuant to Wis. Stat. § 450.10(1)(b)(1), and subject to a forfeiture pursuant to Wis. Stat. § 450.10(2).

ORDER

1. The attached Stipulation is accepted.

2. Respondent is REPRIMANDED.

3. Within ninety (90) days from the date of this Order, Respondent shall pay a forfeiture in the amount of $5,000.

4. Within ninety (90) days from the date of this Order, Respondent shall pay COSTS of this matter in the amount of $820.00. If costs are not paid within ninety (90) days from the date of this Order, interest shall accrue at the statutory rate of 12% per annum, pursuant to Wis. Stat. § 440.22(2).

5. Any requests, petitions, payments of forfeitures or costs (made payable to Department of Safety and Professional Services), and other information required by this Order shall be submitted to:

Department Monitor
Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 7190, Madison, WI 53707-7190
Telephone (608) 266-2112; Fax (608) 266-2264
DSPSMonitoring@wisconsin.gov

Respondent may also submit this information online at: https://dspsmonitoring.wi.gov.

6. In the event Respondent violates any term of this Order, Respondent's license (number 774-43) or Respondent's right to renew its license, may, in the discretion of the Board or its designee, be SUSPENDED, without further notice or hearing, until Respondent has complied with the terms of the Order. The Board may, in addition and/or in the alternative refer any violation of this Order to the Division of Legal Services and Compliance for further investigation and action.

7. This Order is effective on the date of its signing.

WISCONSIN PHARMACY EXAMINING BOARD

By: John Wiitala
A Member of the Board

2/29/2024
Date

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	STIPULATION
TRIAD RX, INC.,	:	
RESPONDENT.	:	ORDER0019890

Division of Legal Services and Compliance Case No. 22 PHM 120

Triad Rx, Inc. (Respondent), and the Division of Legal Services and Compliance, Department of Safety and Professional Services, stipulate as follows:

1. This Stipulation is entered into as a result of a pending investigation by the Division of Legal Services and Compliance. Respondent consents to the resolution of this investigation by Stipulation.

2. Respondent understands that by signing this Stipulation, Respondent voluntarily and knowingly waives the following rights:

- the right to a hearing on the allegations against Respondent, at which time the State has the burden of proving those allegations by a preponderance of the evidence;
- the right to confront and cross-examine the witnesses against Respondent;
- the right to call witnesses on Respondent's behalf and to compel their attendance by subpoena;
- the right to testify on Respondent's own behalf;
- the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision;
- the right to petition for rehearing; and
- all other applicable rights afforded to Respondent under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, the Wisconsin Administrative Code, and other provisions of state or federal law.

3. Respondent is aware of Respondent's right to seek legal representation and has been provided an opportunity to obtain legal counsel before signing this Stipulation.

4. Respondent agrees to the adoption of the attached Final Decision and Order by the Wisconsin Pharmacy Examining Board (Board). The parties to the Stipulation consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives all rights to any appeal of the Board's order, if adopted in the form as attached.

5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation, and the matter shall then be returned to the Division

of Legal Services and Compliance for further proceedings. In the event that the Stipulation is not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by the consideration of this attempted resolution.

6. The parties to this Stipulation agree that the attorney or other agent for the Division of Legal Services and Compliance and any member of the Board ever assigned as an advisor in this investigation may appear before the Board in open or closed session, without the presence of Respondent, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with deliberations on the Stipulation. Additionally, any such advisor may vote on whether the Board should accept this Stipulation and issue the attached Final Decision and Order.

7. Respondent is informed that should the Board adopt this Stipulation, the Board's Final Decision and Order is a public record and will be published in accordance with standard Department procedure.

8. Respondent is further informed that should the Board adopt this Stipulation, the Board's Final Decision and Order will be reported as required by the National Practitioner Databank (NPDB) Guidebook and as otherwise required by any licensure compact or any other state or federal law.

9. The Division of Legal Services and Compliance joins Respondent in recommending the Board adopt this Stipulation and issue the attached Final Decision and Order.

Robert J. Quinn

Triad Rx, Inc., Respondent
Daphne, AL 36526
License No. 774-43

16 Feb. 2024
Date

Brian Juech

Brian J. Juech, Prosecuting Attorney
Department of Safety and Professional Services
Division of Legal Services and Compliance
P.O. Box 7190
Madison, WI 53707-7190

2/19/2024
Date



26258 Pollard Rd
Daphne, AL 36526
251-380-7630

Triad Rx, Inc. ("Triad"), Nevada License No PH02913 hereby reports disciplinary action against Triad's Wisconsin Out-of-State Pharmacy License Number 774-43. Enclosed is a "Final Decision and Order" and "Stipulation" for Wisconsin Pharmacy Examining Board Case No. **22 PHM 120, Order 0019890**.

The Wisconsin Pharmacy Examining Board appears to have taken final agency action on February 29, 2024, and these documents were provided to Triad by regular first-class U.S. Mail postmarked March 1, 2024. Triad received these documents on March 11, 2024.

On the merits, this Wisconsin case is a "sister state" action involving reciprocal discipline. There are no new facts or substantive allegations relative to previously-reported disciplinary matters. Culpability in the Wisconsin case is derived solely from the outcome of a 2017 sterile compounding inspection and the resulting 2022 disciplinary action against Triad by its home state of Alabama. Again, the underlying facts of this matter were reported to your agency no later than approximately a year-and-a-half ago.

Sincerely,

Triad Rx, Inc.

4/26/2024

4EEE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH 03662		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	☐ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	■ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: TRUSTEDEDRX, LLC

Physical Address: 1200 S ROGERS CIRCLE #4A

City: BOCA RATON State: FL Zip: 33487

Mailing Address (if different from physical address): 1200 S ROGERS CIRCLE #4A

City: BOCA RATON State: FL Zip: 33487

Telephone: 855-939-6337 Toll Free # (NAC 639.708, NRS 639.23286): 855-939-6337

Fax: 561-206-6688 Contact Email: RPH@TRUSTEDMEDRX.COM

Website: TRUSTEDMEDRX.COM

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): DAVID STEINBERG

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): PS54676 FL

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: DAVID STEINBERG	NV Pharmacist Registration #: PS54676 FL
Name: Verina Guirguis	NV Pharmacist Registration #: 23341
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: TRUSTEDMEDRX, LLC

Mailing Address: 1200 S ROGERS CIRCLE #4A

City: BOCA RATON State: FL Zip: 33487

Telephone: 855-939-6337 Email: RPH@TRUSTEDMEDRX.COM

Contact Person Name: DAVID STEINBERG

Please check type of partnership (NAC 639.214) ☐ General ☒ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☒ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the PHARMACIST IN CHARGE (title) for TRUSTEDMEDRX, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

DAVID STEINBERG

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

9/3/2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, DAVID STEINBERG hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the PHARMACIST IN CHARGE (title) for TRUSTEDMEDRX, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 3 day of September, 2024

Notary Public

Shaena Renberg
Comm.: HH 452089
Expires: Oct. 8, 2027
Notary Public - State of Florida

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Steinberg

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

9/3/24

Date

Board Use Only	Date Received: 9/5/24	Amount: $500-cc

BROWN FORTUNATO

Colleen T. Byrom
806-345-6311
cbyrom@bf-law.com

April 10, 2023

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

Re: TrustedMedRx Disciplinary Action Summary

Ladies and Gentlemen:

Brown & Fortunato, P.C. has been asked to assist TrustedMedRx, LLC ("TMRx") in preparing its application to the Nevada Board of Pharmacy.

Under the previous ownership, TrustedMedRx, LLC ("TMRx") received the following disciplinary actions:

1. On May 5, 2021, the Alabama State Board of Pharmacy, TMRx, and former TMRx Pharmacist In Charge ("PIC") executed a Consent Order resolving the Board's finding that TMRx failed to notify the Board within 10 days of PIC ceasing to be the Supervising Pharmacist (Alabama defines the PIC as "Supervising Pharmacist"). Pursuant to the Consent Order, TMRx paid an administrative fine of $2,000, and PIC paid an administrative fine of $1,000.

2. On May 19, 2022, the Hawaii Department of Commerce and Consumer Affairs and TMRx executed a Settlement Agreement resolving a finding that TMRx failed to notify the Hawaii Board of Pharmacy within 30 days of the execution of the Consent Order between TMRx and the Alabama State Board of Pharmacy (see item 1. above). Pursuant to the Settlement Agreement, TMRx paid an administrative fine of $1,000.

3. On September 29, 2022, the Maine Board of Pharmacy, the Office of the Maine Attorney General, and TMRx executed a Consent Agreement resolving the Board's findings that (i) TMRx failed to notify the Board within 7 days of a change in the individual designated as the PIC for purposes of TMRx's Maine pharmacy license and (ii) TMRx failed to notify the Board within 10 days of the execution of the Consent Order between TMRx and the Alabama State Board of Pharmacy (see item 1. above). Pursuant to the Consent Agreement, TMRx accepted a reprimand and paid a civil penalty of $1,000.

Complete copies of these actions are attached for your reference.

Please note that the above transpired with previous ownership, supervision, and PIC(s); all of whom have since been replaced. The incoming ownership of TMRx recognizes the importance of, and is committed to, complying with the requirements imposed by all states in which TMRx is licensed, including requirements to notify state licensing agencies of changes or actions taken by other state agencies in a timely manner.

Sincerely,

Colleen T. Byrom

JSM/
Enc.
c:

DocuSign Envelope ID: 1EDC988C-7928-46C6-A1F4-FC1E1D49096F

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
TRUSTEDMEDRX, LLC	)	**BOARD OF PHARMACY**
	)	
Non-Resident Pharmacy Permit No.: 114947	)	
	)	
and	)	**CASE NO: 20-L-0144**
	)	
TRAMAINE PRESTON SMITH	)	
	)	
License No.: 20874	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against TrustedMedRx, LLC and Tramaine Preston Smith (hereinafter referred to as "Smith") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement, as amended, which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the parties engaged in negotiations and as a result, the matters at issue were resolved informally by the parties who agreed to the entry of this Consent Order which includes the following terms:

1. The Board finds TrustedMedRx, LLC has violated the provisions law based upon the conduct set forth in Counts One and Two of the Statement. All other Counts applicable to TrustedMedRx, LLC shall be dismissed with prejudice.

2. The Board finds Smith has violated the provisions of law based upon the

conduct set forth in Count Four of the Statement. All other Counts applicable to Smith shall be dismissed with prejudice.

3. TrustedMedRx, LLC shall pay an administrative fine in the amount of Two Thousand Dollars ($2,000.00) and Smith shall pay an administrative fine in the amount of One Thousand Dollars ($1,000.00) within thirty (30) days of the effective date of this Consent Order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall TrustedMedRx, LLC or Smith attempt to discharge the same.

4. TrustedMedRx, LLC and Smith expressly waive their rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against them and any judicial review. TrustedMedRx, LLC and Smith further waive any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

5. TrustedMedRx, LLC and Smith acknowledge and agree that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing

thereof, result in further disciplinary sanctions against TrustedMedRx, LLC and Smith's permit/license, including, but not limited to revocation.

6. By execution of this Consent Order, TrustedMedRx, LLC and Smith hereby release the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

7. TrustedMedRx, LLC and Smith acknowledge and agree that they have read this Consent Order and that they fully understand the terms, conditions and contents of the same. TrustedMedRx, LLC and Smith acknowledge and agree that they voluntarily and of their own free will accept the terms and conditions set out in this Consent Order and are executing this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and had the right to seek advice of counsel before executing this Consent Order.

DONE this the 30th day of April, 2021.

TrustedMedRx, LLC

BY: _____

ITS: Malcolm Murphy, Chief Operating Officer

Tramaine Preston Smith

_____

DocuSign Envelope ID: 1EDC988C-7926-46C6-A1F4-FC1E1D49096F

DONE this the 5th day of MAY, 2021.

ALABAMA STATE BOARD OF PHARMACY

By: _____
Brenda Denson, PharmD., President

_____
James S. Ward,
Attorney for the Alabama State
Board of Pharmacy

OF COUNSEL:
WARD & COOPER, LLC
2100A Southbridge Parkway
Suite 645
Birmingham, AL 35209
(205) 871-5404

DocuSign Envelope ID: 1EDC988C-7926-46C6-A1F4-FC1E1D48096F

EXHIBIT "A"

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
TRUSTEDMEDRX, LLC	)	**BOARD OF PHARMACY**
	)	
Non-Resident Pharmacy Permit No.: 114947	)	
	)	
and	)	**CASE NO: 20-L-0144**
	)	
TRAMAINE PRESTON SMITH	)	
	)	
License No.: 20874	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: TrustedmedRx, LLC
1200 S. Rogers Circle
Suite 4A
Boca Raton, Florida 33487

Tremaine Preston Smith
8077 Baltic Amber Road
Delray Beach, Florida 33446

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92 (12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on May 18, 2021 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why your license to practice pharmacy in this State should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or why the permit to operate TrustedmedRx, LLC should not be revoked, suspended or placed on probation or a monetary penalty imposed in that it is alleged that you and TrustedmedRx, LLC have been guilty of the following, to wit:

COUNT ONE

As to TrustedmedRx, LLC, violating Code of Alabama (1975), § 34-23-33(12) in that you violated Board Rule 680-X-2.12(8) by you being unable to maintain a designated Supervising Pharmacist and failed to notify the Board within ten (10) days with an action plan to designate another pharmacist as Supervising Pharmacist to-wit: Tramaine Preston Smith ceased to be your Supervising Pharmacist on or about September 18, 2020 and you, as of the date hereof, have not submitted the referenced action plan to the Board.

COUNT TWO

As to TrustedmedRx, LLC, violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of the preceding Count.

COUNT THREE

As to Tramaine Preston Smith, violating Code of Alabama (1975), § 34-23-33(12) in that you violated Board Rule 680-X-2.12(2) by upon assuming the duties of the Supervising Pharmacy of TrustedmedRx, LLC you failed to notify the Board within ten (10) days to-wit: you assumed the duties of the Supervising Pharmacist of TrustedmedRx, LLC on October 2, 2020 but the Board was not notified until December 16, 2020.

COUNT FOUR

As to Tramaine Preston Smith, violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of Count Three above.

Further, pursuant to the provisions of Code of Alabama, (1975), § 20-2-53 and § 41-22-12, you are hereby notified and requested to appear before the Board at the aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture, dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), § 20-2-1, et seq., issued pursuant to Code of Alabama (1975), § 20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

COUNT FIVE

Violating Code of Alabama (1975), § 20-2-54(a)(4) by violating the provisions of Code of Alabama (1975), § 34-23-1 et seq., said violation being based upon the allegations contained in any or all of the preceding Counts of this Statement of Charges and Notice of Hearing.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 18th day of January, 2021.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
TRUSTEDMEDRX, LLC	)	CONSENT AGREEMENT
	)	
Case No. 2022-PHA-18250	)	

PARTIES

This document is a Consent Agreement regarding the pending application of Trustedmedrx, LLC for the renewal of its mail order prescription pharmacy license. The parties to this Consent Agreement are: Trustedmedrx, LLC ("Trustedmedrx"), the Maine Board of Pharmacy ("the Board"), and the Office of the Maine Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

STATEMENT OF FACTS

1. Since September 13, 2019, Trustedmedrx has been licensed in Maine as a mail order prescription pharmacy with a registered location of 1200 S Rogers Circle, Suite 4A, Boca Raton, Florida (license number MO40002707).

2. On October 29, 2020, Carline Applys replaced David Levi Steinberg as the pharmacist in charge ("PIC"), thereby requiring Trustedmedrx to submit a change of PIC application to the Board within 7 days after the PIC change.

3. Trustedmedrx, however, did not file a change of PIC application with the Board until November 16, 2021.

4. Under Board Rules Chapter 11, § 3, upon a change of PIC, a mail order prescription pharmacy must file a change of PIC application with the Board by registered mail no later than seven (7) days after the change.

5. On May 5, 2021, the Alabama State Board of Pharmacy entered a consent order with Trustedmedrx that resolved Case No. 20-L-0144 and imposed discipline against Trustedmedrx's Alabama permit (# 114947).

6. Trustedmedrx then failed to report the Alabama disciplinary action to the Board within 10 days as required by 10 M.R.S. § 8003-G(2)(C).

7. On December 13, 2021, Trustedmedrx applied for the renewal of its license and reported to the Board for the first time that the Alabama State Board of Pharmacy had imposed discipline upon Trustedmedrx's Alabama permit.

8. Pursuant to 10 M.R.S. § 8003(5-A)(A)(5) and Board Rules Chapter 11, § 3, the Board may deny, refuse to renew, suspend, or revoke a license and impose other discipline for failing to file a new application with the Board no later than 7 days after the change of PIC.

9. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C), the Board may deny, refuse to renew, suspend, or revoke a license and impose other discipline for failing to report a license disciplinary action to the Board within 10 days of that action.

10. At its meeting on September 1, 2022, the Board reviewed the above information and voted to preliminarily deny Trustedmedrx's application for renewal of its license to be a mail order prescription pharmacy. In lieu of the denial, the Board also voted to offer Trustedmedrx this Consent Agreement. Unless Trustedmedrx either requests, in writing, a hearing regarding the appeal of the preliminary denial within thirty (30) days of receipt of the Notice of Preliminary Denial, or accepts this Consent Agreement by signing and dating it and returning it to Maine Board of Pharmacy,

Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333-0035, by October 6, 2022, the preliminary denial of Trustedmedrx's application for renewal of licensure as a mail order prescription pharmacy will become final.

COVENANTS

11. Trustedmedrx admits to the facts above and admits that such conduct constitutes grounds for denial of or refusal to renew its license and for the imposition of discipline as follows:

a. Pursuant to 10 M.R.S. § 8003(5-A)(A)(5) for violating a rule of the Board, specifically Board Rules Chapter 11, § 3 for failing to file a new application with the Board no later than 7 days after a change of PIC; and

b. Pursuant to 10 M.R.S. § 8003(5-A)(A) (11) and 10 M.R.S. § 8003-G(2)(C) for failing to report a disciplinary action taken against a license in another jurisdiction within 10 days after the action was taken.

12. As discipline for the violations admitted to in paragraph 11 above, Trustedmedrx agrees to accept the following DISCIPLINARY ACTION:

a) A REPRIMAND; and

b) A CIVIL PENALTY in the amount of one thousand dollars ($1,000.00), which penalty is comprised of a $500.00 for failing to timely report a PIC change and $500.00 for failing to report discipline within 10 days, payment of which shall be made to the "Treasurer, State of Maine" and delivered to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333-0035, and must be submitted with the signed Consent Agreement.

13. Violation of any of the terms or conditions of this Consent Agreement by Trustedmedrx shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

14. The Board and Trustedmedrx agree that no further agency action will be initiated against its license by the Board based upon the specific violations admitted to herein, except or unless Trustedmedrx fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct if other allegations are brought against Trustedmedrx, and this Consent Agreement will be admitted into evidence in any future adjudicatory hearing involving Trustedmedrx. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining appropriate discipline in any further complaints against Trustedmedrx.

15. This Consent Agreement is not appealable and is effective until modified or terminated by the parties hereto.

16. The Board and the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

17. Upon receipt of the signed Consent Agreement and the civil penalty payment, the Board will renew Trustedmedrx's license contingent upon it meeting all other eligibility criteria.

18. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

19. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

20. This Consent Agreement may be signed in counterparts, with all counterparts together constituting one original instrument. Signatures below may be applied and/or saved

electronically, and such electronic signatures will be given the same effect as a paper document signed in ink.

21. Trustedmedrx acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

DATED: 9/22/2022

TRUSTEDMEDRX, LLC

By: _____

Print Name: Stephen Wolf

Title: CEO.

DATED: 9-29-22

_____

EDWARD J. KANE, Esq., President
MAINE BOARD OF PHARMACY

DATED: 9.29.22

_____

JENNIFER A. WILLIS
Assistant Attorney General

SETH J. CORPUZ-LAHNE 10949
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: (808) 586-2660

Attorney for Department of Commerce and Consumer Affairs

2022 JUN 23 A 11: 22

DEPT. OF COMMERCE
AND CONSUMER AFFAIRS

eFiled 6/24/2022 4:19 pm

HEARINGS OFFICE

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of)	PHA 2022-23-L
TRUSTEDMEDRX, LLC,	SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBIT "1"
Respondent.	

241042211

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney(s) and Respondent TRUSTEDMEDRX, LLC (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS:

1. At all relevant times herein, Respondent was permitted as a miscellaneous permit holder by the Board of Pharmacy (hereinafter the "Board") under miscellaneous permit number PMP 1486. The permit was issued on or about March 14, 2018. The permit is set to expire or forfeit on or about December 31, 2023.

2. Respondent's mailing address for purposes of this action is 1200 S. Rogers Circle, Suite 4, Boca Raton, Florida 33487.

3. On or about April 30, 2021, Respondent entered into a Consent Order with the Alabama State Board of Pharmacy ("Alabama Board") in Case No. 20-L-0144 (hereinafter the "Consent Order"). A copy of the Consent Order is attached hereto as Exhibit "1". The Consent

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

Order was based on allegations that Respondent failed to maintain a designated Supervising Pharmacist and failed to notify the Alabama Board within ten (10) days with an action plan to designate another pharmacist as Supervising Pharmacist after Tramaine Preston Smith ceased to be Respondent's Supervising Pharmacist on or about September 18, 2020. Respondent was issued a $2,000.00 fine.

4. RICO alleges Respondent was disciplined by the Alabama Board.

5. RICO alleges Respondent failed to report, in writing to the Board, the Consent Order entered into with the Alabama Board within thirty days.

6. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute: Hawaii Revised Statutes (HRS) § 436B-19(13) (disciplinary action by another state or federal agency for any reason provided by the licensing laws or this section) and Hawaii Administrative Rules (HAR) § 16-95-110(a)(18) (failure to report, in writing to the licensing authority, any disciplinary decision issued against the licensee or applicant within thirty days of the disciplinary decision).

7. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing, and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent, being at all times relevant herein permitted as a miscellaneous permit holder by the Board, acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the permit and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent further understands that RICO enters into this Settlement Agreement, and agrees to the specific terms contained in this Settlement Agreement, based upon Respondent's representations made herein.

6. Respondent represents Exhibit "1" is a true and correct copy of the Consent Order.

7. Respondent understands that any false or untrue statement or any material misrepresentation or omission of fact by Respondent in this Settlement Agreement may be grounds for further disciplinary action under HRS Chapters 436B and 461.

8. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's permit.

9. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

10. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2022-23-L.

11. Respondent acknowledges that upon its approval, this Settlement Agreement constitutes disciplinary action and understands that this Settlement Agreement may be subject to reporting requirements.

12. Respondent understands this Settlement Agreement is public record pursuant to HRS Chapter 92F.

C. TERMS OF SETTLEMENT:

1. Administrative Fine. Respondent agrees to pay a fine in the amount of ONE THOUSAND AND NO/100 DOLLARS ($1,00.00). Payment shall be made by cashier's check or money order made payable to "DCCA - Compliance Resolution Fund" and mailed to the Regulated Industries Complaints Office, Attn: Seth J. Corpuz-Lahne, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this Settlement Agreement is returned to RICO.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph C.1. above, Respondent's miscellaneous permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of licensure to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible Further Sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of miscellaneous permit holders in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5., C.6., C.7., and C.8. below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent, nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion, or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion, or promise made by RICO or any of its agents, employees, representatives, or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below. Each signatory to this Settlement Agreement hereby represents and warrants that he/she is authorized to execute and deliver this Settlement Agreement in the capacity shown below.

DATED: Boca Raton (City) Florida (State) May 16, 2022 (Date).

TRUSTEDMEDRX, LLC
Respondent

By: _____
(Signature)

Bryan Plonsky
(Print Name)

Its CFO
(Print Title)

DATED: Honolulu, Hawaii, May 19, 2022.

_____
SETH J. CORPUZ-LAHNE
Attorney for Department of Commerce
and Consumer Affairs

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF TRUSTEDMEDRX, LLC; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBIT "I"; RICO CASE NO. PHA 2022-23-L

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

ALANNA ISOBE Chairperson	June 16, 2022 DATE
JULIE YURIE TAKISHIMA-LACASA Vice Chairperson	PATRICK ADAMS
MARK BROWN	CATALINA CROSS
KENT KIKUCHI	SHERI TOKUMARU

PVL 4/20/22

DocuSign Envelope ID: 1EDC988C-7926-48C8-A1F4-FC1E1D48096F

IN THE MATTER OF:	)	BEFORE THE ALABAMA STATE
TRUSTEDMEDRX, LLC	)	BOARD OF PHARMACY
Non-Resident Pharmacy Permit No.: 114947	)	
and	)	CASE NO: 20-L-0144
TRAMAINE PRESTON SMITH	)	
License No.: 20874	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against TrustedMedRx, LLC and Tramaine Preston Smith (hereinafter referred to as "Smith") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement, as amended, which is attached hereto as Exhibit "A."

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the parties engaged in negotiations and as a result, the matters at issue were resolved informally by the parties who agreed to the entry of this Consent Order which includes the following terms:

1. The Board finds TrustedMedRx, LLC has violated the provisions law based upon the conduct set forth in Counts One and Two of the Statement. All other Counts applicable to TrustedMedRx, LLC shall be dismissed with prejudice.

2. The Board finds Smith has violated the provisions of law based upon the

Exhibit 1

conduct set forth in Count Four of the Statement. All other Counts applicable to Smith shall be dismissed with prejudice.

3. TrustedMedRx, LLC shall pay an administrative fine in the amount of Two Thousand Dollars ($2,000.00) and Smith shall pay an administrative fine in the amount of One Thousand Dollars ($1,000.00) within thirty (30) days of the effective date of this Consent Order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall TrustedMedRx, LLC or Smith attempt to discharge the same.

4. TrustedMedRx, LLC and Smith expressly waive their rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against them and any judicial review. TrustedMedRx, LLC and Smith further waive any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

5. TrustedMedRx, LLC and Smith acknowledge and agree that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing

thereof, result in further disciplinary sanctions against TrustedMedRx, LLC and Smith's permit/license, including, but not limited to revocation.

6. By execution of this Consent Order, TrustedMedRx, LLC and Smith hereby release the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

7. TrustedMedRx, LLC and Smith acknowledge and agree that they have read this Consent Order and that they fully understand the terms, conditions and contents of the same. TrustedMedRx, LLC and Smith acknowledge and agree that they voluntarily and of their own free will accept the terms and conditions set out in this Consent Order and are executing this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and had the right to seek advice of counsel before executing this Consent Order.

DONE this the 30th day of April, 2021.

TrustedMedRx, LLC

BY: [signature]
ITS: Malcolm Murphy, Chief Operating Officer

Tramaine Preston Smith

[signature]

DocuSign Envelope ID: 1EDC988C-7926-46C6-A1F4-FC1E1D49096F

DONE this the 5th day of MAY, 2021.

ALABAMA STATE BOARD OF PHARMACY

By: _____
Brenda Denson, PharmD., President

_____
James S. Ward,
Attorney for the Alabama State
Board of Pharmacy

OF COUNSEL:
WARD & COOPER, LLC
2100A Southbridge Parkway
Suite 645
Birmingham, AL 35209
(205) 871-5404

DocuSign Envelope ID: 1EDC988C-7928-46C6-A1F4-FC1E1D49096F

EXHIBIT "A"

IN THE MATTER OF:	BEFORE THE ALABAMA STATE
TRUSTEDMEDRX, LLC	BOARD OF PHARMACY
Non-Resident Pharmacy Permit No.: 114947	
and	CASE NO: 20-L-0144
TRAMAINE PRESTON SMITH	
License No.: 20874	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: TrustedmedRx, LLC
1200 S. Rogers Circle
Suite 4A
Boca Raton, Florida 33487

Tremaine Preston Smith
8077 Baltic Amber Road
Delray Beach, Florida 33446

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92 (12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on May 18, 2021 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why your license to practice pharmacy in this State should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or why the permit to operate TrustedmedRx, LLC should not be revoked, suspended or placed on probation or a monetary penalty imposed in that it is alleged that you and TrustedmedRx, LLC have been guilty of the following, to wit:

COUNT ONE

As to TrustedmedRx, LLC, violating Code of Alabama (1975), § 34-23-33(12) in that you violated Board Rule 680-X-2.12(8) by you being unable to maintain a designated Supervising Pharmacist and failed to notify the Board within ten (10) days with an action plan to designate another pharmacist as Supervising Pharmacist to-wit: Tramaine Preston Smith ceased to be your Supervising Pharmacist on or about September 18, 2020 and you, as of the date hereof, have not submitted the referenced action plan to the Board.

COUNT TWO

As to TrustedmedRx, LLC, violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of the preceding Count.

COUNT THREE

As to Tramaine Preston Smith, violating Code of Alabama (1975), § 34-23-33(12) in that you violated Board Rule 680-X-2.12(2) by upon assuming the duties of the Supervising Pharmacy of TrustedmedRx, LLC you failed to notify the Board within ten (10) days to-wit: you assumed the duties of the Supervising Pharmacist of TrustedmedRx, LLC on October 2, 2020 but the Boerd was not notified until December 16, 2020.

COUNT FOUR

As to Tramaine Preston Smith, violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of Count Three above.

Further, pursuant to the provisions of Code of Alabama, (1975), § 20-2-53 and § 41-22-12, you are hereby notified and requested to appear before the Board at the aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture, dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), § 20-2-1, et. seq., issued pursuant to Code of Alabama (1975), § 20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

COUNT FIVE

Violating Code of Alabama (1975), § 20-2-54(a)(4) by violating the provisions of Code of Alabama (1975), § 34-23-1 et seq., said violation being based upon the allegations contained in any or all of the preceding Counts of this Statement of Charges and Notice of Hearing.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 19th day of January, 2021.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

State of Florida
Department of State

I certify from the records of this office that TRUSTEDMEDRX, LLC is a limited liability company organized under the laws of the State of Florida, filed on September 27, 2016, effective March 1, 2013.

The document number of this limited liability company is L16000180553.

I further certify that said limited liability company has paid all fees due this office through December 31, 2023, that its most recent annual report was filed on January 19, 2023, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-ninth day of July, 2024



Secretary of State

Tracking Number: 2845949655CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

File # 24389
Insp # 172909

NAME	PERMIT NUMBER	DATE OF INSPECTION
TrustedMedRx, LLC	30632	03/24/2023
DOING BUSINESS AS TRUSTEDMEDRX		
STREET ADDRESS 1200 S. ROGERS CIRCLE SUITE 4A	TELEPHONE #	EXT
CITY BOCA RATON	COUNTY PALM BEACH	STATE/ZIP FL/33487

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 9 am - 5 pm
Monday N	Tuesday N
Wednesday N	Thursday N
Friday N	Saturday Y
Saturday Hours closed	Sunday Y
Sunday Hours closed	

Registered Pharmacist / Intern / Tech

License # 65307	Licensee Name Shaena Renberg
License Type Pharmacy Tech	
License # 51142	Licensee Name Dianelys Landa
License Type Pharmacy Tech	
License # 60471	Licensee Name Verina Essam Guirguis
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FT4948557	

License Relations

Pharmacy Affiliate

PLONSKY, BRYAN MICHAEL	License #
WOLFE, STEPHEN D	License #

RX DPT MGR/COR/POR

GUIRGUIS, VERINA ESSAM	License # 60471

Special Sterile Compounding

TRUSTEDMEDRX,LLC	License # 30631

INV 359 - Community Requirements

Signage Requirements Section

Signage stating the hours the pharmacy department is open. [64B16-28.1061 (2) F.A.C.]	Yes
A sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons stating, "Prescription Department Closed". [64B16-28.109 F.A.C.]	Yes

INV359 - Community Requirements

Insp # 172909 — TrustedMedRx, LLC — File # 24369

Patient Consultation Area sign is posted. [64B16-30.003, F.A.C]	Yes

Community Requirements General Section

Expired medications removed from the shelves. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]	Yes
Rx Department is open for a minimum of 20 hours per week. [64B16-28.1081 (1) F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05]	Yes
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) & F.A.C] *Daily logs observed, in compliance.*	Yes
Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102 F.A.C.]	Yes
Pharmacy technicians and interns properly identified and supervised [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16-27.420 F.A.C.].	Yes
Legend drugs properly stored. [64B16-28.118 F.A.C.]; [64B16-28.120 F.A.C.]	Yes
Documentation of destruction of controlled substances. [64B16-28.303, F.A.C.] *OutdatedRX*	Yes
Generic equivalent sign is posted. [465.025(7), F.S]	Yes

Additional Community Requirements

Prescription department is clean and safe, has a sink with running water convenient to the prescription department. [64B16-28.102 F.A.C.]	Yes
Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]	Yes
When a pharmacist is not on duty, the prescription department is securely locked, and no other personnel remain in the department. [64B16-28.109 F.A.C.]	Yes
Written policy and procedure manual regarding the number of technician positions and their utilization. [64B16-27.410(2) (a), F.A.C.]	Yes
Documentation signed by Pharmacy technician acknowledging review of the Policy and Procedure manual within 90 days of hire. [64B16-27.410(2) (b), F.A.C.]	Yes
Documentation that Pharmacy technician has been trained in the established job description. [64B16-27.410(2)(c), F.A.C.]	Yes
Pharmacy licenses are current. [465.015(1)(a) F.S.]	Yes
Private consultation area available [6416-28.1035 F.A.C.]	Yes
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Medication properly labeled. [499 F.S.]; [64B16-28.108 F.A.C.]; [893.04(1)(a) F.S.] [21CFR1306.24]; [21CFR1306.14]	Yes
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and summarization of Quality -Related Events which have been reviewed by the CQI committee quarterly are available for inspection. [64B16-27.300 F.A.C.]; [766.101(1)(a)(i) F.S.] *CQI's observed, in compliance.*	Yes
Policy and Procedure available and implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]	Yes
Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	Yes
Written prescriptions for controlled substances are on counterfeit-proof pads from Department-approved vendors [893.065 F.S.]; [456.42(2) F.S.]	Yes
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a) F.S.]; [21CFR1304.11] *Controlled substance inventory dated 3/1/23, OOB.*	Yes
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the origina order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)]	Yes
Controlled substance records and Rx information in computer system are retrievable. [21CFR1304.04], [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	Yes
Controlled substance records are maintained for 4 years [465.022(12) (b) F.S.] [64B16-28.140 F.A.C.]	Yes
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.] *None to report.*	N/A
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b) F.S.]; [465.022(11) (b) F.A.C.] *None to report.*	N/A
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.]	Yes
Compounding records properly maintained. [64B16-28.140(4), F.A.C.] *No compounding conducted at this establishment.*	N/A
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005 F.S.] [61N-1.012 F.A.C.]	Yes
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievab e for inspection. [499.005 (14) F.S.] *McKesson*	Yes
Administration begins not later than 1 hour following start of immediate use CSPs preparation. [64B16-27.797 F.A.C.]	N/A
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility [F.A.C 64B16-27.700(3)(g)]	N/A
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek followup care from his or her primary care physician. [465.1895 (9) F.S.]	N/A
Pharmacist has a written collaborative practice agreement. [465.1865, F.S.]	N/A
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S]	Yes

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10501, F.A.C]

INV359 - Community Requirements

Insp # 172809 | TrustedMedRx, LLC | File # 24369

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	
Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	

Pharmacy engages in Centralized Prescription Filling? [64B16-28.450, F.A.C.]

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	
The originating pharmacy is identified with pharmacy name and address on the prescription container label.	
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	
If a controlled substance, the word "central fill" appears on the face of the original prescription.	
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.	

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.]	
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197 (3)(e), F.S.]	
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S]	

Remarks:

Routine inspection conducted by Inspector Asaro on 3/24/23 along with Verina Guiguis, PDM.
SCS permit not in use, keeping paperwork updated and license current.
No compounding conducted.
No vaccines at this time.

I have read and have had this inspection report and the laws and regulations concerned here n explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature
ASARO, JENNIFER

Date:3/24/2023

Representative:
Verina Guiguis

Date:3/24/2023

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
02/10/2023	PH 30632	138707

THE PHARMACY

QUALIFICATION(S)
Schedule II & III
Community Pharmacy

NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

Expiration Date: FEBRUARY 28, 2025

TRUSTEDMEDRX, LLC
TrustedMedRx
1200 S. ROGERS CIRCLE
SUITE 4A
BOCA RATON, FL 33487

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
State Surgeon General

DISPLAY IF REQUIRED BY LAW

STATE OF FLORIDA AC#
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
02/10/2023	PH 30632	138707

THE PHARMACY

NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

Expiration Date : FEBRUARY 28, 2025

TRUSTEDMEDRX, LLC
TrustedMedRx

REGISTRANT SIGNATURE

QUALIFICATION(S):
Schedule II & III
Community Pharmacy

1
2752

C#1145731

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
02/10/2023	PH 30632	138707

THE PHARMACY

QUALIFICATION(S):
Schedule II & III
Community Pharmacy

NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

Expiration Date: FEBRUARY 28, 2025

TRUSTEDMEDRX, LLC
TrustedMedRx
1200 S. ROGERS CIRCLE
SUITE 4A
BOCA RATON, FL - 33487

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
State Surgeon General

DISPLAY IF REQUIRED BY LAW

VOID

2753

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

AC# 1 1 0 7 _ _

DATE	LICENSE NO.	CONTROL NO.
02/10/2023	PH 30632	138707

THE PHARMACY

NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

Expiration Date : FEBRUARY 28, 2025

TRUSTEDMEDRX, LLC
TrustedMedRx

REGISTRANT SIGNATURE

QUALIFICATION(S):
Schedule II & III
Community Pharmacy

TrustedMedRx, LLC

License Number: PH30632

Data As Of 8/28/2024

Profession	Pharmacy
License	PH30632
License Status	CLEAR/
Qualifications	Schedule II & III Community Pharmacy
License Expiration Date	2/28/2025
License Original Issue Date	02/13/2017
Address of Record	1200 S. ROGERS CIRCLE SUITE 4A BOCA RATON, FL 33487
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

If a link does not appear for the case number, we do not have a scanned copy of the final order available in our database. To obtain a paper copy, please contact Public Records by clicking the link below:

Discipline Public Records Request

You may also contact Public Records by telephone at (850) 245-4252, option 4 or by written correspondence at:
Division of Medical Quality Assurance
Public Records
4052 Bald Cypress Way, Bin C01
Tallahassee, FL 32399-3251

Please include the following:
1. Full name and license number of the practitioner;
2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

Supervising Practitioners

Name	Relationship	Profession	License	Effective Date
STEINBERG, DAVID LEVI	RX DPT MGR/COR/POR	PHARMACIST	54676	07/22/2024

TrustedMedRx, LLC

FEIN: 36-4848798

Name/Title	Date of Birth	SSN	Business Address	Home Address	Business Phone	Home Phone
Stephen Wolfe Owner/CEO	[redacted]		1200 S Rogers Cir, Ste 4 Boca Raton, FL 33487	[redacted] Cadena Dr Boca Raton, FL 33496	(561) 998-6039	[redacted]
Bryan Plonsky Owner/CEO			1200 S Rogers Cir, Ste 4 Boca Raton, FL 33487	[redacted] Parkside Cir S Boca Raton, FL 33486	(561) 998-6039	[redacted]

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler TRUSTEDMEDRX, LLC

Pharmacy/Wholesaler License # (if applicable) PH03662

Physical Address 1200 S ROGERS CIRCLE SUITE 4A

City BOCA RATON State FL Zip 33487

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 855-939-6337 Website TRUSTEDMEDRX.COM

Licensing Company Email RPH@TRUSTEDMEDRX.COM

Section 2: Personal Information

First DAVID Middle _____ Last STEINBERG

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address 1200 S ROGERS CIRCLE SUITE 4A

City BOCA RATON State FL Zip 33487

Telephone 855-939-6337 Email RPH@TRUSTEDMEDRX.COM

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
IDA CROWN JEWISH ACADEMY			1998-2002	
Address		City	State	Zip
8233 CENTRAL PARK AVENUE		SKOKIE	IL	60076
Diploma/Degree obtained, if any				
DIPLOMA				
School Name			From - To (MM/YY – MM/YY)	
UNIVERSITY OF ILLINOIS AT CHICAGO			2002-2006	
Address		City	State	Zip
1200 WEST HARRISON ST		CHICAGO	IL	60607
Diploma/Degree obtained, if any				
BACHELOR OF SCIENCE				
School Name			From - To (MM/YY – MM/YY)	
APPALACHIA COLLEGE OF PHARMACY			2006-2009	
Address		City	State	Zip
1060 DRAGON RD		OAKWOOD	VA	24631
Diploma/Degree obtained, if any				
PHARMD				
School Name			From - To (MM/YY – MM/YY)	
NOVA SOUTHEASTERN UNIVERSITY			2013-2017	
Address		City	State	Zip
3300 S UNIVERSITY DR		FT LAUDERDALE	FL	33328
Diploma/Degree obtained, if any				
JD				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2013-PRESENT	[redacted]AN MATEO DR E	BOCA RATON	FL	33433
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
MEDCO/ EXPRESS SCRIPTS			6/10-02/15	
Business Address		**City**	**State**	**Zip**
REMOTE		BOCA RATON	FL	33487
Phone	**Title**		**Number of Employed Hours**	
	CLINICAL MANAGER		40 /WEEK	

Description of Duties
Managed client relationships between over 15 Health Plans and +3,000,000 patients and Express Scripts including: Medical Mutual of Ohio, HealthNow NY Inc., Highmark Blue Cross Blue Shield, Wisconsin Physicians Services and Arise Health, Public Employee Health Program (PEHP) and Physicians Health

Business Name			From - To (MM/YY – MM/YY)	
TRUSTEDMEDRX, LLC			05/2016-PRESENT	
Business Address		**City**	**State**	**Zip**
1200 S ROGERS CIRCLE SUITE 4A		BOCA RATON	FL	33487
Phone	**Title**		**Number of Employed Hours**	
855-939-6337	PIC		40/ WEEK	

Description of Duties
Grown, lead and manage a growing team of 7 pharmacy technicians and 2 pharmacists across two national mail order pharmacies focused on patient care and niche products.

Business Name			From - To (MM/YY – MM/YY)	
SCRIPTA INSIGHTS INC			10/21-06/2022	
Business Address		**City**	**State**	**Zip**
REMOTE		BOCA RATON	FL	33487
Phone	**Title**		**Number of Employed Hours**	
	DIRECTOR OF PHARAMCY INSIGHTS		40/ WEEK	

Description of Duties
Utilizing my legal background, I am the lead analyst and reviewer on all PBM, TPA and third-party vendor contracts. I provide in-depth analysis on contract terms, discount rates, rebates rates both pharmacy and medical, renewals terms, formulary management and plan design recommendations

Business Name			From - To (MM/YY – MM/YY)	
BENECARD PBF			06/2022-PRESENT	
Business Address		**City**	**State**	**Zip**
REMOTE		BOCA RATON	FL	33487
Phone	**Title**		**Number of Employed Hours**	
	VICE PRESIDENTY			

Description of Duties
Focused on providing evidence-based strategy for our clients. With various market events currently occurring ranging from biosimilar launches and insulin pricing changes to supply chain and LDD contracts, our role is managing contracts several years into the future and navigating developments as

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, DAVID STEINBERG, **certify that as the designated representative for**

TRUSTEDMEDRX, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. DS I am at least 21 years of age;
3. DS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

DAVID STEINBERG
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/3/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

DAVID STEINBERG
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/3/2024
Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Palm Beach

I, David Steinberg, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/3/24
Date

Subscribed and Sworn to before me this 3 day of September.

Shaena Renberg
Notary Public Signature

Shaena Renberg
Comm.: HH 452089
Expires: Oct. 8, 2027
Notary Public - State of Florida

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site TRUSTEDMEDRX, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH04135

Physical Address 1200 S ROGERS CIRCLE SUITE 4A

City BOCA RATON State FL Zip 33487

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 855-939-6337 Website TRUSTEDMEDRX.COM

Licensing Company Email RPH@TRUSTEDMEDRX.COM

Section 2: Personal Information

First STEPHEN Middle _____ Last WOLFE

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Addres[redacted]CADENA DR

City BOCA RATON State FL Zip 33496

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
PENN STATE UNIVERSITY		1989-1993	
Address	**City**	**State**	**Zip**
128 Outreach Building	UNIVERSITY PARK	PA	16802
Diploma/Degree obtained, if any			
BACHELORS IN CRIMINAL JUSTICE			

School Name		From - To (MM/YY – MM/YY)	
HENDERSON HIGH SCHOOL		1985-1989	
Address	**City**	**State**	**Zip**
400 MONTGOMERY AVE	WEST CHESTER	PA	19380
Diploma/Degree obtained, if any			
DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1993-PRESENT	[redacted] CADENA DR	BOCA RATON	FL	33496
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
SENIOR INFORMATION CENTERS			06/01-PRESENT
Business Address	**City**	**State**	**Zip**
1200 S ROGERS CIRCLE SUITE 4	BOCA RATON	FL	33487
Phone	**Title**		
561-998-6039	OWNER AND FOUNDER		

Description of Duties
- Lead program development and implementation.
- Coordinate with legal and financial experts.

Business Name			From - To (MM/YY – MM/YY)
URGENTMEDRX, LLC			06/23- PRESENT
Business Address	**City**	**State**	**Zip**
6971 N FEDERAL HWY SUITE 203	BOCA RATON	FL	33487
Phone	**Title**		
888-536-9963	OWNER AND FOUNDER		

Description of Duties
- Oversee daily operations and strategic direction.
- Manage financial aspects, including financial planning.

Business Name			From - To (MM/YY – MM/YY)
TRUSTED HOMECARE AGENCY			06/22 - PRESENT
Business Address	**City**	**State**	**Zip**
6971 N FEDERAL HWY SUITE 100	BOCA RATON	FL	33487
Phone	**Title**		
561-770-6030	OWNER AND FOUNDER		

Description of Duties
- Oversee daily operations and strategic direction.
- Manage a team of over 10 employees.

Business Name			From - To (MM/YY – MM/YY)
TRUSTEDMEDRX, LLC			03/13-5/23 07/24-PRESE
Business Address	**City**	**State**	**Zip**
1200 S ROGERS CIRCLE SUITE 4A	BOCA RATON	FL	33487
Phone	**Title**		
855-939-6337	OWNER AND FOUNDER		

Description of Duties
- Oversee daily operations and strategic direction.
- Manage financial aspects, including financial planning.

Business Name			From - To (MM/YY – MM/YY)
TRUSTED HOMECARE SERVICES			06/11- PRESENT
Business Address	**City**	**State**	**Zip**
6971 N FEDERAL HWY SUITE 203	BOCA RATON	FL	33487
Phone	**Title**		
561-314-3976	OWNER AND FOUNDER		

Description of Duties
- Lead strategic planning and business development.
- Oversee patient care and service quality.

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9-3-2024
Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Palm Beach

I, Stephen Wolfe, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9-3-2024
Date

Subscribed and Sworn to before me this 3 day of September.

Notary Public Signature

Shaena Renberg
Comm.: HH 452089
Expires: Oct. 8, 2027
Notary Public - State of Florida

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 -- Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site TRUSTEDMEDRX, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH04135

Physical Address 1200 S ROGERS CIRCLE SUITE #4A

City BOCA RATON State FL Zip 33487

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 855-939-6337 Website TRUSTEDMEDRX.COM

Licensing Company Email RPH@TRUSTEDMEDRX.COM

Section 2: Personal Information

First BRYAN Middle _____ Last PLONSKY

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] PARKSIDE CIRCLE S

City BOCA RATON State FL Zip 33486

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
FLORIDA ATLANTIC UNIVERSITY		1991-1993	
Address	**City**	**State**	**Zip**
777 GLADES RD	BOCA RATON	FL	33431
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
HENDERSON HIGH SCHOOL		1985-1989	
Address	**City**	**State**	**Zip**
400 MONTGOMERY AVE	WEST CHESTER	FL	19380
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1993-PRESENT	[redacted]PARKSIDE CIRCLE S	BOCA RATON	FL	33486
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
SENIOR INFORMATION CENTERS	06/01-PRESENT

Business Address	City	State	Zip
1200 S ROGERS CIRCLE SUITE 4	BOCA RATON	FL	33487

Phone	Title
561-998-6039	OWNER AND FOUNDER

Description of Duties
- Assisted over 500 seniors with estate planning.
- Developed educational programs on financial literacy for seniors.

Business Name	From - To (MM/YY – MM/YY)
TRUSTED HOME CARE SERVICES	06/11-PRESENT

Business Address	City	State	Zip
6971 N FEDERAL HWY SUITE 203	BOCA RATON	FL	33487

Phone	Title
561-314-3976	OWNER AND FOUNDER

Description of Duties
- Lead strategic planning and business development.
- Oversee patient care and service quality.

Business Name	From - To (MM/YY – MM/YY)
URGENTMEDRX, LLC	06/18-present

Business Address	City	State	Zip
6971 N FEDERAL HWY SUITE 203	BOCA RATON	FL	33487

Phone	Title
888-536-9963	OWNER AND FOUNDER

Description of Duties
- Oversee daily operations and strategic direction.
- Manage financial aspects, including financial planning.

Business Name	From - To (MM/YY – MM/YY)
TRUSTED HOME CARE AGENCY	06/22-PRESENT

Business Address	City	State	Zip
6971 N FEDERAL HWY SUITE 100	BOCA RATON	FL	33487

Phone	Title
561-770-6030	OWNER AND FOUNDER

Description of Duties
- Oversee daily operations and strategic direction.
- Manage a team of over 10 employees.

Business Name	From - To (MM/YY – MM/YY)
TRUSTEDMEDRX, LLC	3/13-5/23; 7/24-PRESEN

Business Address	City	State	Zip
1200 S ROGERS CIRCLE	BOCA RATON	FL	33487

Phone	Title
855-939-6337	OWNER AND FOUNDER

Description of Duties
- Oversee daily operations and strategic direction.
- Manage financial aspects, including financial planning.

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9-3-2024
Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Palm Beach

I, Bryan Glinsky, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9-3-2024
Date

Subscribed and Sworn to before me this 3 day of September.

Shaena Renberg
Comm.: HH 452089
Expires: Oct. 8, 2027
Notary Public - State of Florida

Shaena Renberg
Notary Public Signature

(Seal)

4FFF

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH PH04135		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: URGENTMEDRX, LLC

Physical Address: 6971 N FEDERAL HWY SUITE 203

City: BOCA RATON State: FL Zip: 33487

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 888-536-9963 Toll Free # (NAC 639.708, NRS 639.23286): 888-536-9963

Fax: 844-253-5061 Contact Email: RPH@URGENTMEDRX.COM

Website: URGENTMEDRX.COM

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): GRACE CARPENTER

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23802

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: GRACE CARPENTER	NV Pharmacist Registration #: 23802
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): Pellucid Ventures, LLC

Corporation/Organization Name: UrgentMedRx, LLC

Mailing Address: 6971 N Federal Hwy, Ste 203

City: Boca Raton State: FL Zip: 33487

Telephone: (888) 536-9963 Email: Rph@urgentmedrx.com

Contact Person Name: Liane Parker - (740) 994-1811 Ext 110; liane@quantifyrc.com

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the PHARMACY MANAGER (title) for URGENTMEDRX, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

GRACE CARPENTER

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

8/28/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, GRACE CARPENTER, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the PHARMACY MANAGER (title) for URGENTMEDRX, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 28 day of August, 2024

Notary Public

Shaena Renberg
Comm.: HH 452089
Expires: Oct. 8, 2027
Notary Public - State of Florida

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Grace Carpenter

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

8/28/24

Date

Board Use Only	Date Received: _____	Amount: 500.00/1#5064

State of Florida
Department of State

I certify from the records of this office that URGENTMEDRX LLC is a limited liability company organized under the laws of the State of Florida, filed on June 15, 2018.

The document number of this limited liability company is L18000148509.

I further certify that said limited liability company has paid all fees due this office through December 31, 2024, that its most recent annual report was filed on April 4, 2024, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Seventh day of August, 2024



Secretary of State

Tracking Number: 5402955402CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

www.FloridaHealth.gov

File # 25668
Insp # 175991

NAME	PERMIT NUMBER	DATE OF INSPECTION
URGENTMEDRX, LLC	31689	02/02/2023
DOING BUSINESS AS		
STREET ADDRESS 6971 N. FEDERAL HIGHWAY SUITE 203	**TELEPHONE #** 561-826-9563	**EXT**
CITY BOCA RATON	**COUNTY** PALM BEACH	**STATE/ZIP** FL/33487

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 9:00 am to 5:00 pm
Monday N	Monday Hours
Tuesday N	Tuesday Hours
Wednesday N	Wednesday Hours
Thursday N	Thursday Hours
Friday N	Friday Hours
Saturday N	Saturday Hours
Sunday N	Sunday Hours

Registered Pharmacist / Intern / Tech

License # 54676	Licensee Name David Levi Steinberg
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FU8024983	

License Relations

Pharmacy Affiliate

PLONSKY, BRYAN MICHAEL	License #
STEINBERG, DAVID LEVI	License # 54676
WOLFE, STEPHEN	License #

RX DPT MGR/COR/POR

CARPENTER, GRACE MARIE	License # 43300

INV 359 - Community Requirements

Signage Requirements Section

Signage stating the hours the pharmacy department is open. [64B16-28.1081 (2) F.A.C.]	Yes
A sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons stating, "Prescription Department Closed". [64B16-28.109 F.A.C.]	Yes
Patient Consultation Area sign is posted. [64B16-30.003, F.A.C]	Yes

Community Requirements General Section

Expired medications removed from the shelves. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]	Yes

INV359 - Community Requirements

URGENTMEDRX, LLC

Rx Department is open for a minimum of 20 hours per week. [64B16-28.1081 (1) F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05]	Yes
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) & F.A.C] *Daily logs observed, in compliance.*	Yes
Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102 F.A.C.]	Yes
Pharmacy technicians and interns properly identified and supervised [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16-27.420 F.A.C.]. *No technicians employed.*	N/A
Legend drugs properly stored. [64B16-28.118 F.A.C.]; [64B16-28.120 F.A.C.]	Yes
Documentation of destruction of controlled substances. [64B16-28.303, F.A.C.] *Outdate RX*	Yes
Generic equivalent sign is posted. [465.025(7), F.S]	Yes

Additional Community Requirements

Prescription department is clean and safe, has a sink with running water convenient to the prescription department. [64B16-28.102 F.A.C.]	Yes
Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]	Yes
When a pharmacist is not on duty, the prescription department is securely locked, and no other personnel remain in the department. [64B16-28.109 F.A.C.]	Yes
Written policy and procedure manual regarding the number of technician positions and their utilization. [64B16-27.410(2) (a), F.A.C.]	Yes
Documentation signed by Pharmacy technician acknowledging review of the Policy and Procedure manual within 90 days of hire. [64B16-27.410(2) (b), F.A.C.] *No technicians employed.*	N/A
Documentation that Pharmacy technician has been trained in the established job description. [64B16-27.410(2)(c), F.A.C.] *No technicians employed.*	N/A
Pharmacy licenses are current. [465.015(1)(a) F.S.]	Yes
Private consultation area available [6416-28.1035 F.A.C.]	Yes
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Medication properly labeled. [499 F.S.]; [64B16-28.108 F.A.C.]; [893.04(1)(e) F.S.] [21CFR1306.24]; [21CFR1306.14]	Yes
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and summarization of Quality -Related Events which have been reviewed by the CQI committee quarterly are available for inspection. [64B16-27.300 F.A.C.]; [766.101(1)(a)(l) F.S.] *CQI's observed, in compliance.*	Yes
Policy and Procedure available and implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]	Yes
Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	Yes
Written prescriptions for controlled substances are on counterfeit-proof pads from Department-approved vendors. [893.065 F.S.]; [456.42(2) F.S.]	Yes
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a) F.S.]; [21CFR1304.11] *January 2023, COB.*	Yes
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)] *In compliance.*	Yes
Controlled substance records and Rx information in computer system are retrievable. [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	Yes
Controlled substance records are maintained for 4 years [465.022(12) (b) F.S.] [64B16-28.140 F.A.C.]	Yes
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.] *None to report.*	N/A
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b) F.S.]; [465.022(11) (b) F.A.C.] *None to report.*	N/A
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.]	Yes
Compounding records properly maintained. [64B16-28.140(4), F.A.C.] *No compounding conducted at this establishment.*	N/A
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005 F.S.] [61N-1.012 F.A.C.]	Yes
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.] *McKesson*	Yes
Administration begins not later than 1 hour following start of immediate use CSPs preparation. [64B16-27.797 F.A.C.]	N/A
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility [F.A.C 64B16-27.700(3)(g)]	N/A
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek followup care from his or her primary care physician. [465.1895 (9) F.S.]	N/A
Pharmacist has a written collaborative practice agreement. [465.1865, F.S.]	N/A
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S]	Yes

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

INV359 - Community Requirements

Insp # 175991

URGENTMEDRX, LLC

File # 25668

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	Yes
Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	Yes

Pharmacy engages in Centralized Prescription Filling? [64B16-28.450, F.A.C.]

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	
The originating pharmacy is identified with pharmacy name and address on the prescription container label.	
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	
If a controlled substance, the word "central fill" appears on the face of the original prescription.	
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.	

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.]	
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197 (3)(e), F.S.]	
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S]	

Remarks:

Routine inspection conducted by Inspector Asaro on 2/2/23 along with Grace Carpenter, PDM.
No technicians employed, no compounding conducted. Facility is in compliance.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

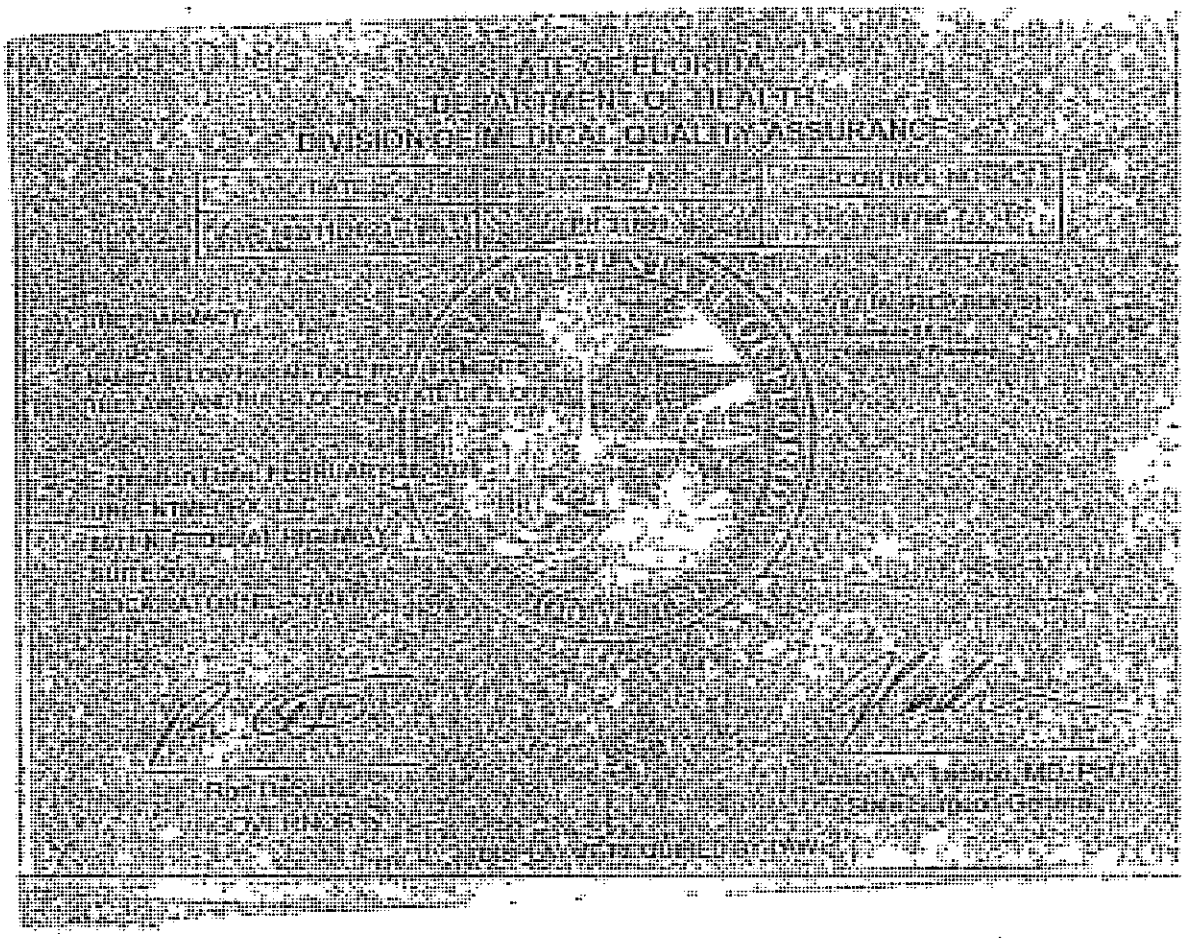
ASARO, JENNIFER

Date:2/2/2023

Representative:

Grace Carpenter

Date:2/2/2023



Florida HEALTH Department of Health

URGENTMEDRX, LLC

License Number: PH31689

Data As Of 8/28/2024

Profession	Pharmacy
License	PH31689
License Status	CLEAR/
Qualifications	Schedule II & III Community Pharmacy
License Expiration Date	2/28/2025
License Original Issue Date	10/05/2018
Address of Record	6971 N. FEDERAL HIGHWAY SUITE 203 BOCA RATON, FL 33487
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

If a link does not appear for the case number, we do not have a scanned copy of the final order available in our database. To obtain a paper copy, please contact Public Records by clicking the link below:

Discipline Public Records Request

You may also contact Public Records by telephone at (850) 245-4252, option 4 or by written correspondence at:
Division of Medical Quality Assurance
Public Records
4052 Bald Cypress Way, Bin C01
Tallahassee, FL 32399-3251

Please include the following:
1. Full name and license number of the practitioner;
2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

Supervising Practitioners

Name	Relationship	Profession	License	Effective Date
CARPENTER, GRACE MARIE	RX DPT MGR/COR/POR	PHARMACIST	43300	05/18/2022

Names of Owners/Operators

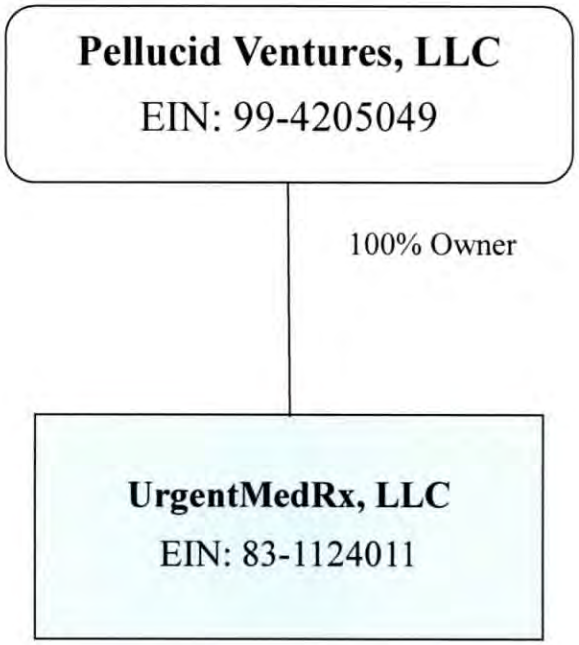
Officers and Manager – **UrgentMedRx, LLC**

Full Name	Title	Address
Sumanth Reddy	Manager/Chairman	[redacted] Penrith Ct, Dublin, OH 43016
Liane Parker	President	[redacted] Cinwood St NW Massillon OH 44646
Justin Goldston	Treasurer/Chief Financial Officer	[redacted] Saint Michael Drive Dallas TX 75232

Parent Company

Legal Name	EIN	Mailing Address	State of Incorporation
Pellucid Ventures, LLC	99-4205049	4035 Cinwood St. NW, Massillon, OH 44646	Delaware

Post-Closing Organizational Structure
as of September 16, 2024



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler URGENTMEDRX, LLC

Pharmacy/Wholesaler License # (if applicable) PH04135

Physical Address 6971 N FEDERAL HWY SUITE 203

City BOCA RATON State FL Zip 33076

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 888-536-9963 Website URGENTMEDRX.COM

Licensing Company Email RPH@URGENTMEDRX.COM

Section 2: Personal Information

First GRACE Middle MARIE Last CARPENTER

Alias(es, nic[redacted]anges, etc.) GARZA, MCNAREN

Date of Birt[redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]NW 57TH ST

City CORAL SPRINGS State FL Zip 33076

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
NOVA SOUTHEASTERN UNIVERSITY SCHOOL OF PHARMACY		2001-2007	
Address	**City**	**State**	**Zip**
3300 S UNIVERSITY DRIVE	FT LAUDERDALE	FL	33328
Diploma/Degree obtained, if any			
PHARMD			

School Name		From - To (MM/YY – MM/YY)	
NOVA SOUTHEASTERN UNIVERSITY UNDERGRADUATE		1999-2001	
Address	**City**	**State**	**Zip**
3300 S UNIVERSITY DRIVE	FT LAUDERDALE	FL	33328
Diploma/Degree obtained, if any			
BS SCIENCE			

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF MIAMI		1997-1999	
Address	**City**	**State**	**Zip**
4300 NW 12TH AVE	MIAMI	FL	33127
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
NOVA HIGH SCHOOL		1993-1997	
Address	**City**	**State**	**Zip**
3600 COLLEGE AVE	Davie	FL	33314
Diploma/Degree obtained, if any			
DIPLOMA			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2008-PRESENT	[redacted] NW 57TH ST	CORAL SPRINGS	FL	33076
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
URGENTMEDRX, LLC			2022-PRESENT
Business Address	**City**	**State**	**Zip**
6971 N FEDERAL HWY SUITE 203	BOCA RATON	FL	33076
Phone	**Title**		**Number of Employed Hours**
888-536-9963	PHARMACY MANAGER		40 HOURS/DAY
Description of Duties			
Reviewing prescriptions, organizing the pharmacy, delivering and labeling medications, and providing information and advice to patients. Ensuring safe medication use, monitor patient history, and stay updated on advancements in meds			

Business Name			From - To (MM/YY – MM/YY)
WINN DIXIE			2021-2022
Business Address	**City**	**State**	**Zip**
1150 NW 54TH ST	MIAMI	FL	33076
Phone	**Title**		**Number of Employed Hours**
305-757-0696	STAFF PHARMACIST		40
Description of Duties			
Reviewing prescriptions, organizing the pharmacy, delivering and labeling medications, and providing information and advice to patients. Ensuring safe medication use, monitor patient history, and stay updated on advancements in meds			

Business Name			From - To (MM/YY – MM/YY)
CVS			2015-2021
Business Address	**City**	**State**	**Zip**
5044 FOREST HILL BLVD	WEST PALM BEACH	FL	33415
Phone	**Title**		**Number of Employed Hours**
561-967-9118	FLOATER PHARMACIST		30-40
Description of Duties			
Reviewing prescriptions, organizing the pharmacy, delivering and labeling medications, and providing information and advice to patients. Ensuring safe medication use, monitor patient history, and stay updated on advancements in meds			

Business Name			From - To (MM/YY – MM/YY)
WALGREENS			2000-2014
Business Address	**City**	**State**	**Zip**
14901 NW 79TH CT	CORAL SPRINGS	FL	33415
Phone	**Title**		**Number of Employed Hours**
	FLOATER PHARMACIST		30-40
Description of Duties			
Reviewing prescriptions, organizing the pharmacy, delivering and labeling medications, and providing information and advice to patients. Ensuring safe medication use, monitor patient history, and stay updated on advancements in meds			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.		Yes	No
1.	Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2.	If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3.	Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4.	Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5.	Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6.	Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7.	Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8.	Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9.	Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10.	Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, GRACE CARPENTER, **certify that as the designated representative for**

URGENTMEDRX, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. GC I am at least 21 years of age;
3. GC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. GC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. GC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. GC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. GC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

GRACE CARPENTER

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/28/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

GRACE CARPENTER

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/28/24
Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Palm Beach

I, Grace Carpenter, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/28/24
Date

Subscribed and Sworn to before me this 28 day of August.

Notary Public Signature

Shaena Renberg
Comm.: HH 452089
Expires: Oct. 8, 2027
Notary Public - State of Florida

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site URGENTMEDRX, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH04135

Physical Address 6971 N FEDERAL HWY, SUITE 203

City BOCA RATON State FL Zip 33487

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 888-536-9963 Website URGENTMEDRX.COM

Licensing Company Email _____

Section 2: Personal Information

First Liane Middle _____ Last Parker

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted] Cinwood St NW

City Massillon State OH Zip 44646

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Stark State College		08/17-05/19	
Address	City	State	Zip
6200 Frank Ave NW	North Canton	OH	44720
Diploma/Degree obtained, if any			
AAS Nursing			

School Name		From - To (MM/YY – MM/YY)	
Jefferson Community College (Eastern Gateway Community College)		08/02-05/05	
Address	City	State	Zip
4000 Sunset Boulevard	Steubenville	OH	43952
Diploma/Degree obtained, if any			
Certificate Practical Nursing			

School Name		From - To (MM/YY – MM/YY)	
Ohio Department of Education		08/02	
Address	City	State	Zip
Front Street, MS 622	Columbus	OH	43215
Diploma/Degree obtained, if any			
GED			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/12-12/19	[redacted]Conrad St	Louisville	OH	44646
01/20-03/20	[redacted]S MAIN ST	Lobelville	TN	37097
03/20-01/21	[redacted]LOWER LICK CREEK RD	Linden	TN	37096
1/21-08/21	[redacted]6th st nw	Canton	OH	44710
08/21- present	[redacted]inwood st NW	Massillon	OH	44646

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: QRC Technical Services LLC			From - To (MM/YY – MM/YY): 11/19present
Business Address: 4226 Penrith CT	City: Dublin	State: OH	Zip: 43016
Phone: 740-994-1811	Title: CEO		
Description of Duties: Owner or virtual national healthcare company providing chronic disease management, remote monitoring, expert billing assistance.			

Business Name: New Century Health			From - To (MM/YY – MM/YY): 02/16-10/19
Business Address: 915 W Imperial Hwy #200,	City: Brea	State: CA	Zip: 92821
Phone: 888-999-7713	Title: Clinical business analyst		
Description of Duties: Clinical business analyst with focus on oncology evidenced based prior auth platform development			

Business Name: Health Help			From - To (MM/YY – MM/YY): 05/10-02/16
Business Address: 16945 Northchase Dr #1200	City: Houston	State: TX	Zip: 77060
Phone: 281-447-7000	Title: Utilization Management Specialist		
Description of Duties: UM Department supervisor, program design, clinical platform creator for prior auth, audit manager			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Liane Parker

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/5/24

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Stark

I, Liane Parker, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/5/24

Date

Subscribed and Sworn to before me this 5 day of September, 2024

Notary Public Signature Comm. exp. June 4, 2028

(Seal)

4GGG

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacist to Engage in the Practice of Pharmacy at a Site other than a Licensed Pharmacy

Rev (04/18/2023)

This application cannot be returned by fax or email.
We must have an original signature to process.

Section 1: Select the following that applies to you.

- ☐ **I am employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity (If you marked this as your answer complete sections 1, 2, 3, 5, 7)**
- ☐ **I am a pharmacist who is employed by or under contract with a Nevada licensed pharmacy located within a hospital or correctional institution (If you marked this answer complete section 1, 2, 3, 5, 7)**
- ☑ **I am NOT employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity (If you marked this as your answer complete sections 1, 2, 4, 5, 6, 7)**

Section 2: General Information

First: Stephanie Middle: A Last: Andersson

NV Pharmacist Registration # 21357

Telephone: [redacted] Email: [redacted]

Section 3: Nevada Licensed Pharmacy as defined in NRS 639.012, or Nevada State Government Entity Information

Pharmacy/State Government Entity Name:

NV Pharmacy License # (if Pharmacy) or State Issued License # (if State Government Entity):

Address:

City: State: Zip:

Employer Contact Name:

Employer Contact Telephone: Employer Contact email:

Section 4: Employer Information

Name or Identity of Employer or Business as registered with the Nevada Secretary of State chapter 76 of NRS:

CVS Caremark

Address: 1300 E. Campbell Rd

City: Richardson State: TX Zip: 75081

Employer Contact Name: Jason Wirt

Employer Contact Telephone: [redacted] Employer Contact email: Jason.Wirt@CVSHealth.com

Section 5: Place where the Pharmacist will Engage in the Practice of Pharmacy (list all sites)

Name of Site (if applicable): Remote / Work-from-home

Address: [redacted] Portola Valley St.

City: Las Vegas State: NV Zip: 89178

Country/Territory/Province: USA

Is this a medical, residential, or business site? ☐ Medical ☑ Residential ☐ Business

Days of the week and hours services will be provided at this site? M-F 9:30am - 6pm PST

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

(Use and make copies of this page if necessary)

Section 6: NAC 639.403 A registered pharmacist who is NOT employed by or under contract with a pharmacy and who is NOT an employee of the State Government MUST complete this section.

1. Provide a description of the services that you intend to provide at the site, to include only those services listed in Section 7 (A) of this application.

Prior authorization: Decision prior authorization request

2. Provide the identification of the types of patients or other persons to whom you intend to provide services.

- MD_office
- commercially insured patients

3. Provide a description of all resources, both paper and electronic, that will be available to you in the course of providing the services.

- AS400
- CAS
- micromedex
- Clinical Pharmacology

4. Provide an explanation of the policy for users of the services when you are unavailable.

CVS caremark utilizing the Source to house various policies & procedures to handle client's prior authorizations.

5. Provide an explanation of the policy regarding the confidentiality and security of the patient data that will be gathered, made, and maintained as part of the services which are provided, including without limitation, paper and electronic records.

Training completed ~~Regarding~~ privacy, confidentiality + security for PHI.
Using CVS caremark provided equiptment.

6. Provide a description of the business plan for the services provided.

Following CVS caremark business plan

Section 7: Laws pertaining to engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy. Please read Section 7 in its entirety. By signing this application, you attest you have read and understood the components in this section.

A. NAC 639 - For all registered pharmacists engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy

1. While engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy, a registered pharmacist may perform only:
    a. The functions described in paragraphs (b), (c), (d) and (g) to (j), inclusive, of subsection 1 or NRS 639.0124, except for dispensing or administering drugs;
    b. The functions described in section 4 of LCB File No. R036.21, except for dispensing a self-administered hormonal contraceptive; and
    c. The administration of immunizations pursuant to a written protocol established in accordance with NAC 639.297 to 639.2978, inclusive.
2. A registered pharmacist who engages in the practice of pharmacy at a location other than the site of a licensed pharmacy shall:
    a. Provide written notice of the site of practice to the Executive Secretary in accordance with NAC 639.225 on this application; (NAC 639.225 states that a Nevada pharmacist, within 10 days after changing residence or place of practice, must give written notice of the change to the Board.)
    b. Ensure that the records of the registered pharmacist are made readily accessible to members of the Board and employees, agents and designees of the Board; and
    c. Comply with all applicable federal and state laws and regulations, including, without limitation:
        i. The Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, and the regulations adopted pursuant thereto, and any other applicable federal or state law concerning the privacy of information regarding health care; and
        ii. Requirements relating to the maintenance or records.
3. A registered pharmacist who engages in the practice of pharmacy at a location other than the site of a licensed pharmacy shall not maintain an inventory of drugs at that location.
4. A registered pharmacist shall not engage in the practice of pharmacy at a location other than the site of a licensed pharmacy if he or she:
    a. Serves as a managing pharmacist; or
    b. Provides pharmaceutical services at:
        i. A facility for modified medical detoxification, as defined in NRS 449.00385;
        ii. An independent center for emergency medical care, as defined in NRS 449.013;
        iii. A facility for intermediate care, as defined in NRS 449.0038;
        iv. A facility for skilled nursing, as defined in NRS 449.0039; or
        v. A surgical center for ambulatory patients, as defined in NRS 449.019.

B. NAC 639 - For a registered pharmacist who is employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity.

For a registered pharmacist who is employed by or under contract with a pharmacy or who is an employee of the State Government may engage in the practice of pharmacy at a location other than the site of a licensed pharmacy shall not engage in the practice of pharmacy at a location other than the site of a licensed pharmacy unless he or she is provided with the same computerized system and access to data regarding a patient for whom a prescription has been submitted that is available to a registered pharmacist in the pharmacy. Such data must include, without limitation:

a. A legible copy of the prescription that is available as an electronic copy or a scanned image in the computerized system of the pharmacy or by facsimile machine; and
b. Any information that is available in the computerized system of the pharmacy that is relevant or necessary for the registered pharmacist to provide pharmaceutical services.

C. NAC 639.403 - For a registered pharmacist who is NOT employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity.

For a registered pharmacist who is NOT employed by or under contract with a pharmacy or who is an employee of the State Government shall not engage in the practice of pharmacy at a site other than the site of a licensed pharmacy unless he or she obtains the approval of the Board to engage in the practice of pharmacy at a site other than the site of a licensed pharmacy. To request such approval, the registered pharmacist must submit this application. The application must be approved before a registered pharmacist may commence any practice.

D. NAC 639.4916 - For a registered pharmacist who is employed by or under contract with a Nevada licensed pharmacy located within a hospital or correctional institution:

1. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide the remote chart order processing services to the hospital or correctional institution that the pharmacy is required by NAC 639.4915 to provide must:
    a. Be trained in the policies and procedures of the hospital or correctional institution regarding all policies and procedures of the hospital or correctional institution with which the registered pharmacist must comply, including, without limitation, the provisions of pharmaceutical services, security, and confidentiality of patient records; and
    b. Be provided with the same computerized system and access to data regarding a patient for whom a chart order has been submitted that would be available to a registered pharmacist employe by the pharmacy located within the hospital or correctional institution, including, without limitation:
        i. The height, weight and age of the patient and any allergies that the patient may have;
        ii. The medical records regarding any medications prescribed to the patient;
        iii. The results of any relevant laboratory tests;
        iv. The health history and notes regarding physical examinations, to the extent that the information is available in the computerized system of the hospital or correctional institution;
        v. Any notes provided by a physician, nurse or other medical staff of the institution, to the extent that those notes are available in the computerized system of the hospital or correctional institution;
        vi. A legible copy of the chart order that is available through a scanned image in the computerized system of the hospital or correctional institution or by facsimile machine; and
        vii. Any other information that is available in the computerized system of the hospital or correctional institution that is relevant or necessary for the registered pharmacist to provide pharmaceutical services.
2. Before a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution provides remote chart order processing services to the hospital or correctional institution, the registered pharmacist must review any relevant information regarding the patient for whom a chart order has been submitted. The registered pharmacist must, before approving a chart order to be filled, evaluate:
    a. The overutilization or underutilization of a medication;
    b. Therapeutic duplication;
    c. The appropriateness of the prescribed dosage and route of administration;
    d. The appropriateness of the directions for use of the medication;
    e. The appropriateness of the duration of the treatment with the prescribed medication;
    f. Any contraindication of the medication and a particular disease, ailment or allergy of the patient;
    g. Any contraindication or interactions between multiple medications prescribed for the patient; and
    h. The potential abuse or misuse of a medication.
3. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution provides remote chart order processing services to the hospital or correctional institution shall comply with the requirements of Section 7 (A) to the same extent as a registered pharmacist engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy pursuant to the provisions in Section 7 (B) and Section 7 (C).
4. In an emergency, a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution may render remote chart order processing services without being provided with all the information required by paragraph (b) of subsection 1 of Section 7 (D) if the registered pharmacist believes, in his or her professional judgement, that he or she has received sufficient information from the staff of the hospital or correctional institution to render the services.
5. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution may refuse to approve the filling of a chart order if, in the judgement of the registered pharmacist, the chart order is not safe or reasonable for the patient. A registered pharmacist who refuses to approve the filling of a chart order pursuant to this subsection must notify the hospital or correctional institution as soon as practicable that he or she has refused to approve the filling of the chart order.
6. Each time that a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution

provides remote chart order processing services pursuant to this section, the registered pharmacist shall make a notation in the computerized system of the hospital or correctional institution that indicates:

a. The name or identifier of the registered pharmacist;
b. The date and time that the registered pharmacist provided the services and, if applicable, approved the filling of a chart order; and
c. The specific services provided by the registered pharmacist.

7. The managing pharmacist of a pharmacy located within a hospital or a correctional institution may limit the remote chart order processing services provided pursuant to this section (Section 7 (D)).

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I attest to the knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices. NRS 639.132

I understand that Nevada law requires a registered pharmacist who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Stephanie Andersson

Print Name

Original Signature, no copies or stamps accepted

10/15/2024

Date

Board Use Only	Date Received: 10/24/24 For applicants who marked box 1 or 2 in Section 1: Executive staff to review, scanned into applicant file. For applicants who marked box 3 in Section 1: Executive staff to review, place on consent agenda.

4HHH

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacist to Engage in the Practice of Pharmacy at a Site other than a Licensed Pharmacy

Rev (04/18/2023)

This application cannot be returned by fax or email.
We must have an original signature to process.

Section 1: Select the following that applies to you.

- ☐ **I am employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity (If you marked this as your answer complete sections 1, 2, 3, 5, 7)**
- ☐ **I am a pharmacist who is employed by or under contract with a Nevada licensed pharmacy located within a hospital or correctional institution (If you marked this answer complete section 1, 2, 3, 5, 7)**
- ☒ **I am NOT employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity (If you marked this as your answer complete sections 1, 2, 4, 5, 6, 7)**

Section 2: General Information

First: KARA Middle: MARIE Last: BALDUZZI

NV Pharmacist Registration # 18074

Telephone: [redacted] Email: [redacted]

Section 3: Nevada Licensed Pharmacy as defined in NRS 639.012, or Nevada State Government Entity Information

Pharmacy/State Government Entity Name: _____

NV Pharmacy License # (if Pharmacy) or State Issued License # (if State Government Entity): _____

Address: _____

City: _____ State: _____ Zip: _____

Employer Contact Name: _____

Employer Contact Telephone: _____ Employer Contact email: _____

Section 4: Employer Information

Name or Identity of Employer or Business as registered with the Nevada Secretary of State chapter 76 of NRS:

Prime Therapeutics

Address: 2900 Ames Crossing Road

City: Eagan State: MN Zip: 55121

Employer Contact Name: Will Botterman

Employer Contact Telephone: [redacted] Employer Contact email: william.botterman@primetherapeutics.com

Section 5: Place where the Pharmacist will Engage in the Practice of Pharmacy (list all sites)

Name of Site (if applicable): home office

Address: [redacted] cayuga parkway

City: Las Vegas State: NV Zip: 89169

Country/Territory/Province: USA

Is this a medical, residential, or business site? ☐ Medical ☑ Residential ☐ Business

Days of the week and hours services will be provided at this site? M-F 6-4:00 pm PST select Saturdays PRN

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

(Use and make copies of this page if necessary)

Section 6: NAC 639.403 A registered pharmacist who is NOT employed by or under contract with a pharmacy and who is NOT an employee of the State Government MUST complete this section.

1. Provide a description of the services that you intend to provide at the site, to include only those services listed in Section 7 (A) of this application.

Reviewing prior authorizations

2. Provide the identification of the types of patients or other persons to whom you intend to provide services.

Medicare Patients of Prime Therapeutics

3. Provide a description of all resources, both paper and electronic, that will be available to you in the course of providing the services.

Daily Med, Micromedex, Pharmacist Letter
All Prime Therapeutics internal resources

4. Provide an explanation of the policy for users of the services when you are unavailable.

I am one of several reviewers it would be covered by other pharmacists on staff

5. Provide an explanation of the policy regarding the confidentiality and security of the patient data that will be gathered, made, and maintained as part of the services which are provided, including without limitation, paper and electronic records.

No paper records are kept
All PHI is kept private, password complete & locked room that only I have access to.

6. Provide a description of the business plan for the services provided.

I am following Prime Therapeutics Business plan.

Section 7: Laws pertaining to engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy. Please read Section 7 in its entirety. By signing this application, you attest you have read and understood the components in this section.

A. NAC 639 - For all registered pharmacists engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy

1. While engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy, a registered pharmacist may perform only:
    a. The functions described in paragraphs (b), (c), (d) and (g) to (j), inclusive, of subsection 1 or NRS 639.0124, except for dispensing or administering drugs;
    b. The functions described in section 4 of LCB File No. R036.21, except for dispensing a self-administered hormonal contraceptive; and
    c. The administration of immunizations pursuant to a written protocol established in accordance with NAC 639.297 to 639.2978, inclusive.
2. A registered pharmacist who engages in the practice of pharmacy at a location other than the site of a licensed pharmacy shall:
    a. Provide written notice of the site of practice to the Executive Secretary in accordance with NAC 639.225 on this application; (NAC 639.225 states that a Nevada pharmacist, within 10 days after changing residence or place of practice, must give written notice of the change to the Board.)
    b. Ensure that the records of the registered pharmacist are made readily accessible to members of the Board and employees, agents and designees of the Board; and
    c. Comply with all applicable federal and state laws and regulations, including, without limitation:
        i. The Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, and the regulations adopted pursuant thereto, and any other applicable federal or state law concerning the privacy of information regarding health care; and
        ii. Requirements relating to the maintenance or records.
3. A registered pharmacist who engages in the practice of pharmacy at a location other than the site of a licensed pharmacy shall not maintain an inventory of drugs at that location.
4. A registered pharmacist shall not engage in the practice of pharmacy at a location other than the site of a licensed pharmacy if he or she:
    a. Serves as a managing pharmacist; or
    b. Provides pharmaceutical services at:
        i. A facility for modified medical detoxification, as defined in NRS 449.00385;
        ii. An independent center for emergency medical care, as defined in NRS 449.013;
        iii. A facility for intermediate care, as defined in NRS 449.0038;
        iv. A facility for skilled nursing, as defined in NRS 449.0039; or
        v. A surgical center for ambulatory patients, as defined in NRS 449.019.

B. NAC 639 - For a registered pharmacist who is employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity.

For a registered pharmacist who is employed by or under contract with a pharmacy or who is an employee of the State Government may engage in the practice of pharmacy at a location other than the site of a licensed pharmacy shall not engage in the practice of pharmacy at a location other than the site of a licensed pharmacy unless he or she is provided with the same computerized system and access to data regarding a patient for whom a prescription has been submitted that is available to a registered pharmacist in the pharmacy. Such data must include, without limitation:

a. A legible copy of the prescription that is available as an electronic copy or a scanned image in the computerized system of the pharmacy or by facsimile machine; and
b. Any information that is available in the computerized system of the pharmacy that is relevant or necessary for the registered pharmacist to provide pharmaceutical services.

C. NAC 639.403 - For a registered pharmacist who is NOT employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity.

For a registered pharmacist who is NOT employed by or under contract with a pharmacy or who is an employee of the State Government shall not engage in the practice of pharmacy at a site other than the site of a licensed pharmacy unless he or she obtains the approval of the Board to engage in the practice of pharmacy at a site other than the site of a licensed pharmacy. To request such approval, the registered pharmacist must submit this application. The application must be approved before a registered pharmacist may commence any practice.

D. NAC 639.4916 - For a registered pharmacist who is employed by or under contract with a Nevada licensed pharmacy located within a hospital or correctional institution.

1. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide the remote chart order processing services to the hospital or correctional institution that the pharmacy is required by NAC 639.4915 to provide must:
    a. Be trained in the policies and procedures of the hospital or correctional institution regarding all policies and procedures of the hospital or correctional institution with which the registered pharmacist must comply, including, without limitation, the provisions of pharmaceutical services, security, and confidentiality of patient records; and
    b. Be provided with the same computerized system and access to data regarding a patient for whom a chart order has been submitted that would be available to a registered pharmacist employe by the pharmacy located within the hospital or correctional institution, including, without limitation:
        i. The height, weight and age of the patient and any allergies that the patient may have;
        ii. The medical records regarding any medications prescribed to the patient;
        iii. The results of any relevant laboratory tests;
        iv. The health history and notes regarding physical examinations, to the extent that the information is available in the computerized system of the hospital or correctional institution;
        v. Any notes provided by a physician, nurse or other medical staff of the institution, to the extent that those notes are available in the computerized system of the hospital or correctional institution;
        vi. A legible copy of the chart order that is available through a scanned image in the computerized system of the hospital or correctional institution or by facsimile machine; and
        vii. Any other information that is available in the computerized system of the hospital or correctional institution that is relevant or necessary for the registered pharmacist to provide pharmaceutical services.
2. Before a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution provides remote chart order processing services to the hospital or correctional institution, the registered pharmacist must review any relevant information regarding the patient for whom a chart order has been submitted. The registered pharmacist must, before approving a chart order to be filled, evaluate:
    a. The overutilization or underutilization of a medication;
    b. Therapeutic duplication;
    c. The appropriateness of the prescribed dosage and route of administration;
    d. The appropriateness of the directions for use of the medication;
    e. The appropriateness of the duration of the treatment with the prescribed medication;
    f. Any contraindication of the medication and a particular disease, ailment or allergy of the patient;
    g. Any contraindication or interactions between multiple medications prescribed for the patient; and
    h. The potential abuse or misuse of a medication.
3. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution provides remote chart order processing services to the hospital or correctional institution shall comply with the requirements of Section 7 (A) to the same extent as a registered pharmacist engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy pursuant to the provisions in Section 7 (B) and Section 7 (C).
4. In an emergency, a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution may render remote chart order processing services without being provided with all the information required by paragraph (b) of subsection 1 of Section 7 (D) if the registered pharmacist believes, in his or her professional judgement, that he or she has received sufficient information from the staff of the hospital or correctional institution to render the services.
5. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution may refuse to approve the filling of a chart order if, in the judgement of the registered pharmacist, the chart order is not safe or reasonable for the patient. A registered pharmacist who refuses to approve the filling of a chart order pursuant to this subsection must notify the hospital or correctional institution as soon as practicable that he or she has refused to approve the filling of the chart order.
6. Each time that a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution

provides remote chart order processing services pursuant to this section, the registered pharmacist shall make a notation in the computerized system of the hospital or correctional institution that indicates:

a. The name or identifier of the registered pharmacist;
b. The date and time that the registered pharmacist provided the services and, if applicable, approved the filling of a chart order; and
c. The specific services provided by the registered pharmacist.

7. The managing pharmacist of a pharmacy located within a hospital or a correctional institution may limit the remote chart order processing services provided pursuant to this section (Section 7 (D)).

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I attest to the knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices. NRS 639.132

I understand that Nevada law requires a registered pharmacist who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

KARA Baldwzzi

Print Name

Original Signature, no copies or stamps accepted

10/3/2024

Date

Board Use Only	Date Received: 10/4/24 For applicants who marked box 1 or 2 in Section 1: Executive staff to review, scanned into applicant file. For applicants who marked box 3 in Section 1: Executive staff to review, place on consent agenda.

4III

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☒ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	☒ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
☐ New MDEG ☒ Ownership Change* ☐ Name Change* ☐ Location Change*	* If making a change, provide current license number: M P00109	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Prosthetic Center of Excellence

MDEG Physical Address: 2047 West Charleston Blvd. #100

City: Las Vegas State: NV Zip: 89102

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Website: www.lvbionics.com

Email: 052200@hanger.com

Name of MDEG Administrator (NAC 639.694): Edwin Rodriquez

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
☒ Patients by prescriptions ☐ Pharmacies[a] ☐ Practitioners[a] ☐ Hospitals/Clinics[a] ☐ Clinics[a] ☐ Wholesalers[a] ☐ Other business entities (specify)[a]: This application is ONLY required if MDEG products will be sold to patients by prescription. [a]If MDEG products will ALSO be sold to the Entities with an (a) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	☐ Medical Gases** ☐ Respiratory Equipment** ☐ Life-sustaining equipment** ☐ Parenteral and Enteral Equipment** ☐ Assistive Equipment ☐ Diabetic Supplies ☒ Orthotics and Prosthetics ☐ Others: **These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954): Name: Edwin Rodriquez Telephone: 661-675-5061

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8a-5p	■ Tue: 8a-5p	■ Wed: 8a-5p	■ Thurs: 8a-5p	■ Fri: 8a-5p
☐ Sat: CLOSED	☐ Sun: CLOSED	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Medicare Number 1260470001
Medicaid Number 1457348823

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: n/a _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: n/a

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Hanger Prosthetics & Orthotics, Inc

Corporation/Organization Name: Hanger, Inc

Mailing Address: 10910 Domain Dr. Suite 300

City: Austin State: Texas Zip: 78758-7807

Telephone: (512) 777-3546 Email: amason@hanger.com

Contact Person Name: Adria Mason

Section 7: Partnership

Partnership Name: n/a

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 8: Sole Owner

Owner's Name: n/a

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months.**	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Adria Mason

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

8/20/2024

Date

Board Use Only	Date Received: 9/16/24	Amount: 500.00/CC

Certain direct and indirect subsidiaries of Hanger Prosthetics & Orthotics, Inc. (a subsidiary of Hanger, Inc.): Advanced OrthoPro, Inc.; American Prosthetics & Orthotics, Inc.; Biomedic Appliances, Inc.; Bio-Tech Prosthetics and Orthotics, Inc.; Bio-Tech Prosthetics and Orthotics of High Point, Inc.; BioTech Prosthetics and Orthotics of Durham, Inc.; Boas Surgical, Inc.; Center for Orthotic & Prosthetic Care of North Carolina, Inc.; Claiborne Prosthetics & Orthotics, Inc.; Corpus Christi Prosthetics, Inc.; Davidson Prosthetics & Orthotics, Inc.; Dienen, Inc.; Eastern Shore Orthotics & Prosthetics, Inc.; Excel Prosthetics & Orthotics, Inc.; Hanger Prosthetics & Orthotics East, Inc. (formerly NovaCare Orthotics & Prosthetics East, Inc.); Hanger Prosthetics & Orthotics West, Inc. (formerly NovaCare Orthotics & Prosthetics West, Inc.); Kenney Ortho Group, Inc.; Midlands Prosthetics & Orthotics, Inc.; Mobility Prosthetics & Orthotics, Inc.; Nascott, Inc.; Next Step Orthopaedics, Inc.; Northern Care, Inc.; Northern Orthopedics, Inc.; Ortho Pro Associates, Inc.; Prosthetic Center of Excellence, a Nevada corporation; Riverside Prosthetics, Inc.; Riverview Orthotics Prosthetics, Inc.; Round Rock Orthotics & Prosthetics, Inc.; Sampson's Prosthetic Laboratory, Inc.; Scheck & Siress Prosthetics, Inc.; Teter Orthotics and Prosthetics, Inc.; Total Orthotic & Prosthetic Solutions, Inc.; and Verhi, Inc.

Directors	Officers
Peter A. Stoy Thomas E. Kiraly	Chief Executive Officer: Peter A. Stoy President: Michael Oros Executive Vice President and Chief Financial Officer: Thomas E. Kiraly Senior Vice President and Chief Compliance Officer: Mitchell Dobson Senior Vice President and Chief Human Resources Officer: Kelsey L. Troy Senior Vice President, General Counsel and Secretary: Thomas E. Hartman Senior Vice President and Chief Clinical Officer: James H. Campbell Assistant Treasurer and Assistant Secretary: Thomas E. Kiraly Assistant Secretary: Scott Rowe Treasurer and Assistant Secretary: Joseph C. Talley Assistant Treasurer: David Carrion

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **PROSTHETIC CENTER OF EXCELLENCE, A NEVADA CORPORATION** as a DOMESTIC CORPORATION (78) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 11/17/1998, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 07/08/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202407084786856
You may verify this certificate online at https://www.nvsilverflume.gov/home

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 01/30/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Erin Bristol
Aon Risk Services Northeast, Inc. New York NY Office One Liberty Plaza 165 Broadway, Suite 3201 New York NY 10006 USA	PHONE (A/C. No. Ext): (866) 283-7122 FAX (A/C. No.): (800) 363-0105 E-MAIL ADDRESS: erin.bristol@aon.com

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Hanger, Inc. & all its wholly owned subsidiaries 10910 Domain Dr. Ste. 300 Austin TX 78758-7807 USA	INSURER A: Travelers Property Cas Co of America	25674
	INSURER B: The Travelers Indemnity Co.	25658
	INSURER C: Federal Insurance Company	20281
	INSURER D: ACE Property & Casualty Insurance Co.	20699
	INSURER E: Chubb Custom Insurance Co.	38989
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570103763730 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
C	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY [ ] PRO-JECT [ ] LOC OTHER:			35948279 SIR applies per policy terms & conditions	01/01/2024	01/01/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $1,000,000 $1,000,000 $2,000,000
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			TJCAP-1R572736-TIL-24	01/01/2024	01/01/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$2,000,000
D	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION $100,000			XEUG28196842008	01/01/2024	01/01/2025	EACH OCCURRENCE AGGREGATE	$5,000,000 $5,000,000
A B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [N] N/A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			UB2X7193742451K All other states UB2X7164642451R For AZ, MA, WI	01/01/2024 01/01/2024	01/01/2025 01/01/2025	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	 $1,000,000 $1,000,000 $1,000,000
E	Hospital Professional/General Liability			79957348 Claims Made SIR applies per policy terms & conditions	01/31/2024	01/01/2025	Each Wrongful Act General Aggregate L	$10,000,000 $10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: Evidence of Insurance. Product Liability/Completed Operations Retro Date 01/01/2004
Prosthetic Center Of Excellence, A Nevada Corporation
2047 W Charleston Blvd Ste 100
Las Vegas, NV 89102-2251

CERTIFICATE HOLDER

Hanger, Inc. &
all its wholly owned subsidiaries
10910 Domain Drive #300
Austin TX 78758 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast, Inc.

Holder Identifier :

Certificate No : 570103763730

©1988-2015 ACORD CORPORATION. All rights reserved.

AGENCY CUSTOMER ID: 570000092454
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Hanger, Inc. & all its wholly owned
POLICY NUMBER: See Certificate Number: 570103763730	
CARRIER: See Certificate Number: 570103763730 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER	
INSURER	
INSURER	
INSURER	

ADDITIONAL POLICIES If a policy below does not include limit information, refer to the corresponding policy on the ACORD certificate form for policy limits.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	OTHER							
C	Products Liability			99486423 Claims Made SIR applies per policy terms & conditions	01/31/2024	01/01/2025	Aggregate	$10,000,000
							Each Occurrence	$10,000,000
							SIR	$1,000,000

© 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Prosthetic Center of Excellence

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 2047 West Charleston Blvd, #100

City Las Vegas State NV Zip 89102

Mailing Address (if different from physical address) [redacted] Domain Drive, Suite [redacted]

City Austin State TX Zip 78758

Telephone [redacted] Website www.ivbionics.com

Licensing Company Email _____

Section 2: Personal Information

First Joseph Middle Charles Last Talley

Alias(es, nicknames, name changes, etc.) Chuck Talley

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] County Road [redacted]

City Burkeville State Tx Zip 75932

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Sam Houston State University			08/1997 - 08/2000	
Address		City	State	Zip
1905 University Ave		Huntsville	Tx	77340
Diploma/Degree obtained, if any				
Bachelor's of Business Administration - Accounting				
School Name			From - To (MM/YY – MM/YY)	
Tyler Junior College			08/1995 - 05/1997	
Address		City	State	Zip
PO Box 9020		Tyler	Tx	75711
Diploma/Degree obtained, if any				
No degree				
School Name			From - To (MM/YY – MM/YY)	
Marshall High School			08/1991 - 05/1995	
Address		City	State	Zip
1900 Maverick Drive		Marshall	Tx	75670
Diploma/Degree obtained, if any				
Earned HS diploma				
School Name			From - To (MM/YY – MM/YY)	
—				
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
—				
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/22 - Present	[redacted] County Road [redacted]	Burkeville	Tx	75932
03/17 - 08/22	[redacted] Geranium Cove	Austin	Tx	78738
08/16 - 03/17	[redacted] Australis Cove	Austin	Tx	78732
10/11 - 08/16	[redacted] Loch Lomond Dr	Arlington	Tx	76012
From - To (MM/YY – MM/YY)	Address —	City	State	Zip
From - To (MM/YY – MM/YY)	Address —	City	State	Zip
From - To (MM/YY – MM/YY)	Address —	City	State	Zip
From - To (MM/YY – MM/YY)	Address —	City	State	Zip
From - To (MM/YY – MM/YY)	Address —	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Hanger, Inc.			From - To (MM/YY – MM/YY): 03/16 - Present	
Business Address: 10910 Domain Drive, Suite 300	City: Austin		State: Tx	Zip: 78758
Phone: 512-777-3952	Title: VP of Finance, Treasurer			
Description of Duties: Corporate financial forecasting, treasury management, accounting and other duties as assigned				
Business Name: Titanium Healthcare, Inc.			From - To (MM/YY – MM/YY): 05/14 - 03/16	
Business Address: 11431-11499 FM 2244 Rd, Ste 124	City: Austin		State: Tx	Zip: 78738
Phone: 469-606-4520	Title: Chief Financial Officer			
Description of Duties: Financial oversight, Investor Relations, SEC Reporting, accounting and other duties as assigned				
Business Name: —			From - To (MM/YY – MM/YY):	
Business Address: —	City:		State:	Zip:
Phone: —	Title:			
Description of Duties: —				
Business Name: —			From - To (MM/YY – MM/YY):	
Business Address: —	City:		State:	Zip:
Phone: —	Title:			
Description of Duties: —				
Business Name: —			From - To (MM/YY – MM/YY):	
Business Address: —	City:		State:	Zip:
Phone: —	Title:			
Description of Duties: —				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		N/A
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
03/04/2016	2019	Tx	Dallas	Dallas
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
DC-16-02520		116th District Court		
Reason/Charge				
Bankruptcy of Company where I was CFO - All Directors and Officers were named as Defendants				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Consolidated Bankruptcy Estates of Tandy			Chapter 7 Bankruptcy	
Name of Business/Industry/Entity				
Tandy Brands Accessories, Inc.				

Provide explanation below:

I, Joseph Charles Talley, Jr. am officer of Prosthetic Center of Excellence ("Hanger Clinic"), the applicant for the Nevada Board of Pharmacy MDEG license. I have been an officer of Hanger Clinic for [Insert number] years. Hanger Clinic is the patient care segment of Hanger, Inc., and is a leading national provider of orthotic and prosthetic services and products. Hanger Clinic has approximately 4,900 employees and operates more than 900 patient care locations across the country which offer specialized orthotic and prosthetic solutions to patients. Given the scope and breadth of its operations, Hanger Clinic (like other organizations of its size) is party to numerous lawsuits in the ordinary course of business. I hereby attest that I do not hold any ownership interest in Hanger Clinic nor I have been named individually in any lawsuit made against Hanger Clinic.

Joseph Charles Talley, Jr.
Original Signature (electronic, copies or stamps not accepted)

08/13/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joseph Talley

Print Name (First, Last)

Joseph Charles Talley, Jr. — 08/13/2024

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Travis

I, Joseph Charles Talley Jr., being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Joseph Charles Talley, Jr. — 08/20/2024

Original Signature — **Date**

Subscribed and Sworn to before me this 20th day of August 2024

Notary Public Signature

BEVERLY SCHWARTZ
Notary Public, State of Texas
Comm. Expires 03-12-2027
Notary ID 126034673
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Prosthetic Center of Excellence

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 2047 West Charleston Blvd, #100

City: Las Vegas State: NV Zip: 89102

Mailing Address (If different from physical address): [redacted] Domain Drive, Suite [redacted]

City: Austin State: TX Zip: 78758

Telephone: [redacted] Website: www.lvbionics.com

Licensing Company Email:

Section 2: Personal Information

First: Thomas Middle: Edward Last: Hartman

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Zen Gardens Way

City: Austin State: TX Zip: 78732

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Wisconsin - Madison		09/88 - 05/91	
Address	**City**	**State**	**Zip**
333 East Campus, Mail #11101	Madison	WI	53715
Diploma/Degree obtained, if any			
Juris Doctor			

School Name		From - To (MM/YY – MM/YY)	
Univeristy of Michigan, Ann Arbor		09/80 - 08/84	
Address	**City**	**State**	**Zip**
200 Fletcher St	Ann Arbor	MI	48109
Diploma/Degree obtained, if any			
Bachelor of Science in Engineering (Industrial & Operations Engineering)			

School Name		From - To (MM/YY – MM/YY)	
Ernest W. Seaholm High School		09/77 - 06/80	
Address	**City**	**State**	**Zip**
2436 W Lincoln St.	Birmingham	MI	48009
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/16 - Present	[redacted]Zen Gardens Way	Austin	TX	78732
04/15 - 01/16	[redacted]Calistoga Way	Austin	TX	78732
04/12 - 04/15	[redacted]Calisotga Way	Austin	TX	78732

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Hanger, Inc.			06/09 - Present
Business Address	**City**	**State**	**Zip**
10910 Domain Drive, Suite 300	Austin	TX	78758
Phone	**Title**		
(512) 777-3800	Senior Vice President, Generla Counsel & Secretary		
Description of Duties			
Serve as chief legal officer for Hanger, Inc. and its direct and indirects subsidiaries and affliates.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

I, Thomas Hartman, am officer of Prosthetic Center of Excellence ("Hanger Clinic"), the applicant for the Nevada Board of Pharmacy MDEG license. I have been an officer of Hanger Clinic for 15 years. Hanger Clinic is the patient care segment of Hanger, Inc., and is a leading national provider of orthotic and prosthetic services and products. Hanger Clinic has approximately 4,900 employees and operates more than 900 patient care locations across the country which offer specialized orthotic and prosthetic solutions to patients. Given the scope and breadth of its operations, Hanger Clinic (like other organizations of its size) is party to numerous lawsuits in the ordinary course of business. I hereby attest that I do not hold any ownership interest in Hanger Clinic nor I have been named individually in any lawsuit made against Hanger Clinic.

Original Signature (electronic, copies or stamps not accepted)

8/20/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Thomas E. Hartman

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/20/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Travis

I, Thomas E Hartman, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

08/20/2024

Date

Subscribed and Sworn to before me this 20th day of August.

Notary Public Signature

KELLY LOBUE WEISS
Notary ID #129980822
My Commission Expires
October 2, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Prosthetic Center of Excellence

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 2047 West Charleston Blvd, #100

City: Las Vegas State: NV Zip: 89102

Mailing Address (if different from physical address): [redacted] Domain Drive, Suite [redacted]

City: Austin State: TX Zip: 78758

Telephone: 512-777-3800 Website: www.lvbionics.com

Licensing Company Email:

Section 2: Personal Information

First: Michael Middle: Harold Last: Oros

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] Green Hills [redacted]

City: Sugar Grove State: IL Zip: 60554

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Northwestern University Kellogg School of Management		09/88-05/99	
Address	City	State	Zip
	Evanston	IL.	
Diploma/Degree obtained, if any			
Certificate Business Management			

School Name		From - To (MM/YY – MM/YY)	
Northwestern University		01/86-01/87	
Address	City	State	Zip
	Chicago	IL	
Diploma/Degree obtained, if any			
Certificates in Orthotics and Prosthetic			

School Name		From - To (MM/YY – MM/YY)	
University of Iowa		09/80-08/1984	
Address	City	State	Zip
	Iowa City	IA	
Diploma/Degree obtained, if any			
Bachelor of Science in General Science			

School Name		From - To (MM/YY – MM/YY)	
West Aurora High School		09/76-06/1980	
Address	City	State	Zip
	Aurora	IL	60506
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/01-08/24	[redacted]Green Hills [redacted]	Sugar Grove	IL	60554
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Hanger			04/20--8/24
Business Address	**City**	**State**	**Zip**
10910 Domain Dr	Austin	TX	78758
Phone	**Title**		
	President Hanger Clinic		

Description of Duties

Strategy and leadership of 900 patient care clinics

Business Name			From - To (MM/YY – MM/YY)
Scheck & Siress			09/14-04/20
Business Address	**City**	**State**	**Zip**
1S376 Summit Ave Ct E	Oakbrook Terrace	IL	60554
Phone	**Title**		
630 424 9392	President & CEO		

Description of Duties

Strategy and leadership of 18 patient care clinics

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✔	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

I, Michael Harold Oros, am an officer of Prosthetic Center of Excellence ("Hanger Clinic"), the applicant for the Nevada Board of Pharmacy MDEG license. I have been an officer of Hanger Clinic for 4 years. Hanger Clinic is the patient care segment of Hanger, Inc., and is a leading national provider of orthotic and prosthetic services and products. Hanger Clinic has approximately 4,900 employees and operates more than 900 patient care locations across the country which offer specialized orthotic and prosthetic solutions to patients. Given the scope and breadth of its operations, Hanger Clinic (like other organizations of its size) is party to numerous lawsuits in the ordinary course of business. I hereby attest that I do not hold any ownership interest in Hanger Clinic nor I have been named individually in any lawsuit made against Hanger Clinic.

Original Signature (electronic, copies or stamps not accepted)

8/14/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Harold Oros

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/14/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Travis

I, MICHAEL HAROLD OROS, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/14/2024

Date

Subscribed and Sworn to before me this 14th day of August.

Notary Public Signature

GEORGE D GANDY NOTARY PUBLIC STATE OF TEXAS NOTARY ID 133126986-5 MY COMM EXP 05-26-2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Prosthetic Center of Excellence

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 2047 West Charleston Blvd, #100

City: Las Vegas State: NV Zip: 89102

Mailing Address (if different from physical address): [redacted] Domain Drive, Suite [redacted]

City: Austin State: TX Zip: 78758

Telephone: 512-777-3800 Website: www.lvbionics.com

Licensing Company Email:

Section 2: Personal Information

First: Peter Middle: Andrew Last: Stoy

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Retama Street

City: Austin State: TX Zip: 78704

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Franklin University		12/21-06/23	
Address	City	State	Zip
201 South Grant Ave	Columbus	OH	43215
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
Ohio University		08/92-06/96	
Address	City	State	Zip
1 Ohio University Dr	Athens	OH	45701
Diploma/Degree obtained, if any			
Bachelor of Arts/Phiosophy			

School Name		From - To (MM/YY – MM/YY)	
Fort Frye High School		09/88-06/92	
Address	City	State	Zip
420 5th St	Beverly	OH	45715
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/23/present	[redacted] Retama Street	Austin	TX	78704
09/21-02/23	[redacted] Sandra Muraida [redacted]	Austin	TX	78703
07/16-09/22	[redacted] Evian Way	Mount Pleasant	SC	29464
06/15-06/16	[redacted] Woodlands Dr	Huntington Beach	CA	92648
12/07-12/14	[redacted] Enclave Dr	Mount Pleasant	SC	29464
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Hanger Inc			11/21-present
Business Address	**City**	**State**	**Zip**
10910 Domain Dr #300	Austin	TX	78758
Phone	**Title**		
512-777-3780	CEO		

Description of Duties
President and CEO of Hanger Inc which is a leading provider of Prosthetic and Customer Orthotic Care

Business Name			From - To (MM/YY – MM/YY)
Sodexo			10/18-10/20
Business Address	**City**	**State**	**Zip**
9801 Washingtonian BLVD	Gaithersburg	MD	20878
Phone	**Title**		
301-987-4000	East Region President Healthcare		

Description of Duties
Responsible for East Region of Unitied States operations for clinical food and nutrition, enviromental services and clinical technolgy management for healtcare division of Sodexo USA.

Business Name			From - To (MM/YY – MM/YY)
Mckesson Corp			11/14-10/18
Business Address	**City**	**State**	**Zip**
6555 N HWY 161	Irving	TX	75039
Phone	**Title**		
(972) 446-4800	SVP Health Systems		

Description of Duties
Responsible for Mckesson Health Systems segment which is responsible for wholesale pharmaceutical distribution and consulting services to hospital systems throughout the United States.

Business Name			From - To (MM/YY – MM/YY)
Cardinal Health			11/01-09/14
Business Address	**City**	**State**	**Zip**
7000 Cardinal Place	Dublin	OH	43017
Phone	**Title**		
614-757-5000	Mid Atlantic Region Vice President		

Description of Duties
Various responsibilites and titles over 14 years but last role at the organization was responsibility for the Med Surge distribution business in the Mid Atlantic United States.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

I, Peter Andrew Stoy, am an officer of Prosthetic Center of Excellence ("Hanger Clinic"), the applicant for the Nevada Board of Pharmacy MDEG license. I have been an officer of Hanger Clinic for 3 years. Hanger Clinic is the patient care segment of Hanger, Inc., and is a leading national provider of orthotic and prosthetic services and products. Hanger Clinic has approximately 4,900 employees and operates more than 900 patient care locations across the country which offer specialized orthotic and prosthetic solutions to patients. Given the scope and breadth of its operations, Hanger Clinic (like other organizations of its size) is party to numerous lawsuits in the ordinary course of business. I hereby attest that I do not hold any ownership interest in Hanger Clinic nor I have been named individually in any lawsuit made against Hanger Clinic.

Original Signature (electronic, copies or stamps not accepted)

8/12/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Peter Stoy

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/12/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Travis

I, Pete Stoy, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/12/24

Date

Subscribed and Sworn to before me this 12th day of August 2024.

Notary Public Signature

BEVERLY SCHWARTZ
Notary Public, State of Texas
Comm. Expires 03-12-2027
Notary ID 126034673
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Prosthetic Center of Excellence

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 2047 West Charleston Blvd, #100

City: Las Vegas State: NV Zip: 89102

Mailing Address (if different from physical address): [redacted] Domain Drive, Suite [redacted]

City: Austin State: TX Zip: 78758

Telephone: 512-777-3800 Website: www.ivbionics.com

Licensing Company Email:

Section 2: Personal Information

First: Scott Middle: Last: Rowe

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] Grand Oaks Loop

City: Cedar Park State: TX Zip: 78613

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirements (NRS 425.520, NRS 639.183)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and all post-secondary schools you have attended, beginning with the most current. (Use a separate piece of paper if additional spaces needed.)

School Name		From - To (MM/YY – MM/YY)	
GOLDEN GATE UNIVERSITY		09/00-04/02	
Address	**City**	**State**	**Zip**
536 MISSION ST	SAN FRANCISCO	CA	94105
Diploma/Degree obtained, if any			
MS TAXATION			
School Name		**From - To (MM/YY – MM/YY)**	
BRIGHAM YOUNG UNIVERSITY		09/90-04/97	
Address	**City**	**State**	**Zip**
	PROVO	UT	84602
Diploma/Degree obtained, if any			
BS ACCOUNTING; (GAP YEARS FOR MISSIONARY SERVICE IN GUATEMALA 09/91-09/93)			
School Name		**From - To (MM/YY – MM/YY)**	
BRIGHTON HIGH SCHOOL		08/87-05/90	
Address	**City**	**State**	**Zip**
2220 BENGAL BLVD	COTTONWOOD HEIGHTS	UT	84121
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional spaces needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/15 - CURRENT	[redacted]GRAND OAKS LOOP	CEDAR PARK	TX	78613
-06/04 - 07/15	[redacted]AUREL ST	EASTVALE	CA	92880

Section 7: Beginning with the most recent employment, list your work history and corporations, partnerships, or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or trustee capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
HANGER, INC.			03/17 - CURRENT
Business Address	**City**	**State**	**Zip**
10910 DOMAIN DR., SUITE 300	AUSTIN	TX	78758
Phone	**Title**		
(512) 777-3800	VP TAX		
Description of Duties			
COMPLIANCE OF INCOME, SALES, PROPERTY TAX FOR ENTIRE COMPANY; HANGER FOUNDATION PRESIDENT			

Business Name			From - To (MM/YY – MM/YY)
FORCEPOINT			10/14 - 02/17
Business Address	**City**	**State**	**Zip**
10900-A STONELAKE BLVD, #350	AUSTIN	TX	78759
Phone	**Title**		
(800) 723-1166	VP WORLDWIDE TAX PLANNING AND COMPLIANCE		
Description of Duties			
COMPLIANCE OF INCOME, SALES, PROPERTY TAX FOR ENTIRE COMPANY			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

I, Scott Rowe, am an officer of Prosthetic Center of Excellence ("Hanger Clinic"), the applicant for the Nevada Board of Pharmacy MDEG license. I have been an officer of Prosthetic Center of Excellence since it was acquired--less than one year ago and an officer of all other Hanger affiliated companies since I started employment with Hanger. Hanger Clinic is the patient care segment of Hanger, Inc., and is a leading national provider of orthotic and prosthetic services and products. Hanger Clinic has approximately 4,900 employees and operates more than 900 patient care locations across the country which offer specialized orthotic and prosthetic solutions to patients. Given the scope and breadth of its operations, Hanger Clinic (like other organizations of its size) is party to numerous lawsuits in the ordinary course of business. I hereby attest that I do not hold any ownership interest in Hanger Clinic nor I have been named individually in any lawsuit made against Hanger Clinic.

Original Signature (electronic, copies or stamps not accepted)

AUG 13, 2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SCOTT ROWE

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

AUG 13, 2024

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Travis

I, Scott Rowe, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Aug 13, 2024

Date

Subscribed and Sworn to before me this 13th day of August 2024

Notary Public Signature

BEVERLY SCHWARTZ
Notary Public, State of Texas
Comm. Expires 03-12-2027
Notary ID 126034673

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Prosthetic Center of Excellence - Hanger Clinic MDEG License # (if applicable): MP00109

Physical Address: 2047 West Charleston Blvd. #100

City: Las Vegas State: Nevada Zip: 89102

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 702.384.1410 Website: www.lvbionics.com www.hangerclinic.com

Licensing Company Email: 052200@hanger.com

Section 2: Personal Information

First: Edwin Middle: Last: Rodriguez

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] West Perry Creek Street

City: Las Vegas State: NV Zip: 89141

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Nevada, Las Vegas		01/2013 - 05/2018	
Address	**City**	**State**	**Zip**
4505 S Maryland Pkwy	Las Vegas	NV	89154
Diploma/Degree obtained, if any			
Bachelor of Science, Kinesiology			
School Name		**From - To (MM/YY – MM/YY)**	
Antelope Valley College		(08/2009 - 12/2012)	
Address	**City**	**State**	**Zip**
3041 W Ave K	Lancaster	CA	93536
Diploma/Degree obtained, if any			
Associate of Science, Social and Behavioral Sciences			
School Name		**From - To (MM/YY – MM/YY)**	
Lancaster High School		(03-07 - 05/09)	
Address	**City**	**State**	**Zip**
44701 32nd Street West	Lancaster	CA	93536
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Palmdale High School			
Address	**City**	**State**	**Zip**
2137 East Ave R	Palmdale	CA	93550
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
(04/2024 - Present)	[redacted] Perry Creek Street	Las Vegas	NV	89141
(04/20 - 04/24	[redacted] Canfield Canyon Ave	Las Vegas	NV	89178
(04/16 - 04/20)	[redacted] Stateline Way	Las Vegas	NV	89110
(01/16 - 04/16)	[redacted] Stars End Street	Las Vegas	NV	89108
(01/14 - 01/16)	[redacted] Ranch Valley Street	Las Vegas	NV	89178
(12/2012 - 01/14)	[redacted] Stateline Way	Las Vegas	NV	89110

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name	From - To (MM/YY – MM/YY)
Prosthetic Center of Excellence	(05/19 - Present)

Business Address	City	State	Zip
2047 W Charleston Blvd #100	Las Vegas	NV	89102

Phone	Title	Number of Employed Hours
702.384.1410	Clinical Assistant	9,500 hours approx.

Description of Duties

Manage patient care from intake to checkout, including conducting assessments, planning and adjusting treatments as directed by a clinician, maintaining documentation, and providing follow-up care. Aid in fabrication as needed.

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title	Number of Employed Hours

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title	Number of Employed Hours

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title	Number of Employed Hours

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title	Number of Employed Hours

Description of Duties

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Edwin Rodriguez, **certify that as the MDEG Administrator for**

Prosthetic Center of Excellence - Hanger Clinic,

that I (initial that you have read and meet the following requirements):

1. ER Have a high school diploma or its equivalent;
2. ER Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. ER Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. ER Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Edwin Rodriguez
Print Name (First, Last)

Edwin Rodriguez
Original Signature (electronic, copies or stamps not accepted)

10/9/2024
Date

Board Use Only	Date Received: 10/10/24

5

ANNUAL DISCIPLINE CASES Reporting Period: January 2024 – October 2024			
FINDING	**HARM**	**DISCIPLINE INDIVIDUAL**	**DISCIPLINE FACILITY**
SC engaged in unprofessional conduct by an APRN when she sold/dispensed dangerous drugs without having obtained a certificate of registration.	N/A	Fined $5,000; assessed $500 in recoverable attorney's fees and costs.	N/A
TH overrode a DUR alert signaling a drug-interaction with another prescription. The prescription was misfilled and provided to the incorrect patient. MW failed to provide counseling or properly counsel patient's mother.	N/A	TH and MW each fined $1,000; assessed $350 in recoverable attorney's fees and costs.	Fined $2,000; assessed $350 in recoverable attorney's fees and costs.
CVS, as pharmacy/pharmacy owner, is responsible for the dispensing errors of its employees where the patient was given clonazepam 0.5mg instead of ibuprofen and amoxicillin which resulted in patient harm.	Yes	N/A	Fined $1,000; assessed $500 in recoverable attorney's fees and costs.
MO issued or caused to be issued at least one hundred twenty (120) prescriptions for controlled substances while travelling out of country. MO participated in deceitful transactions and billed Medicaid for services that respondent did not provide.	N/A	Certificate of Registration No. CS10935 is revoked. MO cannot reapply for a period of ten years. Fined $2,500; assessed $1,754.68 in recoverable attorney's fees and costs.	N/A
PR assisted in unauthorized prescribing when she allowed her medical assistant to use her signature stamp for controlled substance prescriptions.	N/A	Fined $1,500; assessed $500 in recoverable attorney's fees and costs.	N/A
CVS, as pharmacy/pharmacy owner, is responsible for the dispensing errors of its employee who erroneously dispensed Estradoil 0.5mg and failed to counsel the patient which resulted in patient harm.	Yes	N/A	Fined $3,000.00; assessed $2,000.00 in recoverable attorney's fees and costs.

JC, as managing pharmacist, is responsible for the dispensing errors of employees that failed to dispense Doxycycline 50mg simultaneously with another prescription Metronidazole 250mg which were supposed to be taken as the prescribed course of treatment.	N/A	Fined $1,000.00; assessed $500.00 in recoverable attorney's fees and costs	Fined $2,000; assessed $1,000 in recoverable attorney's fees and costs.
CD Rx failed to properly disclose that they had pending administrative actions in Alabama and Louisiana Boards of Pharmacy on their 2020 business renewal application.	N/A	N/A	Fined $1,000; assessed $500 in recoverable attorney's fees and costs.
EA failed to comply with the citation and fine dated June 30, 2023, due to his failure to complete the thirty CE credits required by NAC 639.330 for their pharmacist biennial registration period for November 1, 2019, to October 31, 2021. EA was sent an Order to Show Cause on November 29, 2023, which he failed to appear, and a default was made. Respondent's Certificate of Registration No. 19224 is revoked and cannot reapply for a period of one year; assessed $506.67 in recoverable attorney's fees and costs.	N/A	Certificate of Registration No. 19224 is revoked and cannot reapply for a period of one year; assessed $506.67 in recoverable attorney's fees and costs.	N/A
JI failed to complete the thirty CE credits required by NAC 639.330 for their pharmacist biennial registration period for November 1, 2019, to October 31, 2021. JI was sent an Order to Show Cause on November 29, 2023, which she failed to appear, and a default was made.	N/A	Certificate of Registration No. 09672 is revoked and cannot reapply for a period of one year; assessed $506.67 in recoverable attorney's fees and costs.	N/A

OE failed to comply with the citation and fine dated June 30, 2023, due to her failure to complete the thirty CE credits required by NAC 639.330 for their pharmacist biennial registration period for November 1, 2019, to October 31, 2021. OE sent an Order to Show Cause on November 29, 2023, which she failed to appear, and a default was made.	N/A	Certificate of Registration No. 16558 is revoked and cannot reapply for a period of one year; assessed $506.67 in recoverable attorney's fees and costs.	
VV is responsible for providing preprinted prescription blanks to Kindred Outpatient Wound Care Hospital. VV erroneously entered the prescriber's name Dr. L.R. on the illegal preprinted prescription blank form and dispensed several prescriptions which included a misfill of six tubes of 30g Santyl Ointment rather than one 30g tube.	N/A	Certificate of Registration No. 18969 is placed on probation for a period of two years; public reprimand; fined $5,000 for the violations; assessed $1,000 in recoverable attorney's fees and costs.	
RR failed to make timely payments of the $500 fine and the $500 in attorney's fees and costs pursuant to the agreed upon Stipulation and Order filed September 6, 2023.	N/A	Certificate of Registration No. PT20827 is revoked and cannot petition for reinstatement for a period of one year.	N/A
KT authorized an employee to independently access, possess, store and administer dangerous drugs to patients without practitioner supervision, and without a patient-specific and medication-specific written chart order for the patient and/or medication, to patients with whom Respondent did not establish a bona fide therapeutic relationship. In addition, Respondent falsified patient information and issued false prescriptions to obtain compounded dangerous drugs for office use.	N/A	Certificate of Registration No. CS06260 is placed on probation for a period of one year; public reprimand; fined $2,500 for the violations; and assessed $1,000 in recoverable attorney's fees and costs.	N/A

MS failed to timely renew his Certificate of Registration Nos. CS25265, CS12420, and CS15562 on October 31, 2018, where he issued 2,684 prescriptions of controlled substances to 484 patients in Nevada between November 1, 2018, and June 21, 2023, without a valid controlled substance registration and without accessing the Prescription Monitoring Program (PMP) to review the patient utilization report. Respondent MS applied for a new Certificate of Registration No. CS35699 on June 22, 2023, where he failed to comply with all the requirements for prescribing under Nevada controlled substance registration and failed to review a patient utilization report.	N/A	Certificate of Registration No. CS35699 is placed on probation for a period of two years; public reprimand; fined $16,000 for the violations; and assessed $2,500 in recoverable attorney's fees and costs.	N/A
AA prescribed electronic prescriptions for controlled substances after the Nevada Board of Pharmacy suspended his Certificate of Registration No. CS21324 due to the Nevada Board of Medical Examiners (NSBME) summarily suspending his medical license for violating his prior NSBME disciplinary orders.	N/A	Certificate of Registration No. CS21324 is revoked and cannot petition for reinstatement for a period of two years. Respondent fined $5,000 for the violations; and assessed $1,000 in recoverable attorney's fees and costs.	N/A
MK failed to query a PMP report for any of his prescriptions since January 19, 2016, to June 13, 2021. During the time period of January 19, 2016, to April 17, 2023, Respondent queried only two individual patients which Respondent had over 8,000 filled controlled substance prescriptions for over 6,800 patients.	N/A	Certificate of Registration No. CS23600 is fined $6,500 for the violations; and assessed $1,000 in recoverable attorney's fees and costs.	N/A

PO's Owner received a large shipment of drugs without the managing pharmacist's knowledge.	N/A	N/A	License No. PH04369 is suspended for a period of one year; however, the suspension is stayed. Respondent fined $5,000 for the violations; and assessed $2,000 in recoverable attorney's fees and costs.
CS procured dangerous drugs for Aesthetics MedSpa and allowed an unlicensed person to possess, store, and/or administer these dangerous drugs without any supervision or direction by a practitioner.	N/A	Certificate of Registration No. CS27884 fined $1,500 for the violations; and assessed $1,000 in recoverable attorney's fees and costs.	N/A
DVH is responsible for its employee's unlawful diversion of controlled substances which included 3,243 tablets of hydrocodone, oxycodone, and alprazolam, 103 vials of fentanyl, 218 vials of morphine, and 50 vials of lorazepam, meperidine, and midazolam.	N/A	N/A	License No. IB02134 fined $10,000 for the violations; assessed $1,000 in recoverable attorney's fees and costs; quarterly inspections at the pharmacy's expense; and must maintain a perpetual inventory of all controlled substances in stock in the pharmacy.
ES is responsible for its employee's unlawful diversion of controlled substances which included 3,243 tablets of hydrocodone, oxycodone, and alprazolam, 103 vials of fentanyl, 218 vials of morphine, and 50 vials of lorazepam, meperidine, and midazolam. Respondent ES failed to maintain perpetual inventory of Schedule II controlled substances.	N/A	Certificate of Registration No. 19265 is suspended for a period of one year; however, the suspension is stayed. Respondent fined $2,500 for the violations; and assessed $500 in recoverable attorney's fees and costs.	N/A
MH is responsible for its employee's unlawful diversion of controlled substances which included 3,243 tablets of hydrocodone, oxycodone, and alprazolam, 103 vials of fentanyl, 218 vials of morphine, and 50 vials of lorazepam, meperidine, and midazolam. MH failed to maintain perpetual inventory of Schedule II controlled substances.	N/A	Certificate of Registration No. 18203 is suspended for a period of one year; however, the suspension is stayed. Respondent fined $2,500 for the violations; and assessed $500 in recoverable attorney's fees and costs.	N/A

WP employees misfilled Metformin Hydrochloride ER 500mg tablets ASC, quantity 360, with two bottles of 100 tablets of Metformin Hydrochloride ER 500 MG AS tablets and one bottle of amlodipine besylate tablet, USP 5mg, quantity 500.	Yes	N/A	License No. PH02772 fined $1,000 for the violations; and assessed $750 in recoverable attorney's fees and costs.
CVS exceeded the Nevada pharmacist to pharmaceutical technician supervision ratio of one to three.	N/A	N/A	License No. PH01095 fined $20,000 for the violations; assessed $750 in recoverable attorney's fees and costs; and quarterly inspections for a period of one year at the pharmacy's expense.
EN exceeded the Nevada pharmacist to pharmaceutical technician supervision ratio of one to three.	N/A	Certificate of Registration No. 19578 fined $750 for the violations; and assessed $250 in recoverable attorney's fees and costs.	N/A
LC operated without an administrator and failed to notify the Board within three business days, and they continued to operate as a medical products provider for more than ten business days without an administrator approved by the Board.	N/A	N/A	License No. MP00012 fined $1,000 for the violations; and assessed $1,000 in recoverable attorney's fees and costs.
LC operated without an administrator and failed to notify the Board within three business days, and they continued to operate as a medical products provider for more than ten business days without an administrator approved by the Board.	N/A	N/A	License No. MP00122 fined $5,500 for the violations; and assessed $1,000 in recoverable attorney's fees and costs.

NT filled an oral solution amoxicillin prescription for a 16-month-old toddler. The prescription incorrectly called for a dose large enough to treat a 290-pound adult. Respondent recognized the error on the prescription and attempted to telephone the prescribing practitioner for clarification.	Yes	Certificate of Registration No. 23478 fined $1,000 for the violations; and assessed $500 in recoverable attorney's fees and costs.	N/A
WP conducted business as a pharmacy without having designated and/or employed a managing pharmacist for its pharmacy location between October 6, 2023, to November 17, 2023.	N/A	N/A	License No. PH02587 fined $2,000 for the violations; and assessed $500 in recoverable attorney's fees and costs.
NK was found guilty of making a false record of COVID-19 vaccinations reportedly administered to her former boyfriend.	N/A	Certificate of Registration No. 20034 is revoked, and she cannot petition for reinstatement for a period of two years. Respondent fined $10,000 for the violations; and assessed $8,406.29 in recoverable attorney's fees and costs.	N/A
HM wrote 690 controlled substance prescriptions between March 18, 2018, and January 12, 2022, without having a Nevada Controlled Substance Registration.	N/A	Certificate of Registration No. PR14531 is revoked and cannot petition for reinstatement for a period of one year. Respondent fined $10,000 for the violations; and assessed $544.55 in recoverable attorney's fees and costs.	N/A
KJ prescribed 93 controlled substance prescriptions without a valid Nevada certificate of registration to prescribe controlled substances.	N/A	Certificate of Registration No. DV00607 fined $600 for the violations.	N/A
RDC is responsible for the actions of an employee who filled an oral solution amoxicillin prescription for a 16-month-old toddler. The prescription incorrectly called	Yes	N/A	License No. PH01965 fined $1000 for the violations; and assessed $500 in recoverable attorney's fees and costs.

for a dose large enough to treat a 290-pound adult.			
CVS 08789 is responsible for the actions of an employee who incorrectly administered a dose of meningococcal vaccine to a six-year-old patient.	No	N/A	License No. PH01257 fined $1500 for the violations; and assessed $1000 in attorney's fees and costs.
OM incorrectly administered a dose of meningococcal vaccine to a six-year-old patient.	No	Certificate of Registration No. 23030 fined $1500 for the violations; assessed $1000 in attorney's fees and costs; and must complete ten additional continuing education courses on immunizations.	N/A
MS prescribed controlled substances and failed to maintain and actively use the prescription monitoring program (PMP) and perform queries on patients as required by Nevada Law.	No	Certificate of Registration No. CS21884 fined $5000 for the violations; assessed $1000 in attorney's fees and costs.	N/A
EW served as Medical Director for The Tox Shop where he allowed employees to have independent access to the medication storage containing dangerous drugs, and to access those medications outside Respondent's presence and without Respondent's supervision.	No	Certificate of Registration No. CS32395 is placed on probation for a period of one year; fined $2500 for the violations; and assessed $1000 in attorney's fees and costs.	N/A
RR was the only practitioner who held a certificate of registration to dispense dangerous drugs at Family Doctors of Green Valley (FDGV). Respondent Ramanathan would engage in overseas travel on several occasions and would allow other non-licensed practitioners at FDGV to sell and/or dispense dangerous drugs and controlled substances while using his credentials.	No	Certificate of Registration No. CS14526 fined $5000 for the violations; and assessed $1500 in attorney's fees and costs.	N/A

MM subject to discipline by the Nevada State Board of Medical Examiners for violations related to prescribing controlled substances to treat acute and chronic pain and subsequently surrendered his DEA Registration No. FM2307468 for cause.	No	Certificate of Registration Nos. CS18967 and PD00257 are forfeited; fined $2000 for the violations; and assessed $1000 in attorney's fees and costs.	N/A
MC stole a large quantity of controlled substances. The stolen items included at least 3,243 tablets of hydrocodone, oxycodone, and alprazolam, 103 vials of fentanyl, 218 vials of morphine, and 50 vials of lorazepram, meperidine, and midazolam.	N/A	Certificate of Registration No. PT14524 is revoked, and she cannot petition for reinstatement for a period of ten years; and assessed $1500 in attorney's fees and costs as a condition of reinstatement.	N/A
GM, a non-pharmacist owner, had possession of the pharmacy keys and entered the pharmacy when no registered pharmacist was on duty, all in violation of the Board's regulation.	N/A	Certificate of Registration No. PT18868 fined $2000 for the violations; and assessed $1000 in attorney's fees and costs.	N/A
BV misfilled a prescription of escitatopram oxalate 5mg and erroneously dispensed estradiot 0.5mg. In addition, Respondent Vaknin failed to counsel the patient. Respondent Vaknin did not appear for the May 29-30, 2024, hearing and a default was taken against her registration.	Yes	Certificate of Registration No. 19231 is suspended until October 31, 2025, and must appear before the Board if she plans to renew her registration for the next biennial renewal; fined $4000 for the violations; and assessed $1988.71 in attorney's fees and costs.	N/A
WA was convicted of eight felony counts of distribution of a controlled substance.	N/A	Certificate of Registration NO. CS08254 voluntarily surrendered his Certificate of Registration No. CS08254; and assessed $1878.65 in attorney's fees and costs.	N/A

KP was involved in alcohol impairment while performing his duties as a practitioner.	N/A	Certificate of Registration No. CS10594 is revoked, and Respondent may not reapply for reinstatement for a period of two years; Respondent assessed $1614.48 in attorney's fees and costs.	N/A
HC unlawfully diverted controlled substances for his personal use.	N/A	Certificate of Registration No. PT28442 is revoked, and Respondent may not apply for reinstatement for a period of 10 years; Respondent assessed $1522.69 in attorney's fees and costs.	N/A
JS subject to discipline by the Nevada State Board of Medical Examiners for violations related to prescribing controlled substances to treat pain. In addition, he failed to disclose the disciplinary action to the Nevada Board of Pharmacy on his 2016 biennial renewal application.	N/A	Certificate of Registration No. CS07913 is suspended, but the suspension is stayed and is placed on probation for a period of one year; fined $2000 for the violations; and assessed $1000 in attorney's fees and costs.	N/A
ASPC provided preprinted prescription blanks and is responsible for misfilled prescriptions	N/A	N/A	License No. PH03347 is fined $5000 for the violations; and assessed $1000 in attorney's fees and costs.
KF, as managing pharmacist, is responsible recordkeeping violations related to vaccine administration.	N/A	Certificate of Registration No. 19635 is fined $500 for the violations.	N/A
EK issued prescriptions for compounded semiglutide under the names of her staff to Meta Pharmacy for administration by injection to multiple patients.	N/A	Certificate of Registration No. CS21522 is placed on probation for a period of one year; fined $2500 for the violations; assessed $1000 in attorney's fees and costs; and subject to quarterly inspections no more than $500 for a period of one year at the respondent's expense.	N/A

SB was disciplined for prescribing controlled substances without a valid registration and petitioned The Board to vacate the default Order and requested a re-hearing.	N/A	Certificate of Registration No. CS23773 request was denied.	N/A
JF at his place of practice called Century Wellness Center failed to properly label, segregate and/or dispose of adulterated and/or expired drugs, including multi-dose containers. In addition, Respondent Forsythe possessed in his inventory Veterinary 0.9% Sodium Chloride labeled “For Veterinary Use Only”.	N/A	Certificate of Registration No. CS05385 accept the Order as public reprimand regarding his duties and responsibilities as a practitioner when maintaining inventory of dangerous drugs; submit to a timely Board inspection at his practice; fined $5000 for the violations; and assessed $2384.08 in attorney’s fees and costs.	N/A
KB failed to query patient J.J.’s patient utilization report in the PMP database prior to issuing 22 separate controlled substance prescriptions. In addition, Respondent Burgner failed to query and review for accuracy her MyRx prescriber activity report at least once every six months from December 10, 2015, to June 23, 2022, as required by Nevada Law.	N/A	Certificate of Registration No. CS15148 fined $2,000 for the violations; and assessed $500 in attorney’s fees and costs.	N/A
RG failed to query patient J.J.’s patient utilization report in the PMP database prior to issuing 2 separate controlled substance prescriptions. In addition, Respondent Gonzalez failed to query and review for accuracy her MyRx prescriber activity report at least once every six months from January 29, 2018, to April 7, 2022, as required by Nevada Law.	N/A	Certificate of Registration No. CS11387 fined $2,000 for the violations; and assessed $500 in attorney’s fees and costs.	N/A

CVS is responsible for the acts of its employees who made an error in prescription that resulted in a negative outcome to the patient.	Yes	N/A	License No. PH02471 fined $2,000 for the violations; and assessed $1,000 in attorney's fees and costs.
AJ is responsible for an error in a prescription that resulted in a negative outcome to the patient.	Yes	Certificate of Registration No. 23280 fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A
NA, as verifying pharmacist, Respondent Aguas failed to review the actual physical contents of the prescription and is responsible for an error in the prescription.	Yes	Certificate of Registration No. 14977 fined $500 for the violations.	N/A
CVS, as pharmacy owner, CVS Pharmacy #8806 is responsible for the acts of its employees who made an error in prescription.	Yes	N/A	License No. PH100640 fined $5,000 for the violations; and assessed $4,787.82 in attorney's fees and costs.
MV did not conduct a MyRx review for all prescriptions Respondent has written for part of the calendar years 2017, 2019, and 2021. Respondent only queried nine times between January 1, 2018, to September 18, 2023, where he wrote at least 890 prescriptions for at least 650 unique patients	No	Certificate of Registration No. CS15506 shall accept this as a public reprimand; must comply with all PMP related laws and regulations; fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs.	N/A
CVS is responsible for the acts of an employee-pharmacist who failed to review patient M.C.'s record prior to counseling or reviewed the patient's profile in a manner that was inadequate to provide the patient proper counseling.	No	N/A	License No. PH01336 is fined $2,000 for the violations; and assessed $500 in attorney's fees and costs.
DM failed to review patient M.C.'s record prior to counseling or reviewed the patient's profile in a manner that was inadequate to provide the patient proper counseling.	No	Certificate of Registration No. 14845 is fined $1,000 for the violations; assessed $500 in attorney's fees and costs; and shall complete four additional continuing education credits on the topic of counseling.	N/A

NK was found guilty of making a false record of COVID-19 vaccinations reportedly administered to her former boyfriend and was disciplined by the Board at the April 17-18, 2024, Board Meeting. Thereafter, NS petitioned the Board for reconsideration of the discipline imposed and appeared at the July 17, 2024, Board Meeting. The Board amended the discipline imposed against NS.	No	Certificate of Registration No. 20034 is revoked; however, the revocation is stayed and Respondent is placed on probation for a period of five years; fined $5,000 for the violations; assessed $8,406.29 in attorney's fees and costs; as a condition of probation, Respondent's authority to engage in the practice of pharmacy is suspended for a period of one year from April 18, 2024; and Respondent must complete a 22-hour "Ethics and Professionalism" bootcamp course within 120 days of the Order.	N/A
WP is responsible for the acts of employees who made an error in a prescription that resulted in a negative outcome to a patient.	Yes	N/A	License No. PH01938 fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.
WP is responsible for the acts of employees who made an error in a prescription that resulted in a negative outcome to a patient.	Yes	N/A	License No. PH01964 fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.
GO made an error in a prescription that resulted in a negative outcome to a patient	Yes	Certificate of Registration No. 15190 fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A
As pharmacy/pharmacy owner, WP is responsible for the acts of employees who made an error in a prescription that resulted in a negative outcome to a patient.	Yes	N/A	License No. PH01064 fined $2,000 for the violations; and assessed $1,000 in attorney's fees and costs.

YJ engaged in unprofessional conduct when she made an error in a prescription that resulted in a negative outcome to a patient.	Yes	Certificate of Registration No. 18030 fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A
As pharmacy/pharmacy owner, AP is responsible for the acts of employees that caused a patient with acute bipolar disorder to go without medication for more than thirty days.	Yes	N/A	License No. PH03988 fined $3,000 for the violations; and assessed $2,000 in attorney's fees and costs.
DL allowed his medical assistant to use his credentials to issue electronic prescriptions for controlled substances.	No	Certificate of Registration No. CS06509 fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs.	N/A
Respondent Palumbo permitted registered nurses (RNs) to independently access, possess and administer dangerous drugs, without direct practitioner supervision.	No	Certificate of Registration No. CS26034 is placed on probation for a period of one year; fined $2,500 for the violations; and assessed $1,000 in attorney's fees and costs.	N/A
As managing pharmacist at the time of the events herein, TS is responsible for the acts of its employees at AWP who compounded and sold drug products using active ingredients that 1) do not have a United States Pharmacopoeia-National Formulary monograph; 2) are not a part of an FDA approved drug product, or 3) are not authorized to be used in compounding. In addition, the pharmacy compounded and sold high-risk sterile products with beyond use dates (BUD's) listed on the product label in excess of USP-797 guidelines based on storage conditions without documentation to support the extended BUD.	No	Certificate of Registration No. 08312 is placed on probation for a period of one year; fined $2,000 for the violations; assessed $1,000 in attorney's fees and costs; shall not work as a managing pharmacist of any compounding pharmacy licensed by the Board while on probation; shall not engage in the practice of compounding sterile drug products until he completes 20 extra hours of continuing education (CE) on sterile compounding; and shall complete 10 extra hours of continuing education (CE) on nonsterile compounding.	N/A

AWP is responsible for the acts of its employees who compounded and sold drug products using active ingredients that 1) do not have a United States Pharmacopoeia-National Formulary monograph; 2) are not a part of an FDA approved drug product, or 3) are not authorized to be used in compounding. In addition, the pharmacy compounded and sold high-risk sterile products with beyond use dates (BUD's) listed on the product label in excess of USP-797 guidelines based on storage conditions without documentation to support the extended BUD.	No	N/A	License No. PH02705 is suspended a period of one year, and the suspension is stayed. Respondent fined $8,000 for the violations; assessed $2,000 in attorney's fees and costs; shall not compound sterile drug products during probation period; shall bear and reimburse the Board for quarterly inspection costs in an amount not to exceed $500 per quarterly inspections; shall put into practice all necessary policies and procedures for compounding and dispensing drug products in conformance with federal and state law.
As pharmacy/pharmacy owner, SP is responsible for the acts of its employees who discarded approximately 58,000 prescription records constituting Protected Health Information (PHI) in a in violation of SP company policies and federal/state law.	No	N/A	Pharmacy License No. PH00758 fined $5,000 for the violations; and assessed $2,500 in attorney's fees and costs.
As managing pharmacist at the time of the events herein, LS is responsible for the acts of employees of SP who discarded approximately 58,000 prescription records constituting Protected Health Information (PHI) in violation of SP company policies and federal/state law.	No	Certificate of Registration No. 12687 is suspended until October 31, 2025, and must appear before the Board if she wants to renew/reinstate registration.	N/A
As pharmacy/pharmacy owner, CS is responsible for the acts of its employees who failed to keep a readily accessible paper copy of the prescription for a period of at least two years.	No	N/A	License No. PH01422 fined $500 for the violations; and assessed $500 in attorney's fees and costs.

FE pre-signed two controlled substance prescriptions that were issued to patients by his staff while he was engaged in overseas travel outside of the United States.	No	Certificate of Registration No. CS23430 is revoked; the revocation is stayed, and Respondent is placed on probation for a period of three years; assessed $4,268.97 in attorney's fees and costs; shall complete two hours of training from Board staff on the Nevada Prescriptions Monitoring Program (PMP) compliance; shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs.	N/A
As pharmacy/pharmacy owner, CS is responsible for the acts of its employees who initially dispensed 14 of 56 prescribed tablets of Oxycodone 10 mg to patient T.E., and later dispensed 56 additional tablets on the same prescription, thereby exceeding the prescribed quantity by 14 tablets; pharmacy employees also failed to counsel the patient.	No	N/A	License No. PH01932 fined $1,500 for the violations; and assessed $500 in attorney's fees and costs.
NS is responsible for the acts of the employees whom she supervised; the employees in question initially dispensed 14 of 56 prescribed tablets of Oxycodone 10 mg to patient T.E., and later dispensed 56 additional tablets on the same prescription, thereby exceeding the prescribed quantity by 14 tablets; Respondent also failed to counsel the patient.	No	Certificate of Registration No. 18099 fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A

CD failed to disclose that she previously surrendered her certificate of registration to prescribe controlled substances as issued by the federal Drug Enforcement Administration (DEA). In addition, she admits that she responded “no” to questions on the Board’s application asking whether she had “been the subject of a board citation or administrative action whether completed or pending in any state.”	No	Certificate of Registration Nos. CS35349 and DV00822 are revoked for a period of one year or until she can secure a DEA registration number in Nevada, whichever is later; fined $1,000 for the violations; and assessed $1,000 in attorney’s fees and costs.	N/A
TB failed to access the Prescription Monitoring Program (PMP) database for the purpose of reviewing her prescribing activity and did not review patient utilization reports in instances where such review was required between 2016 and 2023.	No	Certificate of Registration No. CS12793 fined $2,500 for the violations; and assessed $1,000 in attorney’s fees and costs.	N/A
AB failed to access the Prescription Monitoring Program (PMP) database for the purpose of prescribing activity and did not review patient utilization reports in instances where such review was required between December 16, 2019, to July 31, 2023.	No	Certificate of Registration No. CS29531 fined $2,500 for the violations; and assessed $1,000 in attorney’s fees and costs.	N/A
NK never conducted “MyRx” reviews of all the prescriptions that he has written and only conducted three queries on individuals between January 1, 2018, and August 8, 2023. During the time, Respondent wrote over 500 prescriptions for at least 70 unique patients. In addition, Respondent never acquired the means of prescribing prescriptions for controlled substances electronically, despite writing at least forty-five prescriptions for controlled substances to at least 13 unique patients after January 1, 2022, when the Board ceased giving out	No	Certificate of Registration No. CS09587 fined $7,500 for the violations; and assessed $1,000 in attorney’s fees and costs.	N/A

waivers for the electronic prescription requirement.			
HZ wrote a prescription of buprenorphine, a Schedule III controlled substance, when she did not hold an active DEA registration number because she inadvertently allowed her registration to expire without renewal on May 31, 2021.	No	Certificate of Registration Nos. CS09628 and DV00543 fined $5,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A
WP is responsible for the acts of its employees who failed to communicate matters which would enhance therapy through drugs to patient concerning his prescription for codeine-guaifenesin.	No	N/A	Pharmacy License No. PH01628 fined $750 for the violations; and assessed $500 in attorney's fees and costs.
SS failed to communicate matters which would enhance therapy through drugs to patient concerning his prescription for codeine-guaifenesin.	No	Certificate of Registration No. 20772 fined $750 for the violations; and assessed $500 in attorney's fees and costs.	N/A
AM failed to disclose on her October 21, 2022, controlled substance renewal application that her nursing license was on probation. In addition, Respondent did not properly answer the questions on her controlled substance registration renewal posing the following questions: 1) "Since your last renewal or recent licensure have you been the subject of a board citation or an administrative action whether completed or pending in any state?; and 2) "Since your last renewal or recent licensure have you had your license subjected to any discipline for violation of pharmacy or drug laws in any state?"	No	Certificate of Registration No. CS30357 is revoked for a period of one year; and assessed $687.67.	N/A
JS diverted several tablets of butalbital-aspirin-caffeine-codeine for personal use to ease her migraine headaches.	No	Certificate of Registration No. PT24955 is revoked for a period of one year; and assessed $534.36 in attorney's fees and costs.	N/A

PCOE committed unprofessional conduct when they failed to employ a Board approved MDEG Administrator and timely submit a change of ownership.	No	N/A	License No. MP00109 fined $2,000 for the violations; and assessed $500 in attorney's fees and costs.

5A

FILED
OCT 0 4 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAMUEL YU, APRN,** **Certificate of Registration No. CS27231, and** **MEE HAN, APRN,** **Certificate of Registration No. CS22622,** **Respondents.**	**CASE NOS. 22-185-CS-A-S** **22-185-CS-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Samuel Yu, APRN (Yu), held a Nevada controlled substance registration, Certificate of Registration No. CS27231, and Respondent Mee Han (Han), APRN, held a Nevada controlled substance registration, Certificate of Registration No. CS22622, both issued by the Board.

FACTUAL ALLEGATIONS

2. Respondents served as medical directors of Opus Face N Body Aesthetics (Opus), located at 6850 W Spring Mountain Road #102, in Las Vegas, Nevada, during the relevant times frames herein. Han served as medical director from May 2021 until May 2022 and Yu was appointed medical director May 5, 2022. Mee Kwyung Lee (Lee) owned Opus Face and Body and is not a Nevada-licensed practitioner.

3. A Board investigation in June 2022 revealed that during their respective tenures as medical directors of Opus, Respondents permitted Lee and registered nurses (RNs) at Opus to

have independent access to the medication storage containing dangerous drugs, and to access those medications outside Respondents' presence and without Respondents' supervision.

4. The investigation revealed that Respondents permitted RNs at Opus to independently access, possess, furnish and administer dangerous drugs to patients, to provide on-site medical treatment at Opus, including the administration of dangerous drugs by injection, specifically cosmetic injectable fillers, including, without limitation, Allergan's Juvederm Voluma, Volift, Vobella with lidocaine, and Botox drug products, without direct practitioner supervision, to patients with whom Respondents had not established a bona fide therapeutic relationship, and for whom Respondents had neither diagnosed nor determined that a dangerous drug was medically necessary.

5. The investigation revealed that the dangerous drug products in the inventory of Opus that were furnished and administered to patients were intended for distribution in foreign markets and not approved for distribution or use in the U.S.

6. On or about July 11, 2022, the Board issued a cease and desist order with a citation and fine against Lee pursuant to NRS 639.2895 for unlicensed activity.

APPLICABLE LAW

7. No person may possess, furnish or administer a dangerous drug in Nevada without specific statutory authority to do so. NRS 454.213, NRS 454.217, NRS 454.221, NRS 454.316, NRS 454.321; NRS 454.356; NRS 639.100(1).

8. A practitioner may give an RN limited authority to possess and administer dangerous drugs pursuant to NRS 454.213(1)(c), which states in relevant part:

> A drug or medicine referred to in NRS 454.181 to 454.371, inclusive, may be possessed and administered by . . . a registered nurse licensed to practice professional nursing or licensed practical nurse, at the direction of a prescribing physician, physician assistant licensed pursuant to chapter 630 or 633 of NRS, dentist, podiatric physician or advanced practice registered nurse, or pursuant to a chart order, for administration to a patient at another location.

Chart orders are patient-specific and medication-specific. *See* NRS 454.0041; NRS 639.004.

9. It is unlawful to purchase, possess, sell, furnish or administer any drug product intended for distribution in foreign markets and not approved for distribution or use in the U.S. 21 U.S.C. § 331; 21 U.S.C. § 355(a); NRS 454.351(1); NRS 585.490.

10. All controlled substances and dangerous drugs in the possession of an advanced practice registered nurse must be kept in a locked storage area with access restricted to authorized persons. NAC 639.898(1).

11. The Board may suspend or revoke the certificate of registration of an advanced practice registered nurse that has failed to maintain the security of his or her drug supply. NAC 639.900(12).

12. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

13. Aiding or abetting a person in unlicensed practice constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

14. Dispensing a drug to any patient with whom the practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

15. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs, including, without limitation, any provision of chapter 453, 454,585 or 639 of NRS or any regulation pertaining thereto, is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12); NAC 639.900(14).

16. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violations of State Law - Failure to Maintain Security of Dangerous Drugs

17. By permitting Lee and RNs to have unrestricted access to their inventory of dangerous drugs at Opus as alleged in paragraph 3 herein, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NAC 639.898(1), and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.900(12) and (14) and/or NRS 639.210(12).

COUNT TWO

Violations of State Law - Unlawful Possession & Administration of Dangerous Drugs

18. By permitting RNs to independently access, possess, furnish and administer dangerous drugs without direct practitioner supervision, to patients with whom Respondent had not established a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed nor determined that a dangerous drug medically was medically necessary, as alleged in paragraph 4 herein, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.213, NRS 454.217, NRS 454.221, NRS 454.316, NRS 454.321, NRS 454.356 and/or NRS 639.100(1), and are subject to discipline pursuant to NAC 639.900(14) and/or NRS 639.210(12).

COUNT THREE

Violation of Federal and State Law – Using Drugs Not Approved in United States

19. By purchasing, possessing, selling, furnishing and/or administering drug products intended for distribution in foreign markets and not approved for distribution or use in the U.S., as alleged in paragraph 5 herein, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 331, 21 U.S.C. § 355(a), NRS 454.351(1)

and/or NRS 585.490, and are subject to discipline pursuant to NAC 639.900(10) and (14) and/or NRS 639.210(12).

COUNT FOUR

Unprofessional Conduct - Unlawful Possession & Administration of Dangerous Drugs

20. By their conduct as alleged in paragraphs 3-5 herein, Respondents performed their duties as the holders of controlled substance registrations in an incompetent, unskillful or negligent manner, aided and abetted unlicensed practice, and engaged in, or aided and abetted others to engage in, unprofessional conduct as defined in NAC 639.945(i), (j) and (n), and are subject to discipline pursuant to NRS 639.210(4) and/or NAC 639.900(4).

COUNT FIVE

Commission of Acts that Render Registration Inconsistent with the Public Interest

21. By their conduct as alleged in paragraphs 3-5 herein, Respondents have committed acts that render registration inconsistent with the public interest and are subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 4th day of October 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAMUEL YU, APRN,** **Certificate of Registration No. CS27231,** **Respondent.**	**Case No. 22-185-CS-A-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 4th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAMUEL YU, APRN,** **Certificate of Registration No. CS27231,** **Respondent.**	**Case No. 22-185-CS-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

SAMUEL YU, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Samuel Yu, APRN c/o
Yu & I Wellness Center
6268 S. Rainbow Blvd Ste 100
Las Vegas, NV 89118

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
NOV 04 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAMUEL YU, APRN,** **Certificate of Registration No. CS27231,** **MEE HAN, APRN,** **Certificate of Registration No. CS22622,** **Respondents.**	**Case No. 22-185-CS-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent Samuel Yu Ph.D. FNP APRN ("Respondent Yu"), in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds:

   a. Respondent Yu was hired as a medical director in May 2022. As stated in the Medical Director Agreement dated May 5, 2022, one of Respondent Yu's stated duties were to perform remote telehealth services to consult with patients utilizing electronic video communication. As such, he did not physically work inside the clinic located at 68750 W Spring Mountain Rd #102, Las Vegas, Nevada 89146 prior to the June 23, 2022, inspection, but only worked remotely.

b. Respondent Yu was unaware of this Nevada requirement to keep the dangerous drugs independently inaccessible to RNs until the Board inspection of the facility on June 23, 2022.

c. After the Board's inspection on June 23, 2022, when Respondent Yu first became aware of Nevada's locked access requirements, he immediately took steps to ensure that all dangerous drugs were kept in locked storage that only he had access to, that no one could independently access, and he prepared written protocols and guidelines to be followed.

d. Respondent Yu did not authorize the purchase of illegal drugs from non-US entities; this was put into practice by the medical director Mee Han ("Han"), who convinced the owner, Lee, that these practices were legal, when in fact they were not.

e. Respondent Yu was unaware Opus Face and Body ("Opus") was using or purchasing illegal drugs, the owner was also unaware of it because she relied upon Mee Han for this information. Because Respondent Yu was operating remotely as the medical director from May 5, 2022 until June 23, 2022, he was unaware of any of this illegal activity until June 23, 2022, at which time the use of these items ceased.

f. Opus was closed permanently after the June 23, 20222 incident, so no more Opus medical spa business has been operating since then.

g. The accusations fail to distinguish between the actions or inactions of Respondent Yu and Respondent Han, making the accusations appear that Respondent Yu consented to and participated equally and/or jointly in

continuation or furtherance of the illegal and/or improper activities with the prior medical director, Respondent Mee Han.

h. The accusation is incomplete in that it fails to enumerate the things Respondent Yu did after learning about Nevada requirements on June 23, 2022, and the illegal activities of former medical director Han.

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

a. Respondent Yu admits paragraph 1.

b. As to paragraph 2, Respondent Yu does not know the commencement of Han's tenure as medical director therefore denies this part; Respondent Yu admits that Han's tenure continued through May 26, 2022; Respondent Yu and admits that his appointment as medical director was effective on May 5, 2022, and overlapped Han's tenure;

c. Respondent Yu admits this occurred until June 23, 2022. Respondent Yu denies this continued to occur after that date.

d. As to paragraph 3, Respondent Yu admits the allegations occurred until June 23, 2022.

e. As to paragraph 4, Respondent Yu denies all allegations contained therein as to himself, except he admits the RNs had independent access to the dangerous drugs set forth therein until June 23, 2022.

f. As to paragraph 5, Respondent Yu admits that these allegations, up to June 23, 2022.

g. Respondent Yu admits paragraph 6, and also states that Opus has been is permanently closed.

h. As to paragraphs 7 through 16, Respondent Yu does not dispute the express wording of the United States Code ("U.S.C."), the Nevada Revised Statutes ("NRS"), or the Nevada Administrative Code ("NAC") as set forth in these paragraphs but is without sufficient legal knowledge to comment as to their interpretation or application as set forth in this Notice of Intended Action and Accusation, therefore must deny to that extent, and will rely on his attorney for counsel and advice.

i. Respondent Yu denies intentionally or knowingly committing any violations of State or Federal law set forth in paragraphs 17 through 21.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED: 11/4/2024



SAMUEL YU, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the law office of Craig K. Perry & Associates, and that on this 4th day of November, 2024, I served a true and correct copy of the foregoing Answer and Notice of Defense by electronic means by emailing to the following;

Nevada State Board of Pharmacy
Email: TeamBC@pharmacy.nv.gov
Email: bkandt@pharmacy.nv.gov

/s/ Tyrin Kanemeier

TYRIN KANEMEIER
OFFICE MANAGER
CRAIG K. PERRY & ASSOCIATES

5B

FILED
OCT 04 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAMUEL YU, APRN,** **Certificate of Registration No. CS27231, and** **MEE HAN, APRN,** **Certificate of Registration No. CS22622,** **Respondents.**	**CASE NOS. 22-185-CS-A-S** **22-185-CS-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Samuel Yu, APRN (Yu), held a Nevada controlled substance registration, Certificate of Registration No. CS27231, and Respondent Mee Han (Han), APRN, held a Nevada controlled substance registration, Certificate of Registration No. CS22622, both issued by the Board.

FACTUAL ALLEGATIONS

2. Respondents served as medical directors of Opus Face N Body Aesthetics (Opus), located at 6850 W Spring Mountain Road #102, in Las Vegas, Nevada, during the relevant times frames herein. Han served as medical director from May 2021 until May 2022 and Yu was appointed medical director May 5, 2022. Mee Kwyung Lee (Lee) owned Opus Face and Body and is not a Nevada-licensed practitioner.

3. A Board investigation in June 2022 revealed that during their respective tenures as medical directors of Opus, Respondents permitted Lee and registered nurses (RNs) at Opus to

have independent access to the medication storage containing dangerous drugs, and to access those medications outside Respondents' presence and without Respondents' supervision.

4. The investigation revealed that Respondents permitted RNs at Opus to independently access, possess, furnish and administer dangerous drugs to patients, to provide on-site medical treatment at Opus, including the administration of dangerous drugs by injection, specifically cosmetic injectable fillers, including, without limitation, Allergan's Juvederm Voluma, Volift, Vobella with lidocaine, and Botox drug products, without direct practitioner supervision, to patients with whom Respondents had not established a bona fide therapeutic relationship, and for whom Respondents had neither diagnosed nor determined that a dangerous drug was medically necessary.

5. The investigation revealed that the dangerous drug products in the inventory of Opus that were furnished and administered to patients were intended for distribution in foreign markets and not approved for distribution or use in the U.S.

6. On or about July 11, 2022, the Board issued a cease and desist order with a citation and fine against Lee pursuant to NRS 639.2895 for unlicensed activity.

APPLICABLE LAW

7. No person may possess, furnish or administer a dangerous drug in Nevada without specific statutory authority to do so. NRS 454.213, NRS 454.217, NRS 454.221, NRS 454.316, NRS 454.321; NRS 454.356; NRS 639.100(1).

8. A practitioner may give an RN limited authority to possess and administer dangerous drugs pursuant to NRS 454.213(1)(c), which states in relevant part:

> A drug or medicine referred to in NRS 454.181 to 454.371, inclusive, may be possessed and administered by . . . a registered nurse licensed to practice professional nursing or licensed practical nurse, at the direction of a prescribing physician, physician assistant licensed pursuant to chapter 630 or 633 of NRS, dentist, podiatric physician or advanced practice registered nurse, or pursuant to a chart order, for administration to a patient at another location.

Chart orders are patient-specific and medication-specific. *See* NRS 454.0041; NRS 639.004.

9. It is unlawful to purchase, possess, sell, furnish or administer any drug product intended for distribution in foreign markets and not approved for distribution or use in the U.S. 21 U.S.C. § 331; 21 U.S.C. § 355(a); NRS 454.351(1); NRS 585.490.

10. All controlled substances and dangerous drugs in the possession of an advanced practice registered nurse must be kept in a locked storage area with access restricted to authorized persons. NAC 639.898(1).

11. The Board may suspend or revoke the certificate of registration of an advanced practice registered nurse that has failed to maintain the security of his or her drug supply. NAC 639.900(12).

12. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

13. Aiding or abetting a person in unlicensed practice constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

14. Dispensing a drug to any patient with whom the practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

15. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs, including, without limitation, any provision of chapter 453, 454,585 or 639 of NRS or any regulation pertaining thereto, is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12); NAC 639.900(14).

16. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violations of State Law - Failure to Maintain Security of Dangerous Drugs

17. By permitting Lee and RNs to have unrestricted access to their inventory of dangerous drugs at Opus as alleged in paragraph 3 herein, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NAC 639.898(1), and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.900(12) and (14) and/or NRS 639.210(12).

COUNT TWO

Violations of State Law - Unlawful Possession & Administration of Dangerous Drugs

18. By permitting RNs to independently access, possess, furnish and administer dangerous drugs without direct practitioner supervision, to patients with whom Respondent had not established a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed nor determined that a dangerous drug medically was medically necessary, as alleged in paragraph 4 herein, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.213, NRS 454.217, NRS 454.221, NRS 454.316, NRS 454.321, NRS 454.356 and/or NRS 639.100(1), and are subject to discipline pursuant to NAC 639.900(14) and/or NRS 639.210(12).

COUNT THREE

Violation of Federal and State Law – Using Drugs Not Approved in United States

19. By purchasing, possessing, selling, furnishing and/or administering drug products intended for distribution in foreign markets and not approved for distribution or use in the U.S., as alleged in paragraph 5 herein, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 331, 21 U.S.C. § 355(a), NRS 454.351(1)

and/or NRS 585.490, and are subject to discipline pursuant to NAC 639.900(10) and (14) and/or NRS 639.210(12).

COUNT FOUR

Unprofessional Conduct - Unlawful Possession & Administration of Dangerous Drugs

20. By their conduct as alleged in paragraphs 3-5 herein, Respondents performed their duties as the holders of controlled substance registrations in an incompetent, unskillful or negligent manner, aided and abetted unlicensed practice, and engaged in, or aided and abetted others to engage in, unprofessional conduct as defined in NAC 639.945(i), (j) and (n), and are subject to discipline pursuant to NRS 639.210(4) and/or NAC 639.900(4).

COUNT FIVE

Commission of Acts that Render Registration Inconsistent with the Public Interest

21. By their conduct as alleged in paragraphs 3-5 herein, Respondents have committed acts that render registration inconsistent with the public interest and are subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 4th day of October 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MEE HAN, APRN,** **Certificate of Registration No. CS22622,** **Respondent.**	**Case No. 22-185-CS-B-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 4th day of October 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MEE HAN, APRN,** **Certificate of Registration No. CS22622,** **Respondent.**	**Case No. 22-185-CS-B-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

MEE HAN, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Mee Han, APRN c/o
Legacy Women's Health
8480 S Eastern Ave., #F
Las Vegas, NV 89123

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

5C

FILED
OCT - 4 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **YUKO SWEATT, APRN,** **Certificate of Registration No. CS28545,** **Respondent.**	**CASE NO. 22-214-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Yuko Sweatt, APRN, held a Nevada controlled substance registration, Certificate of Registration No. CS28545, issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent co-owned and served as medical director of Elvea Medspa LLC (Elvea), located at 6835 W Charleston Blvd #102, in Las Vegas, Nevada, during the relevant times frames herein. Respondent co-owned Elvea with Ellen Kim (Kim) and Gonzalo Cruz-Schiavone. Kim and Cruz-Schiavone are not Nevada-licensed practitioners.

3. Respondent also served as medical director of Face Line Medi Spa (Face Line), located at 6835 W Charleston Blvd #102, in Las Vegas, Nevada, during the relevant times frames herein. Kim owned Face-Line.

4. A Board investigation in July 2022 revealed that Respondent permitted Kim and registered nurses (RNs) at both Elvea and Face Line to have independent access to the medication storage containing dangerous drugs, and to access those medications outside Respondent's presence and without Respondent's supervision.

5. The investigation revealed that Respondent permitted RNs at both Elvea and Face Line to independently access, possess, furnish and administer dangerous drugs to patients, to provide on-site medical treatment at both Elvea and Face Line, including the administration of dangerous drugs through intravenous (IV) therapy and/or by injection, specifically cosmetic injectable fillers, including, without limitation, Allergan's Juvederm Voluma and Juvederm Ultra XC, ASCE (Adipose Stem Cell Exosome), Restylane and Botox, without direct practitioner supervision, to patients with whom Respondent had not established a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed nor determined that a dangerous drug was medically necessary.

6. The investigation revealed that the dangerous drug products in the inventories of both Elvea and Face Line that were furnished and administered to patients were intended for distribution in foreign markets and not approved for distribution or use in the U.S.

7. On or about October 20, 2022, the Board issued a cease-and-desist order with a citation and fine against Kim pursuant to NRS 639.2895 for unlicensed activity.

APPLICABLE LAW

8. No person may possess, furnish or administer a dangerous drug in Nevada without specific statutory authority to do so. NRS 454.213, NRS 454.217, NRS 454.221, NRS 454.316, NRS 454.321; NRS 454.356; NRS 639.100(1).

9. A practitioner may give an RN limited authority to possess and administer dangerous drugs pursuant to NRS 454.213(1)(c), which states in relevant part:

> A drug or medicine referred to in NRS 454.181 to 454.371, inclusive, may be possessed and administered by . . . a registered nurse licensed to practice professional nursing or licensed practical nurse, at the direction of a prescribing

> physician, physician assistant licensed pursuant to chapter 630 or 633 of NRS, dentist, podiatric physician or advanced practice registered nurse, or pursuant to a chart order, for administration to a patient at another location.

Chart orders are patient-specific and medication-specific. *See* NRS 454.0041; NRS 639.004.

10. It is unlawful to purchase, possess, sell, furnish or administer any drug product intended for distribution in foreign markets and not approved for distribution or use in the U.S. 21 U.S.C. § 331; 21 U.S.C. § 355(a); NRS 454.351(1); NRS 585.490.

11. All controlled substances and dangerous drugs in the possession of an advanced practice registered nurse must be kept in a locked storage area with access restricted to authorized persons. NAC 639.898(1).

12. The Board may suspend or revoke the certificate of registration of an advanced practice registered nurse that has failed to maintain the security of his or her drug supply. NAC 639.900(12).

13. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

14. Aiding or abetting a person in unlicensed practice constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

15. Dispensing a drug to any patient with whom the practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

16. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs, including, without limitation, any

provision of chapter 453, 454,585 or 639 of NRS or any regulation pertaining thereto, is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12); NAC 639.900(14).

17. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violations of State Law - Failure to Maintain Security of Dangerous Drugs

18. By permitting Kim and RNs to have unrestricted access to her inventory of dangerous drugs at both Elvea and Face Line as alleged in paragraph 4 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NAC 639.898(1), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.900(12) and (14) and/or NRS 639.210(12).

COUNT TWO

Violations of State Law - Unlawful Possession & Administration of Dangerous Drugs

19. By permitting RNs to independently access, possess, furnish and administer dangerous drugs without direct practitioner supervision, to patients with whom Respondent had not established a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed nor determined that a dangerous drug medically was medically necessary, as alleged in paragraph 5 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.213, NRS 454.217, NRS 454.221, NRS 454.316, NRS 454.321, NRS 454.356 and/or NRS 639.100(1), and is subject to discipline pursuant to NAC 639.900(14) and/or NRS 639.210(12).

\\\

\\\

\\\

\\\

COUNT THREE

Violation of Federal and State Law – Using Drugs Not Approved in United States

20. By purchasing, possessing, selling, furnishing and/or administering drug products intended for distribution in foreign markets and not approved for distribution or use in the U.S., as alleged in paragraph 6 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 331, 21 U.S.C. § 355(a), NRS 454.351(1) and/or NRS 585.490, and is subject to discipline pursuant to NAC 639.900(10) and (14) and/or NRS 639.210(12).

COUNT FOUR

Unprofessional Conduct - Unlawful Possession & Administration of Dangerous Drugs

21. By her conduct as alleged in paragraphs 4-6 herein, Respondent performed her duties as the holder of a controlled substance registrations in an incompetent, unskillful or negligent manner, aided and abetted unlicensed practice, and engaged in, or aided and abetted others to engage in, unprofessional conduct as defined in NAC 639.945(i), (j) and (n), and is subject to discipline pursuant to NRS 639.210(4) and/or NAC 639.900(4).

COUNT FIVE

Commission of Acts that Render Registration Inconsistent with the Public Interest

22. By her conduct as alleged in paragraphs 4-6 herein, Respondent has committed acts that render registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 4th day of October 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **YUKO SWEATT, APRN,** **Certificate of Registration No. CS28545,** **Respondent.**	**Case No. 22-214-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 4th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **YUKO SWEATT, APRN,** **Certificate of Registration No. CS28545,** **Respondent.**	**Case No. 22-214-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

YUKO SWEATT, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 7th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Yuko Sweatt, APRN
[redacted] Wellness Way
Las Vegas, NV 89106

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway – Suite 206 • Reno, NV 89521

(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444

• Web Page: bop.nv.gov

October 20, 2022

VIA CERTIFIED AND U.S. MAIL

Face Line Medi Spa and/or Elvea Medspa LLC
c/o Ellen Kim
6835 W. Charleston Blvd. #101 and/or #102
Las Vegas, NV 89117

Elvëa Medspa LLC dba Elvëa Medspa
c/o Law Office of John Park, PLLC, Registered Agent
8930 W. Sunset Road, Suite 200
Las Vegas, NV 89148

Meemo LLC dba Face Line
c/o Ellen Kim
8914 Golden Crow Avenue
Las Vegas, NV 89148

Re: CEASE and DESIST/CITATION: Unlicensed Practice/Activity (Case No. 22-214)

Greetings,

The Nevada State Board of Pharmacy ("BOP") has determined that you and/or your compan(ies) are unlawfully purchasing, accessing, possessing, administering, furnishing, prescribing, and/or dispensing dangerous drugs for Nevada patients that are not approved by the United States Food and Drug Administration from your "medical spa" in violation of law. Specifically, you had in your possession Allergan's Juvederm Voluma and Juvederm Ultra XC, ASCE, Restylane, boxes of Botox products manufactured for the South Korean market, Fursultiamine HCl, and Vitamin B complex, not authorized in the United States. You are prohibited from possessing, dispensing, and/or administering dangerous drugs not authorized in the United States.

You have violated, attempted to violate, assisted or abetted in the violation of or conspired to violate, without limitation, NRS 454.213(1), NRS 454.221, NRS 454.316, NRS 454.321, NRS 454.351, NRS 454.356, NRS 639.100(1).

You are hereby ordered pursuant to NRS 639.2895(1) to immediately CEASE and DESIST purchasing, accessing, possessing, administering, furnishing, prescribing, and/or dispensing dangerous drugs for Nevada patients. This letter shall serve as a CITATION pursuant to NRS 639.2895(2) for your unlicensed practice/activity. The Board has assessed you an administrative fine of five thousand dollars ($5,000.00) pursuant to NRS 639.2895(3).

You must pay this administrative fine within 30 days of receipt of this citation, or otherwise contact Board staff to request an alternative payment plan. Payment must be by *cashier's check*, *certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer," to be received at the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

You have the right to appeal this citation by submitting a written request for a hearing to the Board at the Board's Reno office no later than 30 days after receipt of this letter. *See* NRS 639.2895(2).

Please be aware that the foregoing does not preclude a formal investigation or filing of criminal charges. If you have any questions, please do not hesitate to contact me at 775-850-1440 or c.lee@pharmacy.nv.gov.

cc: Joshua M. Dickey, Esq.

Sincerely,

Courtney K. Lee
General Counsel
Nevada State Board of Pharmacy

9171 9690 0935 0278 8961 97

5D

FILED
OCT 09 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, License No. PH02028, and** **JEFFREY LANG, RPH, Registration No. 17503.** **Respondents.**	**Case Nos. 23-239-PH-S** **23-239-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Partell Specialty Pharmacy (Respondent Pharmacy), because Respondent Pharmacy, at the time of the violations alleged herein, held License No. PH02028 issued by the Board pursuant to NRS 639.230, authorizing the business to operate as a pharmacy. Since June 29, 2007, Respondent Pharmacy has held this license to operate a pharmacy issued by the Board pursuant to NRS 639.230.

2. The Board has personal jurisdiction over Respondent Jeffrey Lang, RPh, (Respondent Lang), because Respondent Lang, at the time of the violations alleged herein, held Certificate of Registration No. 17503 issued by the Board pursuant to NRS 639.127, authorizing Respondent to engage in the practice of pharmacy. Since November 6, 2008, Respondent Lang has held this registration to practice pharmacy issued by the Board pursuant to NRS 639.127.

3. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals and medicines and the regulation of the practice of pharmacy. NRS 639.070.

3. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals and medicines and the regulation of the practice of pharmacy. NRS 639.070.

FACTUAL ALLEGATIONS

4. On or about February 28, 2023, Respondent Pharmacy and Respondent Lang dispensed Nutlin to patient T.S. with direction to mix Nutlin with 2mL DMSO and administer .5mL up to 1mL intramuscularly or IV per administration protocol. This prescription was given prescription number 0090060591.

5. Respondent Pharmacy and Respondent Lang also dispensed Pooled Peptides to patient T.S. with instructions to inject 1mL daily per administration protocol. This prescription was given prescription number 0090060593.

6. Respondent Pharmacy and Respondent Lang purchased the drugs used for these prescriptions from an unlicensed wholesaler/manufacturer called Biopeptek Pharmaceuticals.

7. Neither Nutlin nor Pooled Peptides have a *United States Pharmacopeia – National Formulary* Monograph.

8. Neither Nutlin nor Pooled Peptides have components of drugs approved by the Food and Drug Administration.

9. Both Nutlin and Pooled Peptides were prescribed in this instance to cure, mitigate, and/or treat cancer.

10. Neither Nutlin nor Pooled Peptides are considered investigational drugs under Nevada law.

APPLICABLE LAW

11. The definition of drug includes, "[a]rticles and devices intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals." NRS 639.007(2).

12. "Investigational drug, biological product or device" means a drug, biological product or device that: (1) [h]as successfully completed Phase 1 of a clinical trial; (2) [h]as not been approved by

the United States Food and Drug Administration; and (3) [i]s currently being tested in a clinical trial that has been approved by the United States Food and Drug Administration." NRS 454.690(10)(c).

13. The Board may discipline the holder of a license or registration if the holder of said license or registration, "is guilty of unprofessional conduct or conduct contrary to the public interest." NRS 639.210(4).

14. "Any person, including a wholesaler or manufacturer, who engages in the business of wholesale distribution or furnishing controlled substances, poisons, drugs, devices or appliances that are restricted by federal law to sale by or on the order of a physician to any person located within this State shall obtain a license pursuant to the provisions of this chapter." NRS 639.233(1).

15. "For the purpose of this section, a person is "engaged in the business of furnishing" if the person: (a) Solicits or accepts orders for drugs or devices whose sale in this State is restricted by this chapter or chapter 453 or 454 of NRS; or (b) Receives, stores or ships such drugs or devices." NRS 639.233(2).

16. "The furnishing to a practitioner by a pharmacist or a pharmacy of prescription blanks bearing the name or name and address of any pharmacy is an unearned rebate and an inducement to refer patients to such pharmacist or pharmacy." NRS 639.264(2).

17. Prescription drugs may only be sold if the sale is a bona fide transaction. NRS 639.595(1).

18. A transaction is not a bona fide transaction if the circumstances of the purchase do not reasonably indicate that the drug was purchased from a source prohibited by law. NRS 639.595(5)(a)(2).

19. "A pharmacy or pharmacist is not required to obtain a license as a manufacturer to compound drugs if... the active ingredients used to compound the drugs: (1) [h]ave a monograph in and meet or exceed the standards of the United States Pharmacopoeia - National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670; (2) [h]ave been components of drugs approved by the Food and Drug Administration; or (3) [a]re authorized to be used in pharmacy

compounding pursuant to 21 U.S.C. § 353a(b)(1i) or the regulations adopted pursuant thereto." NAC 639.757(1).

20. Unprofessional conduct includes, "[p]erforming any…duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner." NAC 639.945(1)(i).

21. "The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ." NAC 639.945(3).

22. In lieu of a suspension or revocation, the Board may impose a fine of up to $10,000 for each violation committed. NRS 639.255(1)(f) and (3).

COUNT ONE

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Purchasing Drugs from an Unlicensed Wholesaler (Respondent Pharmacy & Respondent Lang)

23. Respondent Pharmacy and Respondent Lang purchased drugs from Biopeptek Pharmaceuticals. Biopeptek Pharmaceuticals was not licensed as a wholesaler in Nevada. NRS 639.233. Nevada law imposes a duty on parties to transactions involving prescription drugs, to engage in bona fide transactions. NRS 639.595(1). By purchasing drugs from an unlicensed wholesaler, Respondent Pharmacy and Respondent Lang purchased drugs from a source prohibited by law. *See* NRS 639.210(4); NRS 639.233; NRS 639.595(5)(a)(2); and NAC 639.945(1)(i).

24. Respondents performed their duties as the holder of a license and registration issued by the Board in an incompetent, unskillful or negligent manner because they purchased drugs from an unlicensed wholesaler, breaching the duty imposed on them by Nevada law. NRS 639.210(4); NRS 639.595(1); NRS 639.595(5)(a)(2); NAC 639.945(1)(i).

25. Having engaged in conduct contrary to the public interest as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

26. Respondent Pharmacy is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT TWO

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Compounding and Dispensing a Product with an Active Ingredient that Does not have a *United States Pharmacopeia – National Formulary* Monograph or Components of Drugs Approved by the Food and Drug Administration (Respondent Pharmacy and Respondent Lang)

27. Respondent Pharmacy and Respondent Lang filled and dispensed Nutlin to patient T.S., listed as prescription number 0090060591. Nutlin does not have a *United States Pharmacopeia – National Formulary* Monograph, nor have its components been approved by the U.S. Food and Drug Administration. NAC 639.757(1).

28. Respondents performed their duties as the holder of a license and registration issued by the Board in an incompetent, unskillful or negligent manner because they filled and dispensed a drug product with an active ingredient that does not have a *United States Pharmacopeia – National Formulary* Monograph, or components that have been approved by the U.S. Food and Drug Administration. NRS 639.210(4); NAC 639.757(1); and NAC 639.945(1)(i).

29. Having engaged in conduct contrary to the public interest as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

30. Respondent Pharmacy is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT THREE

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Compounding and Dispensing a Product that Does not have a *United States Pharmacopeia – National Formulary* Monograph or Components of Drugs Approved by the Food and Drug Administration
(Respondent Pharmacy and Respondent Lang)

31. Respondent Pharmacy and Respondent Lang filled and dispensed Pooled Peptides to patient T.S., listed as prescription number 0090060593. Pooled Peptides does not have a *United States Pharmacopeia – National Formulary* Monograph, nor have its components been approved by the U.S. Food and Drug Administration. NAC 639.757(1).

32. Respondents performed their duties as the holder of a license and registration issued by the Board in an incompetent, unskillful or negligent manner because they filled and dispensed a drug product with an active ingredient that does not have a *United States Pharmacopeia – National Formulary* Monograph, or components that have been approved by the U.S. Food and Drug Administration. NRS 639.210(4); NAC 639.757(1); and NAC 639.945(1)(i).

33. Having engaged in conduct contrary to the public interest as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

34. Respondent Pharmacy is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

\\\

\\\

\\\

\\\

\\\

\\\

COUNT FOUR

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner by Furnishing Prescription Blanks Bearing the Name or Name and Address of Respondent Pharmacy
(Respondent Pharmacy and Respondent Lang)

35. Respondent Pharmacy received both prescriptions at issue in this case via prescription blanks that contained the name of Respondent Pharmacy. The furnishing of prescription blanks that contain the name or name and address of a pharmacy is prohibited by Nevada law. NRS 639.264(2).

36. Respondents performed their duties as the holder of a license and registration issued by the Board in an incompetent, unskillful or negligent manner because they furnished or allowed to be furnished on their behalf prescription blanks that contain the name or name and address of their pharmacy. NRS 639.210(4); NRS 639.264(2); and NAC 639.945(1)(i).

37. Having engaged in conduct contrary to the public interest as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

38. Respondent Pharmacy is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent.

DATED this 9th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, License No. PH02028,** **Respondent.**	**Case No. 23-239-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **gvanderdonck@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 9th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, License No. PH02028,** **Respondent.**	**Case No. 23-239-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

AUTHORIZED REPRESENTATIVE FOR PARTELL SPECIALTY PHARMACY

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Partell Specialty Pharmacy
5835 S Eastern Ave., #101
Las Vegas, NV 89119

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

FILED
NOV 04 2024
NEVADA STATE BOARD OF PHARMACY

JOSEPH S. GILBERT, ESQ.- SBN #. 9033
Joey Gilbert Law
405 Marsh Avenue
Reno, Nevada 89509
Telephone: (775) 284-7700
Attorney for Respondent

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, PARTELL SPECIALTY PHARMACY, License No. PH02028, and JEFFREY LANG, RPH, Registration No. 17503. Respondent.	Case No.: 23-239-PH-S 23-239-RPH-S **ANSWER AND NOTICE OF DEFENSE**

COMES NOW, Respondents, PARTELL SPECIALTY PHARMACY and JEFFREY LANG, RPH (hereinafter referred to as "Respondents") by and through their counsel of record, JOSEPH S. GILBERT, ESQ. of JOEY GILBERT LAW, and answers the Notice of Intended Action and Accusation filed on October 9, 2024 as follows:

JURISDICTION

1. Responding to Paragraph 1 of the Notice of Intended Action and Accusation, Respondent admits that the Nevada State Board of Pharmacy has personal jurisdiction over Respondent Partell Specialty Pharmacy.

2. Responding to Paragraph 2 of the Notice of Intended Action and Accusation, Respondent admits that the Nevada State Board of Pharmacy has personal jurisdiction over Respondent Jeffrey Lang, RPH.

3. Responding to Paragraph 3 of the Notice of Intended Action and Accusation, Respondents admit that the Nevada State Board of Pharmacy has jurisdiction over the subject matter of this accusation.

FACTUAL ALLEGATIONS

4. Responding to Paragraph 4 of the Notice of Intended Action and Accusation, Respondents admit to the allegation.

5. Responding to Paragraph 5 of the Notice of Intended Action and Accusation, Respondents admit to the allegations.

6. Responding to Paragraph 6 of the Notice of Intended Action and Accusation, Respondents admit to the allegation that they purchased Nutlin and Pooled Peptides from Biopeptek Pharmaceuticals. Respondents deny the allegation that they knew Biopeptek was an unlicensed wholesale/manufacturer.

7. This Paragraph contains no allegations. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

8. This Paragraph contains no allegations. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

9. This Paragraph contains no allegations. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

10. This Paragraph contains no allegations. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

APPLICABLE LAW

11. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

12. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

13. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

14. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

15. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

16. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

17. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

18. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

19. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

20. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

21. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

22. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

COUNT ONE

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Purchasing Drugs from an Unlicensed Wholesaler (Respondent Pharmacy & Respondent Lang)

23. Responding to Paragraph 23 of the Notice of Intended Action and Accusation, Respondents admit to purchasing drugs from Biopeptek. Respondents deny all remaining allegations.

24. Responding to Paragraph 24 of the Notice of Intended Action and Accusation, Respondents deny performing their duties in an incompetent, unskillful, or negligent manner under NRS 639.210(4); NRS 639.595(1); NRS 639.595(5)(a)(2); NAC 639.945(1)(i).

25. Responding to Paragraph 25 of the Notice of Intended Action and Accusation, Respondents deny that they engaged in conduct contrary to the public interest and deny that they are subject to discipline by the Board.

26. Responding to Paragraph 26 of the Notice of Intended Action and Accusation, Respondent admits to the allegation.

COUNT TWO

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Compounding and Dispensing a Product with an Active Ingredient that does not have a United States Pharmacopeia-National Formulary Monograph or Components of Drugs Approved by the Food and Drug Administration

(Respondent Pharmacy and Respondent Lang)

27. Responding to Paragraph 27 of the Notice of Intended Action and Accusation, Respondents admit solely to dispensing Nutlin to patient T.S., listed as prescription number 0090060591. Accordingly, Respondents deny all remaining allegations herein.

28. Responding to Paragraph 28 of the Notice of Intended Action and Accusation, Respondents deny performing their duties in an incompetent, unskillful, or negligent manner under NRS 639.210(4); NAC 639.757(1); NAC 639.945(1)(i).

29. Responding to Paragraph 29 of the Notice of Intended Action and Accusation, Respondents deny that they engaged in conduct contrary to the public interest and deny that they are subject to discipline by the Board.

30. Responding to Paragraph 30 of the Notice of Intended Action and Accusation, Respondents admit the allegations.

COUNT THREE

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Compounding and Dispensing a Product with an Active Ingredient that does not have a United States Pharmacopeia-National Formulary Monograph or Components of Drugs Approved by the Food and Drug Administration

(Respondent Pharmacy and Respondent Lang)

31. Responding to Paragraph 31 of the Notice of Intended Action and Accusation, Respondents admit solely to dispensing Nutlin to patient T.S., listed as prescription number 0090060591. Accordingly, Respondents deny all remaining allegations herein.

32. Responding to Paragraph 32 of the Notice of Intended Action and Accusation, Respondents deny performing their duties in an incompetent, unskillful, or negligent manner under NRS 639.210(4); NAC 639.757(1); NAC 639.945(1)(i).

33. Responding to Paragraph 33 of the Notice of Intended Action and Accusation, Respondents deny that they engaged in conduct contrary to the public interest and deny that they are subject to discipline by the Board.

34. Responding to Paragraph 34 of the Notice of Intended Action and Accusation, Respondents admit the allegations.

COUNT FOUR

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner by Furnishing Prescription Blanks Bearing the Name or Name and Address of Respondent Pharmacy (Respondent Pharmacy and Respondent Lang)

35. Responding to Paragraph 35 of the Notice of Intended Action and Accusation, Respondent Pharmacy denies furnishing prescription blanks in violation of Nevada law (NRS 639.264(2)).

36. Responding to Paragraph 36 of the Notice of Intended Action and Accusation, Respondents deny performing their duties in an incompetent, unskillful, or negligent manner under NRS 639.210(4); NAC 639.757(1); NAC 639.945(1)(i).

37. Responding to Paragraph 37 of the Notice of Intended Action and Accusation, Respondents deny that they engaged in conduct contrary to the public interest and deny that they are subject to discipline by the Board.

38. Responding to Paragraph 38 of the Notice of Intended Action and Accusation, Respondents admit the allegations.

WHEREFORE, Respondent respectfully submits this response to the Notice of Intended Action and Accusation. Respondents, Partell Specialty Pharmacy and Jeffrey Lang, RPH, by and

WHEREFORE, Respondent respectfully submits this response to the Notice of Intended Action and Accusation. Respondents, Partell Specialty Pharmacy and Jeffrey Lang, RPH, by and through their counsel of record, Joseph S. Gilbert, Esq. of Joey Gilbert Law, assert that they have consistently met their professional obligations, including full cooperation with the NVBOP's inquiries, transparency regarding their relabeling practices, and adherence to applicable regulations. Respondents further state that during a 2023 visit by Joe Dodge and a male investigator from the NVBOP, they received no indication that their practices were non-compliant or improper. When asked if the pharmacy was compounding these items, Respondents explained the relabeling process, clarifying that the items were not compounded at Partell but were manufactured by the FDA-registered Biopeptek. Respondents' staff also proactively inquired whether there was any issue with this process or if relabeling should be discontinued. The investigator did not suggest any changes or raise any compliance concerns. Respondents remain fully committed to maintaining the highest standards of professional conduct and strict compliance with all relevant laws and regulations.

DATED this 1st day of November, 2024.

JOEY GILBERT LAW

JOSEPH S. GILBERT, ESQ.
Attorney for Respondent,

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 1st day of November, 2024.

PARTELL SPECIALTY PHARMACY

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 1st day of November, 2024.

JEFFREY LANG, RPH

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing **Answer and Notice of Defense** was served upon the following person by electronic transmission and/or by mailing a copy to their last known address, first class mail, postage prepaid for non-registered users, on this 1st day of November, 2024 as follows:

Nevada Board of Pharmacy
985 Damonte Ranch Parkway Suite 206
Reno, NV 89521
Email: TeamBC@pharmacy.nv.gov and gvanderdonck@pharmacy.nv.gov

DATED this 1st day of November, 2024.

JOEY GILBERT LAW

Nancy Vazquez

Nancy Vazquez, Legal Assistant

5E

FILED
OCT 09 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, License No. PH02028, and** **JEFFREY LANG, RPH, Registration No. 17503.** **Respondents.**	**Case Nos. 23-239-PH-S** **23-239-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Partell Specialty Pharmacy (Respondent Pharmacy), because Respondent Pharmacy, at the time of the violations alleged herein, held License No. PH02028 issued by the Board pursuant to NRS 639.230, authorizing the business to operate as a pharmacy. Since June 29, 2007, Respondent Pharmacy has held this license to operate a pharmacy issued by the Board pursuant to NRS 639.230.

2. The Board has personal jurisdiction over Respondent Jeffrey Lang, RPh, (Respondent Lang), because Respondent Lang, at the time of the violations alleged herein, held Certificate of Registration No. 17503 issued by the Board pursuant to NRS 639.127, authorizing Respondent to engage in the practice of pharmacy. Since November 6, 2008, Respondent Lang has held this registration to practice pharmacy issued by the Board pursuant to NRS 639.127.

3. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals and medicines and the regulation of the practice of pharmacy. NRS 639.070.

3. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals and medicines and the regulation of the practice of pharmacy. NRS 639.070.

FACTUAL ALLEGATIONS

4. On or about February 28, 2023, Respondent Pharmacy and Respondent Lang dispensed Nutlin to patient T.S. with direction to mix Nutlin with 2mL DMSO and administer .5mL up to 1mL intramuscularly or IV per administration protocol. This prescription was given prescription number 0090060591.

5. Respondent Pharmacy and Respondent Lang also dispensed Pooled Peptides to patient T.S. with instructions to inject 1mL daily per administration protocol. This prescription was given prescription number 0090060593.

6. Respondent Pharmacy and Respondent Lang purchased the drugs used for these prescriptions from an unlicensed wholesaler/manufacturer called Biopeptek Pharmaceuticals.

7. Neither Nutlin nor Pooled Peptides have a *United States Pharmacopeia – National Formulary* Monograph.

8. Neither Nutlin nor Pooled Peptides have components of drugs approved by the Food and Drug Administration.

9. Both Nutlin and Pooled Peptides were prescribed in this instance to cure, mitigate, and/or treat cancer.

10. Neither Nutlin nor Pooled Peptides are considered investigational drugs under Nevada law.

APPLICABLE LAW

11. The definition of drug includes, "[a]rticles and devices intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals." NRS 639.007(2).

12. "Investigational drug, biological product or device" means a drug, biological product or device that: (1) [h]as successfully completed Phase 1 of a clinical trial; (2) [h]as not been approved by

the United States Food and Drug Administration; and (3) [i]s currently being tested in a clinical trial that has been approved by the United States Food and Drug Administration." NRS 454.690(10)(c).

13. The Board may discipline the holder of a license or registration if the holder of said license or registration, "is guilty of unprofessional conduct or conduct contrary to the public interest." NRS 639.210(4).

14. "Any person, including a wholesaler or manufacturer, who engages in the business of wholesale distribution or furnishing controlled substances, poisons, drugs, devices or appliances that are restricted by federal law to sale by or on the order of a physician to any person located within this State shall obtain a license pursuant to the provisions of this chapter." NRS 639.233(1).

15. "For the purpose of this section, a person is "engaged in the business of furnishing" if the person: (a) Solicits or accepts orders for drugs or devices whose sale in this State is restricted by this chapter or chapter 453 or 454 of NRS; or (b) Receives, stores or ships such drugs or devices." NRS 639.233(2).

16. "The furnishing to a practitioner by a pharmacist or a pharmacy of prescription blanks bearing the name or name and address of any pharmacy is an unearned rebate and an inducement to refer patients to such pharmacist or pharmacy." NRS 639.264(2).

17. Prescription drugs may only be sold if the sale is a bona fide transaction. NRS 639.595(1).

18. A transaction is not a bona fide transaction if the circumstances of the purchase do not reasonably indicate that the drug was purchased from a source prohibited by law. NRS 639.595(5)(a)(2).

19. "A pharmacy or pharmacist is not required to obtain a license as a manufacturer to compound drugs if... the active ingredients used to compound the drugs: (1) [h]ave a monograph in and meet or exceed the standards of the United States Pharmacopoeia - National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670; (2) [h]ave been components of drugs approved by the Food and Drug Administration; or (3) [a]re authorized to be used in pharmacy

compounding pursuant to 21 U.S.C. § 353a(b)(1) or the regulations adopted pursuant thereto." NAC 639.757(1).

20. Unprofessional conduct includes, "[p]erforming any…duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner." NAC 639.945(1)(i).

21. "The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ." NAC 639.945(3).

22. In lieu of a suspension or revocation, the Board may impose a fine of up to $10,000 for each violation committed. NRS 639.255(1)(f) and (3).

COUNT ONE

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Purchasing Drugs from an Unlicensed Wholesaler (Respondent Pharmacy & Respondent Lang)

23. Respondent Pharmacy and Respondent Lang purchased drugs from Biopeptek Pharmaceuticals. Biopeptek Pharmaceuticals was not licensed as a wholesaler in Nevada. NRS 639.233. Nevada law imposes a duty on parties to transactions involving prescription drugs, to engage in bona fide transactions. NRS 639.595(1). By purchasing drugs from an unlicensed wholesaler, Respondent Pharmacy and Respondent Lang purchased drugs from a source prohibited by law. *See* NRS 639.210(4); NRS 639.233; NRS 639.595(5)(a)(2); and NAC 639.945(1)(i).

24. Respondents performed their duties as the holder of a license and registration issued by the Board in an incompetent, unskillful or negligent manner because they purchased drugs from an unlicensed wholesaler, breaching the duty imposed on them by Nevada law. NRS 639.210(4); NRS 639.595(1); NRS 639.595(5)(a)(2); NAC 639.945(1)(i).

25. Having engaged in conduct contrary to the public interest as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

26. Respondent Pharmacy is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT TWO

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Compounding and Dispensing a Product with an Active Ingredient that Does not have a *United States Pharmacopeia – National Formulary* Monograph or Components of Drugs Approved by the Food and Drug Administration (Respondent Pharmacy and Respondent Lang)

27. Respondent Pharmacy and Respondent Lang filled and dispensed Nutlin to patient T.S., listed as prescription number 0090060591. Nutlin does not have a *United States Pharmacopeia – National Formulary* Monograph, nor have its components been approved by the U.S. Food and Drug Administration. NAC 639.757(1).

28. Respondents performed their duties as the holder of a license and registration issued by the Board in an incompetent, unskillful or negligent manner because they filled and dispensed a drug product with an active ingredient that does not have a *United States Pharmacopeia – National Formulary* Monograph, or components that have been approved by the U.S. Food and Drug Administration. NRS 639.210(4); NAC 639.757(1); and NAC 639.945(1)(i).

29. Having engaged in conduct contrary to the public interest as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

30. Respondent Pharmacy is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT THREE

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Compounding and Dispensing a Product that Does not have a *United States Pharmacopeia – National Formulary* Monograph or Components of Drugs Approved by the Food and Drug Administration (Respondent Pharmacy and Respondent Lang)

31. Respondent Pharmacy and Respondent Lang filled and dispensed Pooled Peptides to patient T.S., listed as prescription number 0090060593. Pooled Peptides does not have a *United States Pharmacopeia – National Formulary* Monograph, nor have its components been approved by the U.S. Food and Drug Administration. NAC 639.757(1).

32. Respondents performed their duties as the holder of a license and registration issued by the Board in an incompetent, unskillful or negligent manner because they filled and dispensed a drug product with an active ingredient that does not have a *United States Pharmacopeia – National Formulary* Monograph, or components that have been approved by the U.S. Food and Drug Administration. NRS 639.210(4); NAC 639.757(1); and NAC 639.945(1)(i).

33. Having engaged in conduct contrary to the public interest as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

34. Respondent Pharmacy is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

\\\

\\\

\\\

\\\

\\\

\\\

COUNT FOUR

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner by Furnishing Prescription Blanks Bearing the Name or Name and Address of Respondent Pharmacy
(Respondent Pharmacy and Respondent Lang)

35. Respondent Pharmacy received both prescriptions at issue in this case via prescription blanks that contained the name of Respondent Pharmacy. The furnishing of prescription blanks that contain the name or name and address of a pharmacy is prohibited by Nevada law. NRS 639.264(2).

36. Respondents performed their duties as the holder of a license and registration issued by the Board in an incompetent, unskillful or negligent manner because they furnished or allowed to be furnished on their behalf prescription blanks that contain the name or name and address of their pharmacy. NRS 639.210(4); NRS 639.264(2); and NAC 639.945(1)(i).

37. Having engaged in conduct contrary to the public interest as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

38. Respondent Pharmacy is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent.

DATED this 9th day of October 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JEFFREY LANG, RPH,** **Certificate of Registration No. 17503,** **Respondent.**	**Case No. 23-239-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **gvanderdonck@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 9th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JEFFREY LANG, RPH** **Certificate of Registration No. 17503,** **Respondent.**	**Case No. 23-239-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

JEFFREY LANG, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Jeffrey Lang, RPH
[redacted] Thiros Circle
Las Vegas, NV 89146

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

FILED
NOV 04 2024
NEVADA STATE BOARD OF PHARMACY

JOSEPH S. GILBERT, ESQ.- SBN #. 9033
Joey Gilbert Law
405 Marsh Avenue
Reno, Nevada 89509
Telephone: (775) 284-7700
Attorney for Respondent

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, PARTELL SPECIALTY PHARMACY, License No. PH02028, and JEFFREY LANG, RPH, Registration No. 17503. Respondent.	Case No.: 23-239-PH-S 23-239-RPH-S **ANSWER AND NOTICE OF DEFENSE**

COMES NOW, Respondents, PARTELL SPECIALTY PHARMACY and JEFFREY LANG, RPH (hereinafter referred to as "Respondents") by and through their counsel of record, JOSEPH S. GILBERT, ESQ. of JOEY GILBERT LAW, and answers the Notice of Intended Action and Accusation filed on October 9, 2024 as follows:

JURISDICTION

1. Responding to Paragraph 1 of the Notice of Intended Action and Accusation, Respondent admits that the Nevada State Board of Pharmacy has personal jurisdiction over Respondent Partell Specialty Pharmacy.

2. Responding to Paragraph 2 of the Notice of Intended Action and Accusation, Respondent admits that the Nevada State Board of Pharmacy has personal jurisdiction over Respondent Jeffrey Lang, RPH.

3. Responding to Paragraph 3 of the Notice of Intended Action and Accusation, Respondents admit that the Nevada State Board of Pharmacy has jurisdiction over the subject matter of this accusation.

FACTUAL ALLEGATIONS

4. Responding to Paragraph 4 of the Notice of Intended Action and Accusation, Respondents admit to the allegation.

5. Responding to Paragraph 5 of the Notice of Intended Action and Accusation, Respondents admit to the allegations.

6. Responding to Paragraph 6 of the Notice of Intended Action and Accusation, Respondents admit to the allegation that they purchased Nutlin and Pooled Peptides from Biopeptek Pharmaceuticals. Respondents deny the allegation that they knew Biopeptek was an unlicensed wholesale/manufacturer.

7. This Paragraph contains no allegations. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

8. This Paragraph contains no allegations. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

9. This Paragraph contains no allegations. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

10. This Paragraph contains no allegations. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

APPLICABLE LAW

11. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

12. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

13. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

14. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

15. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

16. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

17. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

18. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

19. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

20. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

21. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

22. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

COUNT ONE

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Purchasing Drugs from an Unlicensed Wholesaler (Respondent Pharmacy & Respondent Lang)

23. Responding to Paragraph 23 of the Notice of Intended Action and Accusation, Respondents admit to purchasing drugs from Biopeptek. Respondents deny all remaining allegations.

24. Responding to Paragraph 24 of the Notice of Intended Action and Accusation, Respondents deny performing their duties in an incompetent, unskillful, or negligent manner under NRS 639.210(4); NRS 639.595(1); NRS 639.595(5)(a)(2); NAC 639.945(1)(i).

25. Responding to Paragraph 25 of the Notice of Intended Action and Accusation, Respondents deny that they engaged in conduct contrary to the public interest and deny that they are subject to discipline by the Board.

26. Responding to Paragraph 26 of the Notice of Intended Action and Accusation, Respondent admits to the allegation.

COUNT TWO

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Compounding and Dispensing a Product with an Active Ingredient that does not have a United States Pharmacopeia-National Formulary Monograph or Components of Drugs Approved by the Food and Drug Administration

(Respondent Pharmacy and Respondent Lang)

27. Responding to Paragraph 27 of the Notice of Intended Action and Accusation, Respondents admit solely to dispensing Nutlin to patient T.S., listed as prescription number 0090060591. Accordingly, Respondents deny all remaining allegations herein.

28. Responding to Paragraph 28 of the Notice of Intended Action and Accusation, Respondents deny performing their duties in an incompetent, unskillful, or negligent manner under NRS 639.210(4); NAC 639.757(1); NAC 639.945(1)(i).

29. Responding to Paragraph 29 of the Notice of Intended Action and Accusation, Respondents deny that they engaged in conduct contrary to the public interest and deny that they are subject to discipline by the Board.

30. Responding to Paragraph 30 of the Notice of Intended Action and Accusation, Respondents admit the allegations.

COUNT THREE

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Compounding and Dispensing a Product with an Active Ingredient that does not have a United States Pharmacopeia-National Formulary Monograph or Components of Drugs Approved by the Food and Drug Administration

(Respondent Pharmacy and Respondent Lang)

31. Responding to Paragraph 31 of the Notice of Intended Action and Accusation, Respondents admit solely to dispensing Nutlin to patient T.S., listed as prescription number 0090060591. Accordingly, Respondents deny all remaining allegations herein.

32. Responding to Paragraph 32 of the Notice of Intended Action and Accusation, Respondents deny performing their duties in an incompetent, unskillful, or negligent manner under NRS 639.210(4); NAC 639.757(1); NAC 639.945(1)(i).

33. Responding to Paragraph 33 of the Notice of Intended Action and Accusation, Respondents deny that they engaged in conduct contrary to the public interest and deny that they are subject to discipline by the Board.

34. Responding to Paragraph 34 of the Notice of Intended Action and Accusation, Respondents admit the allegations.

COUNT FOUR

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner by Furnishing Prescription Blanks Bearing the Name or Name and Address of Respondent Pharmacy (Respondent Pharmacy and Respondent Lang)

35. Responding to Paragraph 35 of the Notice of Intended Action and Accusation, Respondent Pharmacy denies furnishing prescription blanks in violation of Nevada law (NRS 639.264(2)).

36. Responding to Paragraph 36 of the Notice of Intended Action and Accusation, Respondents deny performing their duties in an incompetent, unskillful, or negligent manner under NRS 639.210(4); NAC 639.757(1); NAC 639.945(1)(i).

37. Responding to Paragraph 37 of the Notice of Intended Action and Accusation, Respondents deny that they engaged in conduct contrary to the public interest and deny that they are subject to discipline by the Board.

38. Responding to Paragraph 38 of the Notice of Intended Action and Accusation, Respondents admit the allegations.

WHEREFORE, Respondent respectfully submits this response to the Notice of Intended Action and Accusation. Respondents, Partell Specialty Pharmacy and Jeffrey Lang, RPH, by and

WHEREFORE, Respondent respectfully submits this response to the Notice of Intended Action and Accusation. Respondents, Partell Specialty Pharmacy and Jeffrey Lang, RPH, by and through their counsel of record, Joseph S. Gilbert, Esq. of Joey Gilbert Law, assert that they have consistently met their professional obligations, including full cooperation with the NVBOP's inquiries, transparency regarding their relabeling practices, and adherence to applicable regulations. Respondents further state that during a 2023 visit by Joe Dodge and a male investigator from the NVBOP, they received no indication that their practices were non-compliant or improper. When asked if the pharmacy was compounding these items, Respondents explained the relabeling process, clarifying that the items were not compounded at Partell but were manufactured by the FDA-registered Biopeptek. Respondents' staff also proactively inquired whether there was any issue with this process or if relabeling should be discontinued. The investigator did not suggest any changes or raise any compliance concerns. Respondents remain fully committed to maintaining the highest standards of professional conduct and strict compliance with all relevant laws and regulations.

DATED this 1st day of November, 2024.

JOEY GILBERT LAW

JOSEPH S. GILBERT, ESQ.
Attorney for Respondent,

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 1st day of November, 2024.

PARTELL SPECIALTY PHARMACY

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 1st day of November, 2024.

JEFFREY LANG, RPH

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing **Answer and Notice of Defense** was served upon the following person by electronic transmission and/or by mailing a copy to their last known address, first class mail, postage prepaid for non-registered users, on this 1st day of November, 2024 as follows:

Nevada Board of Pharmacy
985 Damonte Ranch Parkway Suite 206
Reno, NV 89521
Email: TeamBC@pharmacy.nv.gov and gvanderdonck@pharmacy.nv.gov

DATED this 1st day of November, 2024.

JOEY GILBERT LAW

Nancy Vazquez

Nancy Vazquez, Legal Assistant

5F

FILED
MAR 22 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW DIKIN, DO,** **Certificate of Registration No. CS26423,** **Respondent.**	**CASE NO. 23-482-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Matthew Dikin, DO, held a Nevada controlled substance registration, Certificate of Registration No. CS26423, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about October 4, 2023, the Nevada State Board of Osteopathic Medicine (NSBOM) entered an order in Case No. OT2301003, summarily suspending Respondent's NSBOM License No. DO2227 to practice osteopathic medicine for cause on the basis that the health, safety of welfare of the public and any patient served by the Respondent was at risk of imminent or continued harm.

3. The suspension of Respondent's NSBOM License No. DO2227 operated as an immediate suspension of his Certificate of Registration No. CS26423 with the Board pursuant to NRS 639.2107.

4. The NSBOM Case No. OT2301003 was based in pertinent part on criminal charges initiated against Respondent in December 2020 and December 2022.

5. Respondent failed to disclose to the Board the 2020 criminal charges on his 2022 biennial renewal application for Certificate of Registration No. CS26423.

6. Respondent failed to disclose to the Board the suspension of his NSBOM License No. DO2227.

7. Respondent issued a controlled substance prescription in Nevada on October 23, 2023, prescription no. 474042, after the suspension of his Certificate of Registration No. CS26423.

8. From November 29, 2021 to November 29, 2023 Respondent issued thirty-seven controlled substance prescriptions in Nevada utilizing his U.S. Drug Enforcement Administration (DEA) Certificate of Registration No. BD5774042 for the State of Tennessee.

9. On or about December 5, 2023, the NSBOM entered an order in Case No. OT2301003, lifting the summary suspension of Respondent's NSBOM License No. DO2227 to practice osteopathic medicine; however, Respondent has failed to petition the Board for reinstatement of his Certificate of Registration No. CS26423 pursuant to NRS 639.2565.

APPLICABLE LAW

10. A practitioner must hold a license to practice his or her profession in this State and be registered with both the DEA and the Board to possess, administer, prescribe and/or otherwise dispense any controlled substance. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

11. Each controlled substance prescription issued in Nevada must include the practitioner's DEA registration number for this State. 21 CFR § 1306.05(a); NRS 453.385; NAC 453.440(1)(k).

12. When an individual practitioner practices in more than one state, he or she must obtain a separate DEA registration for each state; a DEA registration based on a state license cannot authorize controlled substance prescribing outside that state. 21 CFR § 1301.12(b)(3); *see also* 71 Fed. Reg. 69478 (December 1, 2006).

13. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

14. It is unlawful for a person knowingly or intentionally to omit any material information from any application for registration under NRS Chapter 453. NRS 453.331(1)(e); NRS 639.281(1).

15. The surrender, revocation or a suspension that has not been stayed of any certificate, license or registration of a practitioner, as defined in NRS 453.126, NRS 454.00958 or NRS 639.0125, by a licensing board or the Drug Enforcement Administration operates as an immediate suspension of a certificate, license, registration or permit issued by the Board pursuant to NRS chapters 453, 454 or 639 to possess, administer, prescribe or dispense drugs. NRS 639.2107.

16. The holder of any certificate, license or permit issued by the Board shall report to the Executive Secretary any administrative action taken against the holder by any professional licensing board or any state or federal agency not later than 30 days after the final disposition of the administrative action and provide any documentation of the administrative action requested by the Executive Secretary. NAC 639.229(1)(b).

17. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

18. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration constitutes unprofessional conduct and conduct contrary to the public interest pursuant to NAC

639.945(1)(k) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

19. The Board may suspend or revoke a controlled substance registration upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violations of Federal Controlled Substances Act

20. By issuing controlled substance prescription no. 474042 after the suspension of his Certificate of Registration No. CS26423, and by issuing thirty-seven controlled substance prescriptions in Nevada utilizing his DEA Certificate of Registration No. BD5774042 for Tennessee, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 CFR § 1306.03(a)(1), 21 CFR § 1306.05(a) and/or 21 CFR § 1301.12(b)(3), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(11).

COUNT TWO

Violations of State Controlled Substances Act

21. By issuing controlled substance prescription no. 474042 after the suspension of his Certificate of Registration No. CS26423, and by issuing thirty-seven controlled substance prescriptions in Nevada utilizing his DEA Certificate of Registration No. BD5774042 for Tennessee, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 453.385, NRS 639.100(1), NRS 639.235(1), NRS 639.2813(1) and/or NAC 453.440(1)(k), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(12).

COUNT THREE
Furnishing False Material Information to Board

22. By failing to disclose to the Board the 2020 criminal charges on his 2022 biennial renewal application for Certificate of Registration No. CS26423, Respondent violated NRS 453.331(l)(e) and NRS 639.281(1), and is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1) and/or NRS 639.210(12).

COUNT FOUR
Failure to Disclose Suspension of Nevada Osteopathic Medicine License

23. By failing to disclose to the Board the suspension of his NSBOM License No. DO2227, Respondent violated NAC 639.229(1)(b), and is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1) and/or NRS 639.210(12).

COUNT FIVE
Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

24. By failing to disclose to the Board the 2020 criminal charges on his 2022 biennial renewal application for Certificate of Registration No. CS26423, by failing to disclose to the Board the suspension of his NSBOM License No. DO2227, by issuing controlled substance prescription no. 474042 after the suspension of his Certificate of Registration No. CS26423, and by issuing thirty-seven controlled substance prescriptions in Nevada utilizing his DEA Certificate of Registration No. BD5774042 for Tennessee, Respondent has performed his duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

COUNT SIX
Unprofessional Conduct – Prescribing on Suspended Registration

25. By issuing controlled substance prescriptions after the suspension of his Certificate of Registration No. CS26423, Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(k) and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT SEVEN

Commission of Acts that Render Registration Inconsistent with the Public Interest

26. By failing to disclose to the Board the 2020 criminal charges on his 2022 biennial renewal application for Certificate of Registration No. CS26423, by failing to disclose to the Board the suspension of his NSBOM License No. DO2227, by issuing controlled substance prescription no. 474042 after the suspension of his Certificate of Registration No. CS26423, and by issuing thirty-seven controlled substance prescriptions in Nevada utilizing his DEA Certificate of Registration No. BD5774042 for Tennessee, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 22nd day of MARCH 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW DIKIN, DO,** **Certificate of Registration No. CS26423,** **Respondent.**	**CASE NO. 23-482-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 22nd day of MARCH 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW DIKIN, DO,** **Certificate of Registration No. CS26423,** **Respondent.**	**CASE NO. 23-482-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

MATTHEW DIKIN, DO

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of March 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Matthew Dikin, DO
[redacted]W. Sunset Rd.
Las Vegas, NV 89148

DARLENE NASES
BOARD COORDINATOR

FILED
SEP 21 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW DIKIN, DO,** **Certificate of Registration No. CS26423** **Respondent.**	**Case No. 23-482-CS-S** **ANSWER AND NOTICE OF DEFENSE OF RESPONDENT TO ACCUSATION**

Respondent Mathew Dikin, D.O. hereby files with the Nevada State Board of Pharmacy ("Board"), his Answer and Notice of Defense to the Notice of Intended Action and Accusation ("Accusation") filed on March 22, 2024.

ANSWER TO ACCUSATION

Jurisdiction

Dr. Dikin agrees that the Board has jurisdiction in this matter as set forth in Paragraph 1 of the Accusation. Dr. Dikin further answers the Factual Allegations set forth in the Accusation as follows:

Factual Allegations: Paragraphs 2-9

Paragraph 2: Dr. Dikin acknowledges the factual allegations set forth in Paragraph 2.

Paragraph 3: Dr. Dikin is without sufficient personal knowledge to respond to the factual assertions set forth in Paragraph 3.

Paragraph 4: Dr. Dikin denies the factual allegations set forth in Paragraph 4that the summary suspension of his license was based in part on criminal charges initiated against him in 2020 and 2022; rather it was Dr. Dikin's unintentional failure to disclose his interaction with law enforcement that was partially at issue in the summary suspension.

Paragraph 5: Dr. Dikin acknowledges that he failed to disclose his 2020 misdemeanor criminal charges on his 2022 Board of Pharmacy renewal application. Dr. Dikin utilized a third party to submit the renewal and acknowledges he did not fully vet the renewal application.

Paragraph 6: Dr. Dikin acknowledges that he did not advise the Board of Pharmacy of the summary suspension of his NSBOM license as he was unaware of the requirement to do so and was not advised by his then legal counsel of the requirement.

Paragraph 7: Dr. Dikin acknowledges that he did issue a controlled substance prescription in October 2023 but asserts that he was unaware at the time that his Nevada controlled substance registration was suspended.

Paragraph 8: Dr. Dikin does not have sufficient personal knowledge to substantively respond to the factual allegations set forth in Paragraph 8 but asserts that he was informed by the locums agency that he was working for during the period in question that they had taken care of the legal requirements for him to prescribe in Nevada.

Paragraph 9: Dr. Dikin acknowledges that the NSBOM lifted the summary suspension of his license on December 5, 2023. Dr. Dikin was unaware of the requirement to petition for the reinstatement of his Nevada controlled substance registration and notes that his registration shows as active on the Board of Pharmacy's website.

Applicable Law: Paragraphs 10-19

Dr. Dikin acknowledges that paragraphs 10 through 19 generally reflect the applicable laws.

Counts: Paragraphs 20-26

Paragraph 20/Count I: Dr. Dikin denies the allegations contained in Paragraph 20.

Paragraph 21/Count II: Dr. Dikin denies the allegations in paragraph 21.

Paragraph 22/Count III: Dr. Dikin denies the allegations in paragraph 22.

Paragraph 23/Count IV: Dr. Dikin denies the allegations in paragraph 23

Paragraph 24/Count V: Dr. Dikin denies the allegations contained in Paragraph 24.

Paragraph 25/Count VI: Dr. Dikin denies the allegation contained in Paragraph 25.

Paragraph 26/Count VII: Dr. Dikin denies the allegation contained in Paragraph 26.

NOTICE OF DEFENSE/MITIGATING INFORMATION

During the relevant periods of time at issue in the Accusation, Dr. Dikin was working primarily as a locums physician in various states. The locums agency with whom Dr. Dikin was employed took care of most administrative tasks on his behalf, as related to his locums assignments; Dr. Dikin assumed this to also include the transfer of his DEA registration to the appropriate state.

Additionally, Dr. Dikin was utilizing a third party private secretary to assist in license renewals and submission of required disclosures to his various boards.

Unfortunately, Dr. Dikin later learned that these parties had not properly handled these matters on his behalf. Dr. Dikin fully understands that it is ultimately his responsibility to ensure that disclosures are properly made to his various licensing entities and that he holds a DEA registration in each state that he practices. Dr. Dikin has taken proactive steps to ensure that going

forward he ensures that all information provided on renewal applications is accurate and any required disclosures are timely provided.

Respectfully submitted this 20th day of September, 2024.

Lyn E. Beggs, Esq.
Attorney for Respondent Matthew Dikin, D.O.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW DIKIN, DO,** **Certificate of Registration No. CS26423,** **Respondent.**	**CASE NO. 23-482-CS-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent Matthew Dikin, DO, Certificate of Registration No. CS26423, by and through counsel**,** Lyn E. Beggs, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. The Board has jurisdiction over Respondent and this matter.

2. On or about March 22, 2024, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

3. On or about September 20, 2024, Respondent filed an Answer and Notice of Defense to the Accusation.

4. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

5. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives his rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

7. Respondent admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the Accusation, *to wit*:

A. By issuing controlled substance prescription no. 474042 after the suspension of his Certificate of Registration No. CS26423, and by issuing thirty-seven controlled substance prescriptions in Nevada utilizing his DEA Certificate of Registration No. BD5774042 for Tennessee, Respondent violated 21 U.S.C. § 822(a)(2), 21 U.S.C. 823(f), 21 U.S.C. 841(a), 21 U.S.C. § 842(a), 21 CFR § 1306.03(a)(1), 21 CFR §1306.05(a), CFR §1301.12(b)(3), NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 453.385, NRS 639.100(1), NRS 639.235(1), NRS 639.28130) and/or NAC 453.440(1)(k);

B. By failing to disclose to the Board the 2020 criminal charges on his 2022 biennial renewal application for Certificate of Registration No. CS26423, Respondent violated NRS 453.331 and NRS 639.281(1), and by failing to disclose to the Board the suspension of his NSBOM License No. D02227, Respondent violated NAC 639.229(l)(b); and

C. By his actions Respondent has engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and (k) and committed acts that render his registration inconsistent with the public interest pursuant to NRS 453.236(1)(e).

8. Those violations are plead with particularity in the Accusation, and are grounds for action pursuant to NRS 453.236(1)(e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.255.

9. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties. The certificate of registration of Respondent Matthew Dikin, DO, Certificate of Registration No. CS26423, is revoked pursuant to NRS 453.241(1)(b). The revocation is stayed, and Respondent is placed on probation for a period of three (3) years pursuant to NRS 639.255(1)(b) subject to the following conditions:

A. Respondent shall accept this Stipulation and Order as a public reprimand regarding his duties and responsibilities as a practitioner under NRS Chapters 453 and 639;

B. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of One Thousand Dollars ($1,000.00) for each of the seven counts in the Accusation, for a total of Seven Thousand Dollars ($7,000.00), by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by April 1, 2025;

C. Pursuant to NRS 622.400, Respondent shall pay Three Thousand Dollars ($3,000.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by April 1, 2025; and

D. Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.

Upon successful completion of probation, Respondent's Certificate of Registration No. 26423 will be fully restored.

10. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may lift the stay and immediately revoke Respondent's Certificate of Registration No. 26423 and impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

11. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on December 4, 2024. Respondent will appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

12. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

13. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

14. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 8th day of NOVEMBER 2024

MATTHEW DIKIN, DO
Certificate of Registration No. CS26423

Signed this 11th day of NOVEMBER 2024

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this 11 day of November 2024

LYN E. BEGGS, ESQ.
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Matthew Dikin, DO, Certificate of Registration No. CS26423, in Case No. 23-482-CS-S and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of December 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

5G

FILED
NOV 0 8 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DEEFLAT PHARMACY,** **Pharmacy License No. PH04171, and** **v.** **THU THI PHUONG VO, RPH,** **Certificate of Registration No. 18661,** **Respondents.**	**CASE NOS. 24-282-PH-O** **24-282-RPH-O** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these respondents because at the time of the events alleged herein, Respondent Thu Thi Phuong Vo (Respondent Vo), Certificate of Registration No. 18661, was a pharmacist registered with the Board, and Respondent DeeFlat Pharmacy (Respondent Pharmacy), Pharmacy License No. PH04171, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Respondent DeeFlat Pharmacy, located at 2580 Highway 95, #106, Bullhead City, AZ 86442, was previously issued a citation and fine on December 11, 2019, pursuant to NRS 639.2895(2) for engaging in unlicensed operation in Nevada by dispensing prescription drugs to patients in Nevada from May-August 2019.

3. Respondent Pharmacy was subsequently issued Pharmacy License No. PH04171 on December 19, 2019.

4. Respondent Pharmacy is owned by Tuan Quoc Dinh, who also serves as the managing pharmacist. Tuan Quoc Dinh is a registered pharmacist in Arizona, but not registered in Nevada.

5. Respondent Vo is employed as a pharmacist at Respondent Pharmacy.

6. Respondent failed to disclose on its 2019 Nevada pharmacy license application that the pharmacy would not engage in sterile or non-sterile compounding.

7. A pharmacy that will engage in compounding drug products must disclose same to the Board and undergo an inspection to ensure compliance with all applicable laws and standards relevant to compounding.

8. Respondent Pharmacy did not perform sterile compounding in a sterile environment.

9. Respondent Pharmacy nevertheless engaged in the sterile compounding of popular weight loss drugs, including Semaglutide and Tirzepatide.

10. Respondent Pharmacy dispensed either Semaglutide or Tirzepatide to at least five (5) Nevada patients.

11. Respondent Pharmacy also sold Semaglutide and Tirzepatide to a Nevada licensed pharmacy called Laughlin Pharmacy and Wellness Center.

12. Respondent Pharmacy and Laughlin Pharmacy and Wellness Center are not under common ownership.

13. Respondent Pharmacy did not have policies and procedures or standard operating procedures in place regarding sterile compounding.

14. Respondent Pharmacy did not ensure the competency and proficiency of staff pertaining to compounded drug products it was engaged in dispensing.

15. Respondent Pharmacy did not have a clean room or other similar type of sterile environment.

16. Respondent Pharmacy did not provide an ISO Class 5 environment consistent with Nevada law or the *United States Pharmacopeia – National Formulary*, 2008 edition.

17. Respondent Pharmacy did not properly monitor temperature and humidity in the spaces used for sterile compounding.

18. Respondent Pharmacy did not have a buffer area that provided physical separation from compounding areas.

19. Respondent Pharmacy failed to clean non-sterile measuring, mixing, and purifying devices thoroughly with pyrogen-free or depyrogenated sterile water and then thoroughly drain and dry them immediately before use for high-risk sterile compounding.

20. Respondent Pharmacy did not perform pre-sterilization procedures in an ISO Class 8 environment or better.

21. Respondent Pharmacy did not conduct hand sanitizing and gowning outside of a buffer area.

22. Respondent Pharmacy did not have compounding personal don clean non-shedding gowns.

23. Respondent Pharmacy did not remove debris from underneath fingernails using a nail cleaner under warm running water.

24. Respondent Pharmacy did not ensure compounding personnel engaged in proper hand hygiene.

25. Respondent Pharmacy does not have written policies and procedures or standard operating procedures on the cleaning and disinfecting of the direct and contiguous compounding areas.

26. Respondent Pharmacy failed to maintain documentation of cleaning procedures.

27. Respondent failed to conduct environmental sampling of CSPs.

28. Respondent Pharmacy failed to maintain records of the date and time of preparation of a CSP.

29. Respondent Pharmacy failed to maintain records of the complete formula of the CSP.

30. Respondent Pharmacy failed to maintain records of the container used and the number of units prepared for a CSP.

31. Respondent Pharmacy failed to maintain records of the criteria used to determine the beyond-use-date of CSPs.

32. Respondent Pharmacy indicated on sterile compounded prescriptions drawn up into insulin use one syringes in a non-sterile environment that the beyond-use date for that product was one-year.

33. Respondent Pharmacy failed to maintain records of the performance of quality control procedures.

34. Respondent Pharmacy failed to create and complete master worksheets and preparation worksheets for batch compounding.

35. Respondent Pharmacy failed to properly label immediate use sterile compounded prescriptions properly.

36. Respondent Pharmacy failed to properly label compounded prescriptions, creating labels that do not indicate drug strength, a valid NDC, or a valid "discard after" date.

37. Respondent Pharmacy failed to include instructions regarding refrigeration on labels.

38. Respondent Pharmacy failed to maintain compounding records for preparations.

39. When asked by an Arizona Board of Pharmacy Inspection where the drugs in the syringes came from, staff at Respondent Pharmacy would not disclose the answer.

40. Respondent Pharmacy labeled a prescription for a specific patient as "Ozempic," but the medication inside the syringes was not consistent with what the actual manufacturer packaging looked like.

41. Respondent Pharmacy billed a patient's insurance for name brand Ozempic, but did not dispense a name brand product.

42. Respondent Pharmacy had supplies used for sterile compounding sitting in and around a sink soaking and drying off like dirty dishes.

43. Respondent Pharmacy was dispensing drugs to patients from manufacturers labeled "Research Use Only," for therapeutic use.

44. Respondent Pharmacy owner lied to an Arizona Board of Pharmacy Inspector about whether any compounding took place at Respondent Pharmacy.

45. Compounding records were maintained for only three (3) dispensations, out of more than one-thousand products dispensed.

APPLICABLE LAW

46. In Nevada, the Board may discipline the holder of any registration if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

47. Unprofessional conduct includes, "[m]anufacturing, compounding, selling, dispensing or permitting to be manufactured, compounded, sold or dispensed substandard drugs or preparations." NAC 639.945(1)(a).

48. Unprofessional conduct includes, "[p]erforming or in any way being a party to any fraudulent or deceitful practice or transaction." NAC 639.945(1)(h).

49. Unprofessional conduct includes, "[p]erforming any duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

50. The Board may discipline the holder of any registration if the holder or applicant, "[h]as obtained any certificate, certification, license or permit by the filing of an application, or

any record, affidavit or other information in support thereof, which is false or fraudulent." NRS 639.210(10).

51. The Board may discipline the holder of any registration if the holder or applicant, "[h]as violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs." NRS 639.210(11).

52. The Board may discipline the holder of any registration if the holder or applicant, "[h]as violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy committed by the holder of a certificate, license, registration or permit." NRS 639.210(12).

53. The Board may discipline the holder of any registration if the holder or applicant, "[h]as failed to maintain and make available to a state or federal officer any records in accordance with the provisions of this chapter or chapter 453 or 454 of NRS." NRS 639.210(17).

54. Retail pharmacies must keep records of dangerous drugs dispensed to patients for at least two years. They must also keep invoices of drugs dangerous drugs purchased. NRS 454.286.

55. It is unlawful to compound drugs into Nevada without holding the appropriate license and complying with all regulations adopted by the Board. NRS 639.100(1).

56. To be licensed as an out-of-state pharmacy in Nevada, a pharmacy must, "[p]rovide the following information to the Board:... [t]he name of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board." NRS 639.2328(2)(d)(4).

57. "Any person, including a wholesaler or manufacturer, who engages in the business of wholesale distribution or furnishing controlled substances, poisons, drugs, devices or appliances that are restricted by federal law to sale by or on the order of a physician to any person located within this State shall obtain a license pursuant to the provisions of this chapter." NRS 639.233.

58. "'Wholesale distribution' means the distribution of drugs to persons other than consumers or patients, but does not include: [s]ales within a company; ...[t]he sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug: ...[b]etween health care facilities or pharmacies that are under common control." NRS 639.0155.

59. "If a generic drug or interchangeable biological product is substituted for a drug prescribed by brand name or biological product prescribed, the pharmacist or practitioner shall [n]ote the name of the manufacturer, packer or distributor of the drug or biological product actually dispensed on the prescription; and [i]ndicate the substitution by writing or typing on the label the words "substituted for," or substantially similar language, following the generic name and preceding the brand name of the drug, or following the name of the interchangeable biological product and preceding the brand name of the prescribed biological product, as applicable, unless, at the time the initial substitution of the generic drug or interchangeable biological product for a drug prescribed by brand name or biological product prescribed is made, the person for whom the drug or interchangeable biological product is dispensed elects not to have such an indication written or typed on the label. An election to indicate or not to indicate a substitution on the label pursuant to this subsection applies to both the fill and each refill of the same prescription." NRS 639.2587.

60. A pharmacy must include information regarding refrigeration on the label of a prescription if it will improve therapy by drugs. *See* NRS 639.266(1) and (2).

61. "Biologicals and other drugs must be kept refrigerated if the requirement is stated on the manufacturer's label." NAC 639.650(4).

62. All prescriptions filled by any pharmacy must be dispensed in a container to which is affixed a label or other device which clearly shows: the date; the name, address and prescription serial number of the practitioner who filled the prescription; the names of the prescribing practitioner and of the person for whom prescribed; the number of dosage units; the symptom or purpose for which the drug is prescribed; specific directions for use given by the prescribing practitioner; the expiration date of the effectiveness of the drug or medicine dispensed, if that information is included on the original label of the manufacturer of that drug or medicine. If the expiration date specified by the manufacturer is not less than 1 year after the date of dispensing, the practitioner may use a date that is 1 year after the date of dispensing as the expiration date; the proprietary or generic name of the drug or medicine as written by the prescribing practitioner; and the strength of the drug or medicine. NRS 639.2801.

63. "A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products shall ensure that each pharmacist and pharmaceutical technician engaged in the practice of compounding drug products [i]s competent and proficient in compounding the drug products that the pharmacist or pharmaceutical technician will be authorized and expected to compound; [c]omplies with the provisions of NAC 639.661 to 639.690, inclusive, concerning the drug products which the pharmacist or pharmaceutical technician compounds and the compounded drug products which the pharmacist or pharmaceutical technician dispenses at the pharmacy; and [r]eceives, on an ongoing basis, sufficient training to maintain that competency and proficiency." NAC 639.67013(1).

64. "A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products shall evaluate the competency and proficiency of a pharmacist and pharmaceutical technician." NAC 639.67013(2).

65. "A pharmacy engaged in the practice of compounding drug products shall establish and maintain written policies and procedures for compounding drug products to ensure that each final compounded drug product has the identity, strength, quality and purity which the

compounded drug product is purported or represented to have. Such policies and procedures must include, without limitation: [t]he processes used by the pharmacy to compound drug products; [t]he equipment used by the pharmacy to compound drug products; [e]nsuring that the actual weights and measures of each component are within plus or minus 5 percent of the theoretical weights and measures required for the drug products compounded by the pharmacy; [t]racking, recalling and destroying the drug products compounded by the pharmacy, which must include a requirement that the pharmacy ensure that all drug products which could have been compounded with a particular component be located, recalled and destroyed; and [i]dentifying the drug products or components of drug products that will be considered hazardous drugs." NAC 639.67015(1)(a).

66. A pharmacy engaged in the practice of compounding drug products shall also establish, "[c]ontrol procedures for monitoring each final compounded drug product and validating the compounding processes that may be responsible for causing variability in the final compounded drug product." NAC 639.67015(1)(b) and (c).

67. "Except as otherwise provided in NAC 639.67059, a pharmacy engaged in the practice of compounding sterile compounded drug products shall provide an ISO Class 5 environment." NAC 639.6705(1).

68. "Except as otherwise provided in NAC 639.67059, a pharmacy engaged in the practice of compounding sterile compounded drug products shall test the air in each of its controlled environments to ensure that the environments attain the air quality required by the provisions of NAC 639.661 to 639.690, inclusive, for an ISO Class 5, ISO Class 7 or ISO Class 8 environment, as applicable." NAC 639.67051(1).

69. "For all sterile compounded drug products compounded by a pharmacy, other than an institutional pharmacy, and for all sterile drug products for parenteral nutrition and sterile antineoplastic drug products compounded by an institutional pharmacy, a pharmacist shall make a record verifying the accuracy of each sterile compounded drug product." NAC 639.67055(1).

70. "A compounded drug product is a high-risk sterile compounded drug product if: [t]he compounded drug product is required to be sterile for its effective administration; [t]he sterile compounded drug product is contaminated with or at a high risk of becoming contaminated with infectious microorganisms; and [o]ne or more of the following conditions are present: [o]ne or more of the ingredients or devices used in the compounding process are nonsterile; or [o]ne or more of the ingredients or devices used in the compounding process were sterile but were exposed or are suspected of having been exposed for more than 1 hour to an air quality inferior to an ISO Class 5 environment." NAC 639.67067(1).

71. "A sterile compounded drug product is an immediate-use sterile compounded drug product if: [t]he compounded drug product is intended only for the purpose of emergency care or immediate care of a patient; [t]he compounding of the drug product occurs in an environment other than an ISO Class 5 environment and the compounding process consists of simple aseptic measuring and transfer manipulations performed with not more than six sterile nonhazardous commercial drug products and diagnostic radiopharmaceutical drug products, excluding infusion solutions or diluents; [t]he preparation procedure occurs continuously without delays or interruptions and does not exceed 1 hour unless a period longer than 1 hour is required for the reconstitution of the compounded drug product; [d]uring compounding and before the administration of the compounded drug product, no part of the drug product or critical surfaces and ingredients of the drug product is directly exposed to contact contamination, including, without limitation, human touch, cosmetic flakes or particulates, blood or other bodily substances of a person or nonsterile inanimate sources; and [e]xcept as otherwise provided in paragraph (c), the administration of the compounded drug product begins not later than 1 hour after the start of the preparation of the compounded drug product and the compounded drug product is fully administered as soon as practicable but not longer than 24 hours after the administration of the compounded drug product began or the compounded drug product is disposed of promptly and safely." NAC 639.67073(1).

72. "If an immediate-use sterile compounded drug product is not immediately administered by direct injection into a patient by the person who compounded it, the compounded drug product must bear a label which includes, without limitation: [t]he name and, if the patient has an identification number, the identification number of the patient; [t]he name and amount of each ingredient of the compounded drug product; [t]he initials of the person who compounded the compounded drug product; and [t]he exact date and time of expiration of the compounded drug product." NAC 639.67073(2).

73. "Except as otherwise provided..., a pharmacy engaged in the practice of compounding and dispensing sterile compounded drug products shall require each pharmacist and pharmaceutical technician who compounds sterile compounded drug products to pass a media fill test which must be conducted in the manner provided by chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670, and which must be commensurate to the highest level of risk of compounding sterile compounded drug products that the pharmacist or pharmaceutical technician will be authorized by the pharmacy to perform." NAC 639.67053(1).

74. "A drug or device shall be deemed to be adulterated— If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission

tomography compounding standards and the official monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 379e(a) of this title, or (B) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of section 379e(a) of this title; or (5) if it is a new animal drug which is unsafe within the meaning of section 360b of this title; or (6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of section 360b of this title." 21 U.S. Code § 351(a)(1).

75. "A drug or device shall be deemed to be adulterated— If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label.

Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia." 21 U.S. Code § 351(b)(1).

76. "A drug or device shall be deemed to be misbranded—If its labeling is false or misleading in any particular. Health care economic information provided to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs or devices for coverage or reimbursement, shall not be considered to be false or misleading under this paragraph if the health care economic information relates to an indication approved under section 355, 360(k), 360c(f)(2), or 360e of this title or section 262 of title 42 for such drug or device, is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug or device under section 355, 360(k), 360c(f)(2), or 360e of this title or section 262 of title 42." 21 U.S. Code § 352(a)(1).

77. "A drug or device shall be deemed to be misbranded—If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary." 21 U.S. Code § 352(b).

78. Pursuant to NRS 585.520(1) and (2) it is unlawful to sell or dispense an adulterated or misbranded drug (as defined in NRS 585.380, NRS 585.400, NRS 585.410, NRS 585.420 and/or NRS 585.460). Pursuant to NRS 454.351(1) it is unlawful to sell or dispense any drug which may

not be lawfully introduced into interstate commerce under the Federal Food, Drug, and Cosmetic Act.

COUNT ONE
Filing of a False Application – (Respondent Pharmacy)

79. Respondent Pharmacy submitted a Pharmacy application to the Board on or around September 16, 2019. On the submitted application, Respondent Pharmacy selected that they would not be engaged in sterile compounding. Despite Respondent Pharmacy indicating that they would not be engaged in sterile compounding, Respondent Pharmacy dispensed sterile compounded prescriptions into Nevada.

80. Based upon the facts alleged above, Respondent Pharmacy filed an application with the Board that was false. NRS 639.210(17). Respondent Pharmacy submitted a false application because Respondent Pharmacy engaged in compounding without disclosing so to the Board. Respondent Pharmacy had ample opportunity to contact the Board and disclose that they were engaged in sterile compounding, yet the failed to do so.

81. Having filed an application with the Board that is false as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(17); NRS 639.255; NAC 639.945; and NAC 639.955.

COUNT TWO
Unprofessional Conduct - Performing or in Any Way Being a Party to Any Fraudulent or Deceitful Practice or Transaction (Respondent Pharmacy)

82. Respondent Pharmacy was inspected by an Arizona Board of Pharmacy Compliance Officer on May 15, 2023. Respondent Pharmacy's owner was present during the inspection. During the inspection, Respondent Pharmacy's owner and staff lied multiple times to the Arizona Board of Pharmacy Compliance Officer. Namely, Respondent Pharmacy's owner and

staff lied about whether they were engaged in compounding and where compounding materials located in the pharmacy by the Compliance Officer came from.

83. Because of these lies, Respondent Pharmacy engaged in fraudulent and deceitful practices. NRS 639.210(4); NAC 639.945(1)(h). Respondent Pharmacy engaged in fraudulent and deceitful practices in an attempt to mask the fact that they were engaged in unauthorized sterile compounding. NRS 639.210(4); NAC 639.945(1)(h).

84. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

COUNT THREE

Unprofessional Conduct - Manufacturing, Compounding, Selling, Dispensing or Permitting to be Manufactured, Compounded, Sold or Dispensed Substandard Drugs or Preparations (Respondent Pharmacy and Respondent Vo)

85. Respondent Pharmacy compounded, sold, and dispensed sterile compounded drugs into the State of Nevada despite not possessing or maintaining the appropriate supplies and conditions to engage in sterile compounding. Respondent compounded, sold, and dispensed five total sterile compounded prescriptions into Nevada, one of which being Tirzepatide Cyanoco 10MG/ML for patient D.P., listed as prescription no. 00638587. Because Respondent Pharmacy did not possess the proper environment or supplies to engage in sterile compounding, any compounded sterile preparations (CSPs) dispensed into Nevada by Respondent Pharmacy are substandard. NRS 639.210(4); NAC 639.945(1)(a).

86. Having compounded, sold, and dispensed substandard drugs or preparations into Nevada, as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

87. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FOUR

Unprofessional Conduct - Manufacturing, Compounding, Selling, Dispensing or Permitting to be Manufactured, Compounded, Sold or Dispensed Substandard Drugs or Preparations (Respondent Pharmacy and Respondent Vo)

88. Respondent Pharmacy compounded, sold, and dispensed sterile compounded drugs into the State of Nevada despite not possessing or maintaining the appropriate supplies and conditions to engage in sterile compounding. Respondent compounded, sold, and dispensed five total sterile compounded prescriptions into Nevada, one of which being Tirzepatide Cyanoco 10MG/ML for patient T.S., listed as prescription no. 00645075. Because Respondent Pharmacy did not possess the proper environment or supplies to engage in sterile compounding, any compounded sterile preparations (CSPs) dispensed into Nevada by Respondent Pharmacy are substandard. NRS 639.210(4); NAC 639.945(1)(a).

89. Having compounded, sold, and dispensed substandard drugs or preparations into Nevada, as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

90. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FIVE

Unprofessional Conduct - Manufacturing, Compounding, Selling, Dispensing or Permitting to be Manufactured, Compounded, Sold or Dispensed Substandard Drugs or Preparations (Respondent Pharmacy and Respondent Vo)

91. Respondent Pharmacy compounded, sold, and dispensed sterile compounded drugs into the State of Nevada despite not possessing or maintaining the appropriate supplies and conditions to engage in sterile compounding. Respondent compounded, sold, and dispensed five total sterile compounded prescriptions into Nevada, one of which being Tirzepatide Cyanoco 10MG/ML for patient S.M., listed as prescription no. 00647772. Because Respondent Pharmacy did not possess the proper environment or supplies to engage in sterile compounding, any

compounded sterile preparations (CSPs) dispensed into Nevada by Respondent Pharmacy are substandard. NRS 639.210(4); NAC 639.945(1)(a).

92. Having compounded, sold, and dispensed substandard drugs or preparations into Nevada, as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

93. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT SIX

Unprofessional Conduct - Manufacturing, Compounding, Selling, Dispensing or Permitting to be Manufactured, Compounded, Sold or Dispensed Substandard Drugs or Preparations (Respondent Pharmacy and Respondent Vo)

94. Respondent Pharmacy compounded, sold, and dispensed sterile compounded drugs into the State of Nevada despite not possessing or maintaining the appropriate supplies and conditions to engage in sterile compounding. Respondent compounded, sold, and dispensed five total sterile compounded prescriptions into Nevada, one of which being Tirzepatide Cyanoco 10MG/ML for patient T.S., listed as prescription no. 00649160. Because Respondent Pharmacy did not possess the proper environment or supplies to engage in sterile compounding, any compounded sterile preparations (CSPs) dispensed into Nevada by Respondent Pharmacy are substandard. NRS 639.210(4); NAC 639.945(1)(a).

95. Having compounded, sold, and dispensed substandard drugs or preparations into Nevada, as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

96. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT SEVEN

Unprofessional Conduct - Manufacturing, Compounding, Selling, Dispensing or Permitting to be Manufactured, Compounded, Sold or Dispensed Substandard Drugs or Preparations (Respondent Pharmacy and Respondent Vo)

97. Respondent Pharmacy compounded, sold, and dispensed sterile compounded drugs into the State of Nevada despite not possessing or maintaining the appropriate supplies and conditions to engage in sterile compounding. Respondent compounded, sold, and dispensed five total sterile compounded prescriptions into Nevada, one of which being Tirzepatide Cyanoco 10MG/ML for patient T.S., listed as prescription no. 00649160 (sold and dispensed on a different date than the dispensation listed in Count Six). Because Respondent Pharmacy did not possess the proper environment or supplies to engage in sterile compounding, any compounded sterile preparations (CSPs) dispensed into Nevada by Respondent Pharmacy are substandard. NRS 639.210(4); NAC 639.945(1)(a).

98. Having compounded, sold, and dispensed substandard drugs or preparations into Nevada, as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

99. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT EIGHT

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

100. Respondent Pharmacy engaged in sterile compounding and sold and dispensed prescription no. 00638587 to patient D.P. despite not maintaining a sterile environment as required by Nevada law. NRS 639.210(4); NAC 639.670(c); and NAC 639.945(1)(i).

101. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent performed its

duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it sold and dispensed a CSP despite not possessing and sterile environment. NRS 639.210(4); NAC 639.670(c); and NAC 639.945(1)(i).

102. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

103. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT NINE

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

104. Respondent Pharmacy engaged in sterile compounding and sold and dispensed prescription no. 00645075 to patient T.R. despite not maintaining a sterile environment as required by Nevada law. NRS 639.210(4); NAC 639.670(c); and NAC 639.945(1)(i).

105. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it sold and dispensed a CSP despite not possessing and sterile environment. NRS 639.210(4); NAC 639.670(c); and NAC 639.945(1)(i).

106. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

107. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TEN

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

108. Respondent Pharmacy engaged in sterile compounding and sold and dispensed prescription no. 00647772 to patient S.M. despite not maintaining a sterile environment as required by Nevada law. NRS 639.210(4); NAC 639.670(c); and NAC 639.945(1)(i).

109. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it sold and dispensed a CSP despite not possessing and sterile environment. NRS 639.210(4); NAC 639.670(c); and NAC 639.945(1)(i).

110. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

111. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT ELEVEN

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

112. Respondent Pharmacy engaged in sterile compounding and sold and dispensed prescription no. 00649160 to patient T.R. despite not maintaining a sterile environment as required by Nevada law. NRS 639.210(4); NAC 639.670(c); and NAC 639.945(1)(i).

113. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent

manner because it sold and dispensed a CSP despite not possessing and sterile environment. NRS 639.210(4); NAC 639.670(c); and NAC 639.945(1)(i).

114. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

115. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWELVE

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

116. Respondent Pharmacy engaged in sterile compounding and sold and dispensed prescription no. 00649160 to patient T.R. (dispensed on a different day than the prescription listed in Count Eleven) despite not maintaining a sterile environment as required by Nevada law. NRS 639.210(4); NAC 639.670(c); and NAC 639.945(1)(i).

117. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it sold and dispensed a CSP despite not possessing and sterile environment. NRS 639.210(4); NAC 639.670(c); and NAC 639.945(1)(i).

118. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

119. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTEEN

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

120. Respondent Pharmacy failed to implement Standard Operating Procedures (SOPs) or Policies and Procedures in regard to CSPs as required by Nevada law. NAC 639.670(c); NAC 639.67015(1)(a).

121. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to have in place SOPs or Policies and Procedures as required by Nevada law. NRS 639.210(4); NAC 639.670(c); 639.67015(1)(a); and NAC 639.945(1)(i).

122. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

123. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FOURTEEN

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy)

124. It is the duty of a compounding pharmacy to ensure that all staff engaged in compounding are competent to do so. NAC 639.67013(1) and (2). It is also the responsibility of the pharmacy to ensure that each pharmacist and pharmaceutical technician who compounds sterile compounded drug products to pass a media fill test which must be conducted in the manner provided by chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670, and which must be commensurate to the highest level of risk of compounding sterile compounded drug products that the pharmacist or pharmaceutical technician will be authorized by the pharmacy to perform." NAC 639.67053(1).

Respondent Pharmacy failed to ensure that its staff engaged in sterile compounding was competent to do so and failed to ensure that staff members passed the media fill test as required by Nevada law. NAC 639.67013(1) and (2); NAC 639.67053(1).

125. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to ensure that its staff engaged in sterile compounded were competent to do so and it failed to ensure staff took and passed a media fill test. NRS 639.210(4); NAC 639.67013(1) and (2); 639.67053(1); and NAC 639.945(1)(i).

126. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

COUNT FIFTEEN

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

127. Respondent Pharmacy failed to provide the required ISO class environment necessary for engaging in sterile compounding laid out in the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670 and Nevada law. NAC 639.670(1)(c); NAC 639.6705(1); and NAC 639.67073(1).

128. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to provide an ISO class environment consistent with the requirements of Nevada law. NRS 639.210(4); NAC 639.670(1)(c); NAC 639.6705(1); NAC 639.67073(1); and NAC 639.945(1)(i).

129. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

130. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT SIXTEEN

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

131. Respondent Pharmacy failed to maintain and test to ensure maintenance of proper pressure differentials in areas where sterile compounding is performed as required in the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

132. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to maintain and test to ensure continued maintenance of proper pressure differentials in areas where sterile compounding was performed. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

133. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

134. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT SEVENTEEN

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

135. Respondent Pharmacy failed to maintain a buffer area or space that provides a physical separation from compounding areas as required in the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

136. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to maintain a buffer area or space that provides a physical separation from compounding areas. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

137. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

138. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT EIGHTEEN

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

139. Respondent Pharmacy failed to ensure that non-sterile measuring, mixing, and purifying devices were cleaned properly, pursuant to the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

140. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy

performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to ensure that non-sterile measuring, mixing, and purifying devices were properly cleaned. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

141. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

142. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT NINETEEN

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

143. Respondent Pharmacy failed to engage in proper pre-sterilization procedures for high-risk CSPs as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c); NAC 639.67067(1).

144. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to engage in proper pre-sterilization procedures for high-risk sterile compounding. NRS 639.210(4); NAC 639.670(1)(c); NAC 639.67067(1); and NAC 639.945(1)(i).

145. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

146. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWENTY

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

147. Respondent Pharmacy failed to ensure staff engaged in sterile compounding followed hand cleaning and hand hygiene procedures as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

148. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to ensure staff engaged in sterile compounding followed proper hand cleaning and hand hygiene procedures. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

149. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

150. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWENTY-ONE

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

151. Respondent Pharmacy failed to ensure that sterile compounding staff were donning gowns in the ante-area, prior to entering the buffer area when engaging in sterile compounding as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

152. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in

an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to ensure that sterile compounding staff were donning gowns in the ante-area, prior to entering the buffer area when engaging in sterile compounding. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

153. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

154. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWENTY-TWO

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

155. Respondent Pharmacy failed to ensure sterile compounding staff was removing debris in fingernails using a nail cleaner under warm running water as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

156. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to ensure that sterile compounding staff was removing debris in fingernails using a nail cleaner under warm running water. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

157. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

158. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWENTY-THREE

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

159. Respondent Pharmacy failed to document cleaning procedures in sterile compounding areas as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

160. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to document cleaning procedures in sterile compounding areas. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

161. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

162. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWENTY-FOUR

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

163. Respondent Pharmacy failed to perform environmental sampling of CSPs as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

164. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy

performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to perform environmental testing of CSPs. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

165. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

166. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWENTY-FIVE

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

167. Respondent Pharmacy failed to maintain records of the date and time of preparation of CSPs as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

168. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to maintain records of the date and time of preparation of CSPs. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

169. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

170. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWENTY-SIX

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

171. Respondent Pharmacy failed to maintain records of complete formulas of CSPs as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c). Respondent Pharmacy staff was unable to disclose to the Arizona Board of Pharmacy where certain parts of CSPs made in their pharmacy came from or what they were.

172. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to maintain records of complete formulas of CSPs. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

173. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

174. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWENTY-SEVEN

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

175. Respondent Pharmacy failed to maintain records of the container used and the number of units prepared for a CSP as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

176. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in

an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to maintain records of the container used and the number of units prepared for a CSP. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

177. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

178. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWENTY-EIGHT

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

179. Respondent Pharmacy failed to maintain records of the criteria used to determine beyond-use dates as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

180. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to maintain records of the container used and the number of units prepared for a CSP. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

181. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

182. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWENTY-NINE

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

183. Respondent Pharmacy improperly labeled "Semaglutide" prescriptions drawn up into insulin use only syringes as having a beyond-use dates of one year. Respondent Pharmacy did not base this determination on any drug specific scientific evidence, data, documentation, or literature as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

184. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it improperly labeled a sterile medication drawn up into insulin use only syringes as having a beyond-use date of one year without any drug specific scientific evidence, data, documentation, or literature to back the determination up. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

185. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

186. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTY

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

187. Respondent Pharmacy failed to maintain records of the performance of quality control procedures as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

188. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to maintain records of quality control procedures. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

189. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

190. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTY-ONE

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

191. Respondent Pharmacy and its sterile compounding staff failed to create and complete master worksheets and preparation worksheets for batch compounding as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

192. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it and its staff failed to create and complete master worksheets and preparation worksheets for batch compounding. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

193. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

194. A pharmacy/pharmacy owner is liable for all acts and omissions of the people they employ. NAC 639.945(3).

195. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTY-TWO

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

196. Respondent Pharmacy sold and dispensed prescriptions that were immediate use sterile compounds and failed to properly label those prescriptions as immediate use sterile compounds. NAC 639.670(1)(c); NAC 639.67073(2). Respondent Pharmacy compounded prescription drugs that should have been compounded in a sterile environment in an environment that was not sterile nor was it the proper ISO class environment to not require the CSP to be an immediate use CSP. NAC 639.67073(1). Respondent Pharmacy nevertheless failed to properly label the CSP as an immediate use CSP and include all labeling requirements consistent with Nevada law. 639.670(1)(c); NAC 639.67073(1) and (2).

197. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to properly label immediate use sterile compounds as such. NRS 639.210(4); NAC 639.670(1)(c); NAC 639.67073(1) and (2); and NAC 639.945(1)(i).

198. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

199. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTY-THREE

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

200. Every pharmacy must affix a label to each prescription that clearly shows the strength of the drug or medicine and the expiration date. NRS 639.2801. Respondent Pharmacy dispensed prescriptions with labels that did not include this information.

201. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it dispensed prescriptions with labels that did not clearly show the strength of the drug or the expiration date. NRS 639.210(4); NRS 639.2801; and NAC 639.945(1)(i).

202. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

203. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTY-FOUR

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

204. Respondent Pharmacy failed to include information regarding refrigeration requirements of prescriptions despite a manufacturer requirement that Semaglutide be refrigerated. Drugs must be kept refrigerated if the requirement is stated on the manufacturer's label. NAC 639.650(4). Respondent Pharmacy had a duty to notify patients of the refrigeration requirement because there is a duty to communicate all matters that will improve therapy by drugs, including

by using labels to convey important information. NRS 639.266(1) and (2). Respondent Pharmacy failed to communicate matters that would improve therapy by drugs.

205. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to include refrigeration information on the label when it would have improved therapy by drugs. NRS 639.210(4); NRS 639.266(1) and (2); NAC 639.650(4); and NAC 639.945(1)(i).

206. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

207. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTY-FIVE

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

208. Respondent Pharmacy failed to maintain records of compounded sterile preparations. NRS 454.286; NAC 639.670(1)(c); NAC 639.67055(1). An inspection by the Arizona Board of Pharmacy revealed that compounding records were maintained for only three dispensations, out of more than one-thousand products dispensed.

209. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to keep records of CSPs. NRS 639.210(4); NRS 454.286; NAC 639.670(1)(c); NAC 639.67055(1); and NAC 639.945(1)(i).

210. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

211. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTY-SIX

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

212. Respondent Pharmacy incorrectly labeled a non-brand name drug as a brand-named drug. NRS 639.2587; NRS 639.2801. When a pharmacy substitutes a non-name brand drug for a name brand drug, they must disclose so on the prescription label. NRS 639.2587. Additionally, pharmacies must include the correct name of the drug product on the label. NRS 639.2801. Respondent Pharmacy dispensed a non-brand name drug but labeled it "Ozempic."

213. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it labeled a non-brand name drug as the brand name drug. NRS 639.210(4); NRS 639.2587; NRS 639.2801; and NAC 639.945(1)(i).

214. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

215. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTY-SEVEN

Violations of the Federal Food Drug & Cosmetic Act – Dispensing Adulterated and/or Misbranded Drugs into Nevada (Respondent Pharmacy and Respondent Vo)

216. Respondent Pharmacy dispensed Tirzepatide Cyanoco 10MG/ML to patient D.P. under prescription number 00638587. The dispensed drug was compounded by Respondent Pharmacy in conditions not suitable for sterile compounding. If a drug has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, it is deemed an adulterated drug. 21 U.S. Code § 351(a)(1). Additionally, a drug will be deemed a misbranded drug if its labeling is false or misleading. 21 U.S. Code § 352(a)(1).

217. Respondent Pharmacy compounded, sold, and dispensed five (5) prescriptions to Nevada patients, including the one listed above under improper and unsanitary conditions. Because of this, the drugs are deemed to be adulterated and/or misbranded. 21 U.S. Code § 351(a)(1); 21 U.S. Code § 352(a)(1). Selling and dispensing adulterated and/or misbranded drugs is a violation of the Federal Food Drug & Cosmetic Act. The Board may discipline a Respondent for violations of that Act. NRS 639.210(11).

218. Having dispensed adulterated and/or misbranded drugs into Nevada as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(11); NRS 639.255; NAC 639.945; and NAC 639.955.

219. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTY-EIGHT

Violations of the Federal Food Drug & Cosmetic Act – Dispensing Adulterated and/or Misbranded Drugs into Nevada (Respondent Pharmacy and Respondent Vo)

220. Respondent Pharmacy dispensed Tirzepatide Cyanoco 10MG/ML to patient T.R. under prescription number 00645075. The dispensed drug was compounded by Respondent Pharmacy in conditions not suitable for sterile compounding. If a drug has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby

it may have been rendered injurious to health, it is deemed an adulterated drug. 21 U.S. Code § 351(a)(1). Additionally, a drug will be deemed a misbranded drug if its labeling is false or misleading. 21 U.S. Code § 352(a)(1).

221. Respondent Pharmacy compounded, sold, and dispensed five (5) prescriptions to Nevada patients, including the one listed above under improper and unsanitary conditions. Because of this, the drugs are deemed to be adulterated and/or misbranded. 21 U.S. Code § 351(a)(1); 21 U.S. Code § 352(a)(1). Selling and dispensing adulterated and/or misbranded drugs is a violation of the Federal Food Drug & Cosmetic Act. The Board may discipline a Respondent for violations of that Act. NRS 639.210(11).

222. Having dispensed adulterated and/or misbranded drugs into Nevada as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(11); NRS 639.255; NAC 639.945; and NAC 639.955.

223. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTY-NINE

Violations of the Federal Food Drug & Cosmetic Act – Dispensing Adulterated and/or Misbranded Drugs into Nevada (Respondent Pharmacy and Respondent Vo)

224. Respondent Pharmacy dispensed Tirzepatide Cyanoco 10MG/ML to patient S.M. under prescription number 00647772. The dispensed drug was compounded by Respondent Pharmacy in conditions not suitable for sterile compounding. If a drug has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, it is deemed an adulterated drug. 21 U.S. Code § 351(a)(1). Additionally, a drug will be deemed a misbranded drug if its labeling is false or misleading. 21 U.S. Code § 352(a)(1).

225. Respondent Pharmacy compounded, sold, and dispensed five (5) prescriptions to Nevada patients, including the one listed above under improper and unsanitary conditions. Because

of this, the drugs are deemed to be adulterated and/or misbranded. 21 U.S. Code § 351(a)(1); 21 U.S. Code § 352(a)(1). Selling and dispensing adulterated and/or misbranded drugs is a violation of the Federal Food Drug & Cosmetic Act. The Board may discipline a Respondent for violations of that Act. NRS 639.210(11).

226. Having dispensed adulterated and/or misbranded drugs into Nevada as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(11); NRS 639.255; NAC 639.945; and NAC 639.955.

227. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FOURTY

Violations of the Federal Food Drug & Cosmetic Act – Dispensing Adulterated and/or Misbranded Drugs into Nevada (Respondent Pharmacy and Respondent Vo)

228. Respondent Pharmacy dispensed Tirzepatide Cyanoco 10MG/ML to patient T.R. under prescription number 00649160. The dispensed drug was compounded by Respondent Pharmacy in conditions not suitable for sterile compounding. If a drug has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, it is deemed an adulterated drug. 21 U.S. Code § 351(a)(1). Additionally, a drug will be deemed a misbranded drug if its labeling is false or misleading. 21 U.S. Code § 352(a)(1).

229. Respondent Pharmacy compounded, sold, and dispensed five (5) prescriptions to Nevada patients, including the one listed above under improper and unsanitary conditions. Because of this, the drugs are deemed to be adulterated and/or misbranded. 21 U.S. Code § 351(a)(1); 21 U.S. Code § 352(a)(1). Selling and dispensing adulterated and/or misbranded drugs is a violation of the Federal Food Drug & Cosmetic Act. The Board may discipline a Respondent for violations of that Act. NRS 639.210(11).

230. Having dispensed adulterated and/or misbranded drugs into Nevada as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(11); NRS 639.255; NAC 639.945; and NAC 639.955.

231. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FOURTY-ONE

Violations of the Federal Food Drug & Cosmetic Act – Dispensing Adulterated and/or Misbranded Drugs into Nevada (Respondent Pharmacy and Respondent Vo)

232. Respondent Pharmacy dispensed Tirzepatide Cyanoco 10MG/ML to patient T.R. under prescription number 00649160 (dispensed on a different day than the previous Count). The dispensed drug was compounded by Respondent Pharmacy in conditions not suitable for sterile compounding. If a drug has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, it is deemed an adulterated drug. 21 U.S. Code § 351(a)(1). Additionally, a drug will be deemed a misbranded drug if its labeling is false or misleading. 21 U.S. Code § 352(a)(1).

233. Respondent Pharmacy compounded, sold, and dispensed five (5) prescriptions to Nevada patients, including the one listed above under improper and unsanitary conditions. Because of this, the drugs are deemed to be adulterated and/or misbranded. 21 U.S. Code § 351(a)(1); 21 U.S. Code § 352(a)(1). Selling and dispensing adulterated and/or misbranded drugs is a violation of the Federal Food Drug & Cosmetic Act. The Board may discipline a Respondent for violations of that Act. NRS 639.210(11).

234. Having dispensed adulterated and/or misbranded drugs into Nevada as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(11); NRS 639.255; NAC 639.945; and NAC 639.955.

235. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FOURTY-TWO

Violations of State Law – Dispensing Compounded Drugs into Nevada without the Authority to do so (Respondent Pharmacy and Respondent Vo)

236. No person or entity may compound, sell, and dispense prescription drugs in this state without obtaining the proper license to do so. NRS 639.100(1). The Board has specific licenses related to compounding pharmacies. Obtaining these licenses comes with more detailed inspections and scrutiny due to the significant number of rules necessary to engage in compounding safely. NAC 639.670(1)(c). When Respondent Pharmacy applied to the Board for a Nevada pharmacy license, they disclosed to the Board that they would not be engaged in compounding. At no point did Respondent Pharmacy ever notify the Board that they would be or were engaged in compounding.

237. Despite this, Respondent Pharmacy compounded, sold, and dispensed five (5) prescriptions to Nevada patients, including Tirzepatide Cyanoco 10MG/ML to patient D.P. under prescription number 00638587. Respondent Pharmacy never possessed the correct license to engage in compounding. Because of this, Respondent Pharmacy violated NRS 639.100(1). Respondent Pharmacy is subject to discipline for this violation pursuant to NRS 639.210(12).

238. Having violated state law as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(12); NRS 639.255; NAC 639.945; and NAC 639.955.

239. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FOURTY-THREE

Violations of State Law - Dispensing Compounded Drugs into Nevada without the Authority to do so (Respondent Pharmacy and Respondent Vo)

240. No person or entity may compound, sell, and dispense prescription drugs in this state without obtaining the proper license to do so. NRS 639.100(1). The Board has specific licenses related to compounding pharmacies. Obtaining these licenses comes with more detailed inspections and scrutiny due to the significant number of rules necessary to engage in

compounding safely. NAC 639.670(1)(c). When Respondent Pharmacy applied to the Board for a Nevada pharmacy license, they disclosed to the Board that they would not be engaged in compounding. At no point did Respondent Pharmacy ever notify the Board that they would be or were engaged in compounding.

241. Despite this, Respondent Pharmacy compounded, sold, and dispensed five (5) prescriptions to Nevada patients, including Tirzepatide Cyanoco 10MG/ML to patient T.R. under prescription number 00645075. Respondent Pharmacy never possessed the correct license to engage in compounding. Because of this, Respondent Pharmacy violated NRS 639.100(1). Respondent Pharmacy is subject to discipline for this violation pursuant to NRS 639.210(12).

242. Having violated state law as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(12); NRS 639.255; NAC 639.945; and NAC 639.955.

243. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FOURTY-FOUR

Violations of State Law - Dispensing Compounded Drugs into Nevada without the Authority to do so (Respondent Pharmacy and Respondent Vo)

244. No person or entity may compound, sell, and dispense prescription drugs in this state without obtaining the proper license to do so. NRS 639.100(1). The Board has specific licenses related to compounding pharmacies. Obtaining these licenses comes with more detailed inspections and scrutiny due to the significant number of rules necessary to engage in compounding safely. NAC 639.670(1)(c). When Respondent Pharmacy applied to the Board for a Nevada pharmacy license, they disclosed to the Board that they would not be engaged in compounding. At no point did Respondent Pharmacy ever notify the Board that they would be or were engaged in compounding.

245. Despite this, Respondent Pharmacy compounded, sold, and dispensed five (5) prescriptions to Nevada patients, including Tirzepatide Cyanoco 10MG/ML to patient S.M. under

prescription number 00647772. Respondent Pharmacy never possessed the correct license to engage in compounding. Because of this, Respondent Pharmacy violated NRS 639.100(1). Respondent Pharmacy is subject to discipline for this violation pursuant to NRS 639.210(12).

246. Having violated state law as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(12); NRS 639.255; NAC 639.945; and NAC 639.955.

247. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FOURTY-FIVE

Violations of State Law - Dispensing Compounded Drugs into Nevada without the Authority to do so (Respondent Pharmacy and Respondent Vo)

248. No person or entity may compound, sell, and dispense prescription drugs in this state without obtaining the proper license to do so. NRS 639.100(1). The Board has specific licenses related to compounding pharmacies. Obtaining these licenses comes with more detailed inspections and scrutiny due to the significant number of rules necessary to engage in compounding safely. NAC 639.670(1)(c). When Respondent Pharmacy applied to the Board for a Nevada pharmacy license, they disclosed to the Board that they would not be engaged in compounding. At no point did Respondent Pharmacy ever notify the Board that they would be or were engaged in compounding.

249. Despite this, Respondent Pharmacy compounded, sold, and dispensed five (5) prescriptions to Nevada patients, including Tirzepatide Cyanoco 10MG/ML to patient T.R. under prescription number 00649160. Respondent Pharmacy never possessed the correct license to engage in compounding. Because of this, Respondent Pharmacy violated NRS 639.100(1). Respondent Pharmacy is subject to discipline for this violation pursuant to NRS 639.210(12).

250. Having violated state law as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(12); NRS 639.255; NAC 639.945; and NAC 639.955.

251. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FOURTY-SIX

Violations of State Law - Dispensing Compounded Drugs into Nevada without the Authority to do so (Respondent Pharmacy and Respondent Vo)

252. No person or entity may compound, sell, and dispense prescription drugs in this state without obtaining the proper license to do so. NRS 639.100(1). The Board has specific licenses related to compounding pharmacies. Obtaining these licenses comes with more detailed inspections and scrutiny due to the significant number of rules necessary to engage in compounding safely. NAC 639.670(1)(c). When Respondent Pharmacy applied to the Board for a Nevada pharmacy license, they disclosed to the Board that they would not be engaged in compounding. At no point did Respondent Pharmacy ever notify the Board that they would be or were engaged in compounding.

253. Despite this, Respondent Pharmacy compounded, sold, and dispensed five (5) prescriptions to Nevada patients, including Tirzepatide Cyanoco 10MG/ML to patient T.R. under prescription number 00649160 (dispensed on a different date than the previous Count). Respondent Pharmacy never possessed the correct license to engage in compounding. Because of this, Respondent Pharmacy violated NRS 639.100(1). Respondent Pharmacy is subject to discipline for this violation pursuant to NRS 639.210(12).

254. Having violated state law as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(12); NRS 639.255; NAC 639.945; and NAC 639.955.

255. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FOURTY-SEVEN

Unprofessional Conduct – Unlicensed Activity – Engaging in Wholesaling of Prescription Drugs without the Proper License to do so (Respondent Pharmacy and Respondent Vo)

256. Any person or entity engaged in wholesale distribution of drugs, restricted to sale by or on the order of a physician in this state must obtain a wholesale license. NRS 639.233. Respondent Pharmacy engaged in wholesale distribution when it shipped compounded medications to another pharmacy in Nevada that it did not share common ownership with. NRS 639.0155. Additionally, Respondent Pharmacy is not a registered outsourcing facility under Section 503B of the Federal Food Drug & Cosmetic Act. In order for Respondent Pharmacy to engage in wholesale distribution, they need to apply for and obtain a wholesale license from the Board. NRS 639.233.

257. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it labeled a non-brand name drug as the brand name drug. NRS 639.210(4); NRS 639.233; NRS 639.0155; and NAC 639.945(1)(i).

258. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

259. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FORTY-EIGHT

Violations of State Law –Dispensing Adulterated and/or Misbranded Drugs into Nevada (Respondent Pharmacy and Respondent Vo)

260. By dispensing adulterated and/or misbranded sterile drug products into Nevada as alleged herein, respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.351(1), NRS 585.520(1) and (2) and/or NRS 639.100(1), and are

therefore subject to discipline pursuant to NRS 639.210(12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificate of registration of these respondents.

DATED this 6th day of NOVEMBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DEEFLAT PHARMACY,** **License No. PH04171,** **Respondent.**	**Case No. 24-282-PH-O** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **bkandt@pharmacyu.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file-stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 6th day of NOVEMBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DEEFLAT PHARMACY,** **License No. PH04171,** **Respondent.**	**Case No. 24-282-PH-O** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

AUTHORIZED REPRESENTATIVE FOR DEEFLAT PHARMACY

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of Nov. 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

DeeFlat Pharmacy
2580 Highway 95 #106
Bullhead City, AZ 86442

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

5H

FILED
NOV 0 8 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DEEFLAT PHARMACY,** **Pharmacy License No. PH04171, and** **v.** **THU THI PHUONG VO, RPH,** **Certificate of Registration No. 18661,** **Respondents.**	**CASE NOS. 24-282-PH-O** **24-282-RPH-O** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these respondents because at the time of the events alleged herein, Respondent Thu Thi Phuong Vo (Respondent Vo), Certificate of Registration No. 18661, was a pharmacist registered with the Board, and Respondent DeeFlat Pharmacy (Respondent Pharmacy), Pharmacy License No. PH04171, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Respondent DeeFlat Pharmacy, located at 2580 Highway 95, #106, Bullhead City, AZ 86442, was previously issued a citation and fine on December 11, 2019, pursuant to NRS 639.2895(2) for engaging in unlicensed operation in Nevada by dispensing prescription drugs to patients in Nevada from May-August 2019.

3. Respondent Pharmacy was subsequently issued Pharmacy License No. PH04171 on December 19, 2019.

4. Respondent Pharmacy is owned by Tuan Quoc Dinh, who also serves as the managing pharmacist. Tuan Quoc Dinh is a registered pharmacist in Arizona, but not registered in Nevada.

5. Respondent Vo is employed as a pharmacist at Respondent Pharmacy.

6. Respondent failed to disclose on its 2019 Nevada pharmacy license application that the pharmacy would not engage in sterile or non-sterile compounding.

7. A pharmacy that will engage in compounding drug products must disclose same to the Board and undergo an inspection to ensure compliance with all applicable laws and standards relevant to compounding.

8. Respondent Pharmacy did not perform sterile compounding in a sterile environment.

9. Respondent Pharmacy nevertheless engaged in the sterile compounding of popular weight loss drugs, including Semaglutide and Tirzepatide.

10. Respondent Pharmacy dispensed either Semaglutide or Tirzepatide to at least five (5) Nevada patients.

11. Respondent Pharmacy also sold Semaglutide and Tirzepatide to a Nevada licensed pharmacy called Laughlin Pharmacy and Wellness Center.

12. Respondent Pharmacy and Laughlin Pharmacy and Wellness Center are not under common ownership.

13. Respondent Pharmacy did not have policies and procedures or standard operating procedures in place regarding sterile compounding.

14. Respondent Pharmacy did not ensure the competency and proficiency of staff pertaining to compounded drug products it was engaged in dispensing.

15. Respondent Pharmacy did not have a clean room or other similar type of sterile environment.

16. Respondent Pharmacy did not provide an ISO Class 5 environment consistent with Nevada law or the *United States Pharmacopeia – National Formulary*, 2008 edition.

17. Respondent Pharmacy did not properly monitor temperature and humidity in the spaces used for sterile compounding.

18. Respondent Pharmacy did not have a buffer area that provided physical separation from compounding areas.

19. Respondent Pharmacy failed to clean non-sterile measuring, mixing, and purifying devices thoroughly with pyrogen-free or depyrogenated sterile water and then thoroughly drain and dry them immediately before use for high-risk sterile compounding.

20. Respondent Pharmacy did not perform pre-sterilization procedures in an ISO Class 8 environment or better.

21. Respondent Pharmacy did not conduct hand sanitizing and gowning outside of a buffer area.

22. Respondent Pharmacy did not have compounding personal don clean non-shedding gowns.

23. Respondent Pharmacy did not remove debris from underneath fingernails using a nail cleaner under warm running water.

24. Respondent Pharmacy did not ensure compounding personnel engaged in proper hand hygiene.

25. Respondent Pharmacy does not have written policies and procedures or standard operating procedures on the cleaning and disinfecting of the direct and contiguous compounding areas.

26. Respondent Pharmacy failed to maintain documentation of cleaning procedures.

27. Respondent failed to conduct environmental sampling of CSPs.

28. Respondent Pharmacy failed to maintain records of the date and time of preparation of a CSP.

29. Respondent Pharmacy failed to maintain records of the complete formula of the CSP.

30. Respondent Pharmacy failed to maintain records of the container used and the number of units prepared for a CSP.

31. Respondent Pharmacy failed to maintain records of the criteria used to determine the beyond-use-date of CSPs.

32. Respondent Pharmacy indicated on sterile compounded prescriptions drawn up into insulin use one syringes in a non-sterile environment that the beyond-use date for that product was one-year.

33. Respondent Pharmacy failed to maintain records of the performance of quality control procedures.

34. Respondent Pharmacy failed to create and complete master worksheets and preparation worksheets for batch compounding.

35. Respondent Pharmacy failed to properly label immediate use sterile compounded prescriptions properly.

36. Respondent Pharmacy failed to properly label compounded prescriptions, creating labels that do not indicate drug strength, a valid NDC, or a valid "discard after" date.

37. Respondent Pharmacy failed to include instructions regarding refrigeration on labels.

38. Respondent Pharmacy failed to maintain compounding records for preparations.

39. When asked by an Arizona Board of Pharmacy Inspection where the drugs in the syringes came from, staff at Respondent Pharmacy would not disclose the answer.

40. Respondent Pharmacy labeled a prescription for a specific patient as "Ozempic," but the medication inside the syringes was not consistent with what the actual manufacturer packaging looked like.

41. Respondent Pharmacy billed a patient's insurance for name brand Ozempic, but did not dispense a name brand product.

42. Respondent Pharmacy had supplies used for sterile compounding sitting in and around a sink soaking and drying off like dirty dishes.

43. Respondent Pharmacy was dispensing drugs to patients from manufacturers labeled "Research Use Only," for therapeutic use.

44. Respondent Pharmacy owner lied to an Arizona Board of Pharmacy Inspector about whether any compounding took place at Respondent Pharmacy.

45. Compounding records were maintained for only three (3) dispensations, out of more than one-thousand products dispensed.

APPLICABLE LAW

46. In Nevada, the Board may discipline the holder of any registration if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

47. Unprofessional conduct includes, "[m]anufacturing, compounding, selling, dispensing or permitting to be manufactured, compounded, sold or dispensed substandard drugs or preparations." NAC 639.945(1)(a).

48. Unprofessional conduct includes, "[p]erforming or in any way being a party to any fraudulent or deceitful practice or transaction." NAC 639.945(1)(h).

49. Unprofessional conduct includes, "[p]erforming any duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

50. The Board may discipline the holder of any registration if the holder or applicant, "[h]as obtained any certificate, certification, license or permit by the filing of an application, or

any record, affidavit or other information in support thereof, which is false or fraudulent." NRS 639.210(10).

51. The Board may discipline the holder of any registration if the holder or applicant, "[h]as violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs." NRS 639.210(11).

52. The Board may discipline the holder of any registration if the holder or applicant, "[h]as violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy committed by the holder of a certificate, license, registration or permit." NRS 639.210(12).

53. The Board may discipline the holder of any registration if the holder or applicant, "[h]as failed to maintain and make available to a state or federal officer any records in accordance with the provisions of this chapter or chapter 453 or 454 of NRS." NRS 639.210(17).

54. Retail pharmacies must keep records of dangerous drugs dispensed to patients for at least two years. They must also keep invoices of drugs dangerous drugs purchased. NRS 454.286.

55. It is unlawful to compound drugs into Nevada without holding the appropriate license and complying with all regulations adopted by the Board. NRS 639.100(1).

56. To be licensed as an out-of-state pharmacy in Nevada, a pharmacy must, "[p]rovide the following information to the Board:... [t]he name of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board." NRS 639.2328(2)(d)(4).

57. "Any person, including a wholesaler or manufacturer, who engages in the business of wholesale distribution or furnishing controlled substances, poisons, drugs, devices or appliances that are restricted by federal law to sale by or on the order of a physician to any person located within this State shall obtain a license pursuant to the provisions of this chapter." NRS 639.233.

58. "'Wholesale distribution' means the distribution of drugs to persons other than consumers or patients, but does not include: [s]ales within a company; ...[t]he sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug: ...[b]etween health care facilities or pharmacies that are under common control." NRS 639.0155.

59. "If a generic drug or interchangeable biological product is substituted for a drug prescribed by brand name or biological product prescribed, the pharmacist or practitioner shall [n]ote the name of the manufacturer, packer or distributor of the drug or biological product actually dispensed on the prescription; and [i]ndicate the substitution by writing or typing on the label the words "substituted for," or substantially similar language, following the generic name and preceding the brand name of the drug, or following the name of the interchangeable biological product and preceding the brand name of the prescribed biological product, as applicable, unless, at the time the initial substitution of the generic drug or interchangeable biological product for a drug prescribed by brand name or biological product prescribed is made, the person for whom the drug or interchangeable biological product is dispensed elects not to have such an indication written or typed on the label. An election to indicate or not to indicate a substitution on the label pursuant to this subsection applies to both the fill and each refill of the same prescription." NRS 639.2587.

60. A pharmacy must include information regarding refrigeration on the label of a prescription if it will improve therapy by drugs. *See* NRS 639.266(1) and (2).

61. "Biologicals and other drugs must be kept refrigerated if the requirement is stated on the manufacturer's label." NAC 639.650(4).

62. All prescriptions filled by any pharmacy must be dispensed in a container to which is affixed a label or other device which clearly shows: the date; the name, address and prescription serial number of the practitioner who filled the prescription; the names of the prescribing practitioner and of the person for whom prescribed; the number of dosage units; the symptom or purpose for which the drug is prescribed; specific directions for use given by the prescribing practitioner; the expiration date of the effectiveness of the drug or medicine dispensed, if that information is included on the original label of the manufacturer of that drug or medicine. If the expiration date specified by the manufacturer is not less than 1 year after the date of dispensing, the practitioner may use a date that is 1 year after the date of dispensing as the expiration date; the proprietary or generic name of the drug or medicine as written by the prescribing practitioner; and the strength of the drug or medicine. NRS 639.2801.

63. "A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products shall ensure that each pharmacist and pharmaceutical technician engaged in the practice of compounding drug products [i]s competent and proficient in compounding the drug products that the pharmacist or pharmaceutical technician will be authorized and expected to compound; [c]omplies with the provisions of NAC 639.661 to 639.690, inclusive, concerning the drug products which the pharmacist or pharmaceutical technician compounds and the compounded drug products which the pharmacist or pharmaceutical technician dispenses at the pharmacy; and [r]eceives, on an ongoing basis, sufficient training to maintain that competency and proficiency." NAC 639.67013(1).

64. "A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products shall evaluate the competency and proficiency of a pharmacist and pharmaceutical technician." NAC 639.67013(2).

65. "A pharmacy engaged in the practice of compounding drug products shall establish and maintain written policies and procedures for compounding drug products to ensure that each final compounded drug product has the identity, strength, quality and purity which the

compounded drug product is purported or represented to have. Such policies and procedures must include, without limitation: [t]he processes used by the pharmacy to compound drug products; [t]he equipment used by the pharmacy to compound drug products; [e]nsuring that the actual weights and measures of each component are within plus or minus 5 percent of the theoretical weights and measures required for the drug products compounded by the pharmacy; [t]racking, recalling and destroying the drug products compounded by the pharmacy, which must include a requirement that the pharmacy ensure that all drug products which could have been compounded with a particular component be located, recalled and destroyed; and [i]dentifying the drug products or components of drug products that will be considered hazardous drugs." NAC 639.67015(1)(a).

66. A pharmacy engaged in the practice of compounding drug products shall also establish, "[c]ontrol procedures for monitoring each final compounded drug product and validating the compounding processes that may be responsible for causing variability in the final compounded drug product." NAC 639.67015(1)(b) and (c).

67. "Except as otherwise provided in NAC 639.67059, a pharmacy engaged in the practice of compounding sterile compounded drug products shall provide an ISO Class 5 environment." NAC 639.6705(1).

68. "Except as otherwise provided in NAC 639.67059, a pharmacy engaged in the practice of compounding sterile compounded drug products shall test the air in each of its controlled environments to ensure that the environments attain the air quality required by the provisions of NAC 639.661 to 639.690, inclusive, for an ISO Class 5, ISO Class 7 or ISO Class 8 environment, as applicable." NAC 639.67051(1).

69. "For all sterile compounded drug products compounded by a pharmacy, other than an institutional pharmacy, and for all sterile drug products for parenteral nutrition and sterile antineoplastic drug products compounded by an institutional pharmacy, a pharmacist shall make a record verifying the accuracy of each sterile compounded drug product." NAC 639.67055(1).

70. "A compounded drug product is a high-risk sterile compounded drug product if: [t]he compounded drug product is required to be sterile for its effective administration; [t]he sterile compounded drug product is contaminated with or at a high risk of becoming contaminated with infectious microorganisms; and [o]ne or more of the following conditions are present: [o]ne or more of the ingredients or devices used in the compounding process are nonsterile; or [o]ne or more of the ingredients or devices used in the compounding process were sterile but were exposed or are suspected of having been exposed for more than 1 hour to an air quality inferior to an ISO Class 5 environment." NAC 639.67067(1).

71. "A sterile compounded drug product is an immediate-use sterile compounded drug product if: [t]he compounded drug product is intended only for the purpose of emergency care or immediate care of a patient; [t]he compounding of the drug product occurs in an environment other than an ISO Class 5 environment and the compounding process consists of simple aseptic measuring and transfer manipulations performed with not more than six sterile nonhazardous commercial drug products and diagnostic radiopharmaceutical drug products, excluding infusion solutions or diluents; [t]he preparation procedure occurs continuously without delays or interruptions and does not exceed 1 hour unless a period longer than 1 hour is required for the reconstitution of the compounded drug product; [d]uring compounding and before the administration of the compounded drug product, no part of the drug product or critical surfaces and ingredients of the drug product is directly exposed to contact contamination, including, without limitation, human touch, cosmetic flakes or particulates, blood or other bodily substances of a person or nonsterile inanimate sources; and [e]xcept as otherwise provided in paragraph (c), the administration of the compounded drug product begins not later than 1 hour after the start of the preparation of the compounded drug product and the compounded drug product is fully administered as soon as practicable but not longer than 24 hours after the administration of the compounded drug product began or the compounded drug product is disposed of promptly and safely." NAC 639.67073(1).

72. "If an immediate-use sterile compounded drug product is not immediately administered by direct injection into a patient by the person who compounded it, the compounded drug product must bear a label which includes, without limitation: [t]he name and, if the patient has an identification number, the identification number of the patient; [t]he name and amount of each ingredient of the compounded drug product; [t]he initials of the person who compounded the compounded drug product; and [t]he exact date and time of expiration of the compounded drug product." NAC 639.67073(2).

73. "Except as otherwise provided..., a pharmacy engaged in the practice of compounding and dispensing sterile compounded drug products shall require each pharmacist and pharmaceutical technician who compounds sterile compounded drug products to pass a media fill test which must be conducted in the manner provided by chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670, and which must be commensurate to the highest level of risk of compounding sterile compounded drug products that the pharmacist or pharmaceutical technician will be authorized by the pharmacy to perform." NAC 639.67053(1).

74. "A drug or device shall be deemed to be adulterated— If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission

tomography compounding standards and the official monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 379e(a) of this title, or (B) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of section 379e(a) of this title; or (5) if it is a new animal drug which is unsafe within the meaning of section 360b of this title; or (6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of section 360b of this title." 21 U.S. Code § 351(a)(1).

75. "A drug or device shall be deemed to be adulterated— If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label.

Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia." 21 U.S. Code § 351(b)(1).

76. "A drug or device shall be deemed to be misbranded—If its labeling is false or misleading in any particular. Health care economic information provided to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs or devices for coverage or reimbursement, shall not be considered to be false or misleading under this paragraph if the health care economic information relates to an indication approved under section 355, 360(k), 360c(f)(2), or 360e of this title or section 262 of title 42 for such drug or device, is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug or device under section 355, 360(k), 360c(f)(2), or 360e of this title or section 262 of title 42." 21 U.S. Code § 352(a)(1).

77. "A drug or device shall be deemed to be misbranded—If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary." 21 U.S. Code § 352(b).

78. Pursuant to NRS 585.520(1) and (2) it is unlawful to sell or dispense an adulterated or misbranded drug (as defined in NRS 585.380, NRS 585.400, NRS 585.410, NRS 585.420 and/or NRS 585.460). Pursuant to NRS 454.351(1) it is unlawful to sell or dispense any drug which may

not be lawfully introduced into interstate commerce under the Federal Food, Drug, and Cosmetic Act.

COUNT ONE
Filing of a False Application – (Respondent Pharmacy)

79. Respondent Pharmacy submitted a Pharmacy application to the Board on or around September 16, 2019. On the submitted application, Respondent Pharmacy selected that they would not be engaged in sterile compounding. Despite Respondent Pharmacy indicating that they would not be engaged in sterile compounding, Respondent Pharmacy dispensed sterile compounded prescriptions into Nevada.

80. Based upon the facts alleged above, Respondent Pharmacy filed an application with the Board that was false. NRS 639.210(17). Respondent Pharmacy submitted a false application because Respondent Pharmacy engaged in compounding without disclosing so to the Board. Respondent Pharmacy had ample opportunity to contact the Board and disclose that they were engaged in sterile compounding, yet the failed to do so.

81. Having filed an application with the Board that is false as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(17); NRS 639.255; NAC 639.945; and NAC 639.955.

COUNT TWO
Unprofessional Conduct - Performing or in Any Way Being a Party to Any Fraudulent or Deceitful Practice or Transaction (Respondent Pharmacy)

82. Respondent Pharmacy was inspected by an Arizona Board of Pharmacy Compliance Officer on May 15, 2023. Respondent Pharmacy's owner was present during the inspection. During the inspection, Respondent Pharmacy's owner and staff lied multiple times to the Arizona Board of Pharmacy Compliance Officer. Namely, Respondent Pharmacy's owner and

staff lied about whether they were engaged in compounding and where compounding materials located in the pharmacy by the Compliance Officer came from.

83. Because of these lies, Respondent Pharmacy engaged in fraudulent and deceitful practices. NRS 639.210(4); NAC 639.945(1)(h). Respondent Pharmacy engaged in fraudulent and deceitful practices in an attempt to mask the fact that they were engaged in unauthorized sterile compounding. NRS 639.210(4); NAC 639.945(1)(h).

84. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

COUNT THREE

Unprofessional Conduct - Manufacturing, Compounding, Selling, Dispensing or Permitting to be Manufactured, Compounded, Sold or Dispensed Substandard Drugs or Preparations (Respondent Pharmacy and Respondent Vo)

85. Respondent Pharmacy compounded, sold, and dispensed sterile compounded drugs into the State of Nevada despite not possessing or maintaining the appropriate supplies and conditions to engage in sterile compounding. Respondent compounded, sold, and dispensed five total sterile compounded prescriptions into Nevada, one of which being Tirzepatide Cyanoco 10MG/ML for patient D.P., listed as prescription no. 00638587. Because Respondent Pharmacy did not possess the proper environment or supplies to engage in sterile compounding, any compounded sterile preparations (CSPs) dispensed into Nevada by Respondent Pharmacy are substandard. NRS 639.210(4); NAC 639.945(1)(a).

86. Having compounded, sold, and dispensed substandard drugs or preparations into Nevada, as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

87. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FOUR

Unprofessional Conduct - Manufacturing, Compounding, Selling, Dispensing or Permitting to be Manufactured, Compounded, Sold or Dispensed Substandard Drugs or Preparations (Respondent Pharmacy and Respondent Vo)

88. Respondent Pharmacy compounded, sold, and dispensed sterile compounded drugs into the State of Nevada despite not possessing or maintaining the appropriate supplies and conditions to engage in sterile compounding. Respondent compounded, sold, and dispensed five total sterile compounded prescriptions into Nevada, one of which being Tirzepatide Cyanoco 10MG/ML for patient T.S., listed as prescription no. 00645075. Because Respondent Pharmacy did not possess the proper environment or supplies to engage in sterile compounding, any compounded sterile preparations (CSPs) dispensed into Nevada by Respondent Pharmacy are substandard. NRS 639.210(4); NAC 639.945(1)(a).

89. Having compounded, sold, and dispensed substandard drugs or preparations into Nevada, as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

90. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FIVE

Unprofessional Conduct - Manufacturing, Compounding, Selling, Dispensing or Permitting to be Manufactured, Compounded, Sold or Dispensed Substandard Drugs or Preparations (Respondent Pharmacy and Respondent Vo)

91. Respondent Pharmacy compounded, sold, and dispensed sterile compounded drugs into the State of Nevada despite not possessing or maintaining the appropriate supplies and conditions to engage in sterile compounding. Respondent compounded, sold, and dispensed five total sterile compounded prescriptions into Nevada, one of which being Tirzepatide Cyanoco 10MG/ML for patient S.M., listed as prescription no. 00647772. Because Respondent Pharmacy did not possess the proper environment or supplies to engage in sterile compounding, any

compounded sterile preparations (CSPs) dispensed into Nevada by Respondent Pharmacy are substandard. NRS 639.210(4); NAC 639.945(1)(a).

92. Having compounded, sold, and dispensed substandard drugs or preparations into Nevada, as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

93. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT SIX

Unprofessional Conduct - Manufacturing, Compounding, Selling, Dispensing or Permitting to be Manufactured, Compounded, Sold or Dispensed Substandard Drugs or Preparations (Respondent Pharmacy and Respondent Vo)

94. Respondent Pharmacy compounded, sold, and dispensed sterile compounded drugs into the State of Nevada despite not possessing or maintaining the appropriate supplies and conditions to engage in sterile compounding. Respondent compounded, sold, and dispensed five total sterile compounded prescriptions into Nevada, one of which being Tirzepatide Cyanoco 10MG/ML for patient T.S., listed as prescription no. 00649160. Because Respondent Pharmacy did not possess the proper environment or supplies to engage in sterile compounding, any compounded sterile preparations (CSPs) dispensed into Nevada by Respondent Pharmacy are substandard. NRS 639.210(4); NAC 639.945(1)(a).

95. Having compounded, sold, and dispensed substandard drugs or preparations into Nevada, as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

96. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT SEVEN

Unprofessional Conduct - Manufacturing, Compounding, Selling, Dispensing or Permitting to be Manufactured, Compounded, Sold or Dispensed Substandard Drugs or Preparations (Respondent Pharmacy and Respondent Vo)

97. Respondent Pharmacy compounded, sold, and dispensed sterile compounded drugs into the State of Nevada despite not possessing or maintaining the appropriate supplies and conditions to engage in sterile compounding. Respondent compounded, sold, and dispensed five total sterile compounded prescriptions into Nevada, one of which being Tirzepatide Cyanoco 10MG/ML for patient T.S., listed as prescription no. 00649160 (sold and dispensed on a different date than the dispensation listed in Count Six). Because Respondent Pharmacy did not possess the proper environment or supplies to engage in sterile compounding, any compounded sterile preparations (CSPs) dispensed into Nevada by Respondent Pharmacy are substandard. NRS 639.210(4); NAC 639.945(1)(a).

98. Having compounded, sold, and dispensed substandard drugs or preparations into Nevada, as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

99. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT EIGHT

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

100. Respondent Pharmacy engaged in sterile compounding and sold and dispensed prescription no. 00638587 to patient D.P. despite not maintaining a sterile environment as required by Nevada law. NRS 639.210(4); NAC 639.670(c); and NAC 639.945(1)(i).

101. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent performed its

duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it sold and dispensed a CSP despite not possessing and sterile environment. NRS 639.210(4); NAC 639.670(c); and NAC 639.945(1)(i).

102. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

103. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT NINE

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

104. Respondent Pharmacy engaged in sterile compounding and sold and dispensed prescription no. 00645075 to patient T.R. despite not maintaining a sterile environment as required by Nevada law. NRS 639.210(4); NAC 639.670(c); and NAC 639.945(1)(i).

105. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it sold and dispensed a CSP despite not possessing and sterile environment. NRS 639.210(4); NAC 639.670(c); and NAC 639.945(1)(i).

106. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

107. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TEN

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

108. Respondent Pharmacy engaged in sterile compounding and sold and dispensed prescription no. 00647772 to patient S.M. despite not maintaining a sterile environment as required by Nevada law. NRS 639.210(4); NAC 639.670(c); and NAC 639.945(1)(i).

109. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it sold and dispensed a CSP despite not possessing and sterile environment. NRS 639.210(4); NAC 639.670(c); and NAC 639.945(1)(i).

110. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

111. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT ELEVEN

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

112. Respondent Pharmacy engaged in sterile compounding and sold and dispensed prescription no. 00649160 to patient T.R. despite not maintaining a sterile environment as required by Nevada law. NRS 639.210(4); NAC 639.670(c); and NAC 639.945(1)(i).

113. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent

manner because it sold and dispensed a CSP despite not possessing and sterile environment. NRS 639.210(4); NAC 639.670(c); and NAC 639.945(1)(i).

114. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

115. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWELVE

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

116. Respondent Pharmacy engaged in sterile compounding and sold and dispensed prescription no. 00649160 to patient T.R. (dispensed on a different day than the prescription listed in Count Eleven) despite not maintaining a sterile environment as required by Nevada law. NRS 639.210(4); NAC 639.670(c); and NAC 639.945(1)(i).

117. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it sold and dispensed a CSP despite not possessing and sterile environment. NRS 639.210(4); NAC 639.670(c); and NAC 639.945(1)(i).

118. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

119. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTEEN

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

120. Respondent Pharmacy failed to implement Standard Operating Procedures (SOPs) or Policies and Procedures in regard to CSPs as required by Nevada law. NAC 639.670(c); NAC 639.67015(1)(a).

121. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to have in place SOPs or Policies and Procedures as required by Nevada law. NRS 639.210(4); NAC 639.670(c); 639.67015(1)(a); and NAC 639.945(1)(i).

122. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

123. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FOURTEEN

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy)

124. It is the duty of a compounding pharmacy to ensure that all staff engaged in compounding are competent to do so. NAC 639.67013(1) and (2). It is also the responsibility of the pharmacy to ensure that each pharmacist and pharmaceutical technician who compounds sterile compounded drug products to pass a media fill test which must be conducted in the manner provided by chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670, and which must be commensurate to the highest level of risk of compounding sterile compounded drug products that the pharmacist or pharmaceutical technician will be authorized by the pharmacy to perform." NAC 639.67053(1).

Respondent Pharmacy failed to ensure that its staff engaged in sterile compounding was competent to do so and failed to ensure that staff members passed the media fill test as required by Nevada law. NAC 639.67013(1) and (2); NAC 639.67053(1).

125. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to ensure that its staff engaged in sterile compounded were competent to do so and it failed to ensure staff took and passed a media fill test. NRS 639.210(4); NAC 639.67013(1) and (2); 639.67053(1); and NAC 639.945(1)(i).

126. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

COUNT FIFTEEN

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

127. Respondent Pharmacy failed to provide the required ISO class environment necessary for engaging in sterile compounding laid out in the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670 and Nevada law. NAC 639.670(1)(c); NAC 639.6705(1); and NAC 639.67073(1).

128. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to provide an ISO class environment consistent with the requirements of Nevada law. NRS 639.210(4); NAC 639.670(1)(c); NAC 639.6705(1); NAC 639.67073(1); and NAC 639.945(1)(i).

129. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

130. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT SIXTEEN

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

131. Respondent Pharmacy failed to maintain and test to ensure maintenance of proper pressure differentials in areas where sterile compounding is performed as required in the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

132. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to maintain and test to ensure continued maintenance of proper pressure differentials in areas where sterile compounding was performed. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

133. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

134. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT SEVENTEEN

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

135. Respondent Pharmacy failed to maintain a buffer area or space that provides a physical separation from compounding areas as required in the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

136. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to maintain a buffer area or space that provides a physical separation from compounding areas. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

137. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

138. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT EIGHTEEN

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

139. Respondent Pharmacy failed to ensure that non-sterile measuring, mixing, and purifying devices were cleaned properly, pursuant to the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

140. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy

performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to ensure that non-sterile measuring, mixing, and purifying devices were properly cleaned. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

141. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

142. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT NINETEEN

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

143. Respondent Pharmacy failed to engage in proper pre-sterilization procedures for high-risk CSPs as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c); NAC 639.67067(1).

144. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to engage in proper pre-sterilization procedures for high-risk sterile compounding. NRS 639.210(4); NAC 639.670(1)(c); NAC 639.67067(1); and NAC 639.945(1)(i).

145. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

146. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWENTY

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

147. Respondent Pharmacy failed to ensure staff engaged in sterile compounding followed hand cleaning and hand hygiene procedures as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

148. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to ensure staff engaged in sterile compounding followed proper hand cleaning and hand hygiene procedures. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

149. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

150. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWENTY-ONE

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

151. Respondent Pharmacy failed to ensure that sterile compounding staff were donning gowns in the ante-area, prior to entering the buffer area when engaging in sterile compounding as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

152. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in

an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to ensure that sterile compounding staff were donning gowns in the ante-area, prior to entering the buffer area when engaging in sterile compounding. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

153. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

154. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWENTY-TWO

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

155. Respondent Pharmacy failed to ensure sterile compounding staff was removing debris in fingernails using a nail cleaner under warm running water as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

156. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to ensure that sterile compounding staff was removing debris in fingernails using a nail cleaner under warm running water. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

157. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

158. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWENTY-THREE

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

159. Respondent Pharmacy failed to document cleaning procedures in sterile compounding areas as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

160. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to document cleaning procedures in sterile compounding areas. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

161. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

162. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWENTY-FOUR

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

163. Respondent Pharmacy failed to perform environmental sampling of CSPs as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

164. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy

performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to perform environmental testing of CSPs. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

165. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

166. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWENTY-FIVE

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

167. Respondent Pharmacy failed to maintain records of the date and time of preparation of CSPs as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

168. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to maintain records of the date and time of preparation of CSPs. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

169. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

170. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWENTY-SIX

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

171. Respondent Pharmacy failed to maintain records of complete formulas of CSPs as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c). Respondent Pharmacy staff was unable to disclose to the Arizona Board of Pharmacy where certain parts of CSPs made in their pharmacy came from or what they were.

172. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to maintain records of complete formulas of CSPs. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

173. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

174. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWENTY-SEVEN

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

175. Respondent Pharmacy failed to maintain records of the container used and the number of units prepared for a CSP as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

176. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in

an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to maintain records of the container used and the number of units prepared for a CSP. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

177. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

178. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWENTY-EIGHT

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

179. Respondent Pharmacy failed to maintain records of the criteria used to determine beyond-use dates as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

180. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to maintain records of the container used and the number of units prepared for a CSP. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

181. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

182. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT TWENTY-NINE

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

183. Respondent Pharmacy improperly labeled "Semaglutide" prescriptions drawn up into insulin use only syringes as having a beyond-use dates of one year. Respondent Pharmacy did not base this determination on any drug specific scientific evidence, data, documentation, or literature as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

184. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it improperly labeled a sterile medication drawn up into insulin use only syringes as having a beyond-use date of one year without any drug specific scientific evidence, data, documentation, or literature to back the determination up. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

185. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

186. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTY

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

187. Respondent Pharmacy failed to maintain records of the performance of quality control procedures as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

188. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to maintain records of quality control procedures. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

189. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

190. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTY-ONE

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

191. Respondent Pharmacy and its sterile compounding staff failed to create and complete master worksheets and preparation worksheets for batch compounding as required by the *United States Pharmacopeia - National Formulary*, 2008 edition, adopted by reference. NAC 639.670(1)(c).

192. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it and its staff failed to create and complete master worksheets and preparation worksheets for batch compounding. NRS 639.210(4); NAC 639.670(1)(c); and NAC 639.945(1)(i).

193. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

194. A pharmacy/pharmacy owner is liable for all acts and omissions of the people they employ. NAC 639.945(3).

195. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTY-TWO

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

196. Respondent Pharmacy sold and dispensed prescriptions that were immediate use sterile compounds and failed to properly label those prescriptions as immediate use sterile compounds. NAC 639.670(1)(c); NAC 639.67073(2). Respondent Pharmacy compounded prescription drugs that should have been compounded in a sterile environment in an environment that was not sterile nor was it the proper ISO class environment to not require the CSP to be an immediate use CSP. NAC 639.67073(1). Respondent Pharmacy nevertheless failed to properly label the CSP as an immediate use CSP and include all labeling requirements consistent with Nevada law. 639.670(1)(c); NAC 639.67073(1) and (2).

197. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to properly label immediate use sterile compounds as such. NRS 639.210(4); NAC 639.670(1)(c); NAC 639.67073(1) and (2); and NAC 639.945(1)(i).

198. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

199. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTY-THREE

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

200. Every pharmacy must affix a label to each prescription that clearly shows the strength of the drug or medicine and the expiration date. NRS 639.2801. Respondent Pharmacy dispensed prescriptions with labels that did not include this information.

201. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it dispensed prescriptions with labels that did not clearly show the strength of the drug or the expiration date. NRS 639.210(4); NRS 639.2801; and NAC 639.945(1)(i).

202. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

203. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTY-FOUR

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

204. Respondent Pharmacy failed to include information regarding refrigeration requirements of prescriptions despite a manufacturer requirement that Semaglutide be refrigerated. Drugs must be kept refrigerated if the requirement is stated on the manufacturer's label. NAC 639.650(4). Respondent Pharmacy had a duty to notify patients of the refrigeration requirement because there is a duty to communicate all matters that will improve therapy by drugs, including

by using labels to convey important information. NRS 639.266(1) and (2). Respondent Pharmacy failed to communicate matters that would improve therapy by drugs.

205. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to include refrigeration information on the label when it would have improved therapy by drugs. NRS 639.210(4); NRS 639.266(1) and (2); NAC 639.650(4); and NAC 639.945(1)(i).

206. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

207. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTY-FIVE

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

208. Respondent Pharmacy failed to maintain records of compounded sterile preparations. NRS 454.286; NAC 639.670(1)(c); NAC 639.67055(1). An inspection by the Arizona Board of Pharmacy revealed that compounding records were maintained for only three dispensations, out of more than one-thousand products dispensed.

209. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to keep records of CSPs. NRS 639.210(4); NRS 454.286; NAC 639.670(1)(c); NAC 639.67055(1); and NAC 639.945(1)(i).

210. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

211. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTY-SIX

Unprofessional Conduct - Performing Any Duties as the Holder of a License Issued by the Board in an Incompetent, Unskillful or Negligent Manner (Respondent Pharmacy and Respondent Vo)

212. Respondent Pharmacy incorrectly labeled a non-brand name drug as a brand-named drug. NRS 639.2587; NRS 639.2801. When a pharmacy substitutes a non-name brand drug for a name brand drug, they must disclose so on the prescription label. NRS 639.2587. Additionally, pharmacies must include the correct name of the drug product on the label. NRS 639.2801. Respondent Pharmacy dispensed a non-brand name drug but labeled it "Ozempic."

213. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it labeled a non-brand name drug as the brand name drug. NRS 639.210(4); NRS 639.2587; NRS 639.2801; and NAC 639.945(1)(i).

214. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

215. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTY-SEVEN

Violations of the Federal Food Drug & Cosmetic Act – Dispensing Adulterated and/or Misbranded Drugs into Nevada (Respondent Pharmacy and Respondent Vo)

216. Respondent Pharmacy dispensed Tirzepatide Cyanoco 10MG/ML to patient D.P. under prescription number 00638587. The dispensed drug was compounded by Respondent Pharmacy in conditions not suitable for sterile compounding. If a drug has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, it is deemed an adulterated drug. 21 U.S. Code § 351(a)(1). Additionally, a drug will be deemed a misbranded drug if its labeling is false or misleading. 21 U.S. Code § 352(a)(1).

217. Respondent Pharmacy compounded, sold, and dispensed five (5) prescriptions to Nevada patients, including the one listed above under improper and unsanitary conditions. Because of this, the drugs are deemed to be adulterated and/or misbranded. 21 U.S. Code § 351(a)(1); 21 U.S. Code § 352(a)(1). Selling and dispensing adulterated and/or misbranded drugs is a violation of the Federal Food Drug & Cosmetic Act. The Board may discipline a Respondent for violations of that Act. NRS 639.210(11).

218. Having dispensed adulterated and/or misbranded drugs into Nevada as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(11); NRS 639.255; NAC 639.945; and NAC 639.955.

219. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTY-EIGHT

Violations of the Federal Food Drug & Cosmetic Act – Dispensing Adulterated and/or Misbranded Drugs into Nevada (Respondent Pharmacy and Respondent Vo)

220. Respondent Pharmacy dispensed Tirzepatide Cyanoco 10MG/ML to patient T.R. under prescription number 00645075. The dispensed drug was compounded by Respondent Pharmacy in conditions not suitable for sterile compounding. If a drug has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby

it may have been rendered injurious to health, it is deemed an adulterated drug. 21 U.S. Code § 351(a)(1). Additionally, a drug will be deemed a misbranded drug if its labeling is false or misleading. 21 U.S. Code § 352(a)(1).

221. Respondent Pharmacy compounded, sold, and dispensed five (5) prescriptions to Nevada patients, including the one listed above under improper and unsanitary conditions. Because of this, the drugs are deemed to be adulterated and/or misbranded. 21 U.S. Code § 351(a)(1); 21 U.S. Code § 352(a)(1). Selling and dispensing adulterated and/or misbranded drugs is a violation of the Federal Food Drug & Cosmetic Act. The Board may discipline a Respondent for violations of that Act. NRS 639.210(11).

222. Having dispensed adulterated and/or misbranded drugs into Nevada as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(11); NRS 639.255; NAC 639.945; and NAC 639.955.

223. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT THIRTY-NINE

Violations of the Federal Food Drug & Cosmetic Act – Dispensing Adulterated and/or Misbranded Drugs into Nevada (Respondent Pharmacy and Respondent Vo)

224. Respondent Pharmacy dispensed Tirzepatide Cyanoco 10MG/ML to patient S.M. under prescription number 00647772. The dispensed drug was compounded by Respondent Pharmacy in conditions not suitable for sterile compounding. If a drug has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, it is deemed an adulterated drug. 21 U.S. Code § 351(a)(1). Additionally, a drug will be deemed a misbranded drug if its labeling is false or misleading. 21 U.S. Code § 352(a)(1).

225. Respondent Pharmacy compounded, sold, and dispensed five (5) prescriptions to Nevada patients, including the one listed above under improper and unsanitary conditions. Because

of this, the drugs are deemed to be adulterated and/or misbranded. 21 U.S. Code § 351(a)(1); 21 U.S. Code § 352(a)(1). Selling and dispensing adulterated and/or misbranded drugs is a violation of the Federal Food Drug & Cosmetic Act. The Board may discipline a Respondent for violations of that Act. NRS 639.210(11).

226. Having dispensed adulterated and/or misbranded drugs into Nevada as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(11); NRS 639.255; NAC 639.945; and NAC 639.955.

227. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FOURTY

Violations of the Federal Food Drug & Cosmetic Act – Dispensing Adulterated and/or Misbranded Drugs into Nevada (Respondent Pharmacy and Respondent Vo)

228. Respondent Pharmacy dispensed Tirzepatide Cyanoco 10MG/ML to patient T.R. under prescription number 00649160. The dispensed drug was compounded by Respondent Pharmacy in conditions not suitable for sterile compounding. If a drug has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, it is deemed an adulterated drug. 21 U.S. Code § 351(a)(1). Additionally, a drug will be deemed a misbranded drug if its labeling is false or misleading. 21 U.S. Code § 352(a)(1).

229. Respondent Pharmacy compounded, sold, and dispensed five (5) prescriptions to Nevada patients, including the one listed above under improper and unsanitary conditions. Because of this, the drugs are deemed to be adulterated and/or misbranded. 21 U.S. Code § 351(a)(1); 21 U.S. Code § 352(a)(1). Selling and dispensing adulterated and/or misbranded drugs is a violation of the Federal Food Drug & Cosmetic Act. The Board may discipline a Respondent for violations of that Act. NRS 639.210(11).

230. Having dispensed adulterated and/or misbranded drugs into Nevada as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(11); NRS 639.255; NAC 639.945; and NAC 639.955.

231. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FOURTY-ONE

Violations of the Federal Food Drug & Cosmetic Act – Dispensing Adulterated and/or Misbranded Drugs into Nevada (Respondent Pharmacy and Respondent Vo)

232. Respondent Pharmacy dispensed Tirzepatide Cyanoco 10MG/ML to patient T.R. under prescription number 00649160 (dispensed on a different day than the previous Count). The dispensed drug was compounded by Respondent Pharmacy in conditions not suitable for sterile compounding. If a drug has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, it is deemed an adulterated drug. 21 U.S. Code § 351(a)(1). Additionally, a drug will be deemed a misbranded drug if its labeling is false or misleading. 21 U.S. Code § 352(a)(1).

233. Respondent Pharmacy compounded, sold, and dispensed five (5) prescriptions to Nevada patients, including the one listed above under improper and unsanitary conditions. Because of this, the drugs are deemed to be adulterated and/or misbranded. 21 U.S. Code § 351(a)(1); 21 U.S. Code § 352(a)(1). Selling and dispensing adulterated and/or misbranded drugs is a violation of the Federal Food Drug & Cosmetic Act. The Board may discipline a Respondent for violations of that Act. NRS 639.210(11).

234. Having dispensed adulterated and/or misbranded drugs into Nevada as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(11); NRS 639.255; NAC 639.945; and NAC 639.955.

235. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FOURTY-TWO

Violations of State Law – Dispensing Compounded Drugs into Nevada without the Authority to do so (Respondent Pharmacy and Respondent Vo)

236. No person or entity may compound, sell, and dispense prescription drugs in this state without obtaining the proper license to do so. NRS 639.100(1). The Board has specific licenses related to compounding pharmacies. Obtaining these licenses comes with more detailed inspections and scrutiny due to the significant number of rules necessary to engage in compounding safely. NAC 639.670(1)(c). When Respondent Pharmacy applied to the Board for a Nevada pharmacy license, they disclosed to the Board that they would not be engaged in compounding. At no point did Respondent Pharmacy ever notify the Board that they would be or were engaged in compounding.

237. Despite this, Respondent Pharmacy compounded, sold, and dispensed five (5) prescriptions to Nevada patients, including Tirzepatide Cyanoco 10MG/ML to patient D.P. under prescription number 00638587. Respondent Pharmacy never possessed the correct license to engage in compounding. Because of this, Respondent Pharmacy violated NRS 639.100(1). Respondent Pharmacy is subject to discipline for this violation pursuant to NRS 639.210(12).

238. Having violated state law as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(12); NRS 639.255; NAC 639.945; and NAC 639.955.

239. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FOURTY-THREE

Violations of State Law - Dispensing Compounded Drugs into Nevada without the Authority to do so (Respondent Pharmacy and Respondent Vo)

240. No person or entity may compound, sell, and dispense prescription drugs in this state without obtaining the proper license to do so. NRS 639.100(1). The Board has specific licenses related to compounding pharmacies. Obtaining these licenses comes with more detailed inspections and scrutiny due to the significant number of rules necessary to engage in

compounding safely. NAC 639.670(1)(c). When Respondent Pharmacy applied to the Board for a Nevada pharmacy license, they disclosed to the Board that they would not be engaged in compounding. At no point did Respondent Pharmacy ever notify the Board that they would be or were engaged in compounding.

241. Despite this, Respondent Pharmacy compounded, sold, and dispensed five (5) prescriptions to Nevada patients, including Tirzepatide Cyanoco 10MG/ML to patient T.R. under prescription number 00645075. Respondent Pharmacy never possessed the correct license to engage in compounding. Because of this, Respondent Pharmacy violated NRS 639.100(1). Respondent Pharmacy is subject to discipline for this violation pursuant to NRS 639.210(12).

242. Having violated state law as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(12); NRS 639.255; NAC 639.945; and NAC 639.955.

243. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FOURTY-FOUR

Violations of State Law - Dispensing Compounded Drugs into Nevada without the Authority to do so (Respondent Pharmacy and Respondent Vo)

244. No person or entity may compound, sell, and dispense prescription drugs in this state without obtaining the proper license to do so. NRS 639.100(1). The Board has specific licenses related to compounding pharmacies. Obtaining these licenses comes with more detailed inspections and scrutiny due to the significant number of rules necessary to engage in compounding safely. NAC 639.670(1)(c). When Respondent Pharmacy applied to the Board for a Nevada pharmacy license, they disclosed to the Board that they would not be engaged in compounding. At no point did Respondent Pharmacy ever notify the Board that they would be or were engaged in compounding.

245. Despite this, Respondent Pharmacy compounded, sold, and dispensed five (5) prescriptions to Nevada patients, including Tirzepatide Cyanoco 10MG/ML to patient S.M. under

prescription number 00647772. Respondent Pharmacy never possessed the correct license to engage in compounding. Because of this, Respondent Pharmacy violated NRS 639.100(1). Respondent Pharmacy is subject to discipline for this violation pursuant to NRS 639.210(12).

246. Having violated state law as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(12); NRS 639.255; NAC 639.945; and NAC 639.955.

247. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FOURTY-FIVE

Violations of State Law - Dispensing Compounded Drugs into Nevada without the Authority to do so (Respondent Pharmacy and Respondent Vo)

248. No person or entity may compound, sell, and dispense prescription drugs in this state without obtaining the proper license to do so. NRS 639.100(1). The Board has specific licenses related to compounding pharmacies. Obtaining these licenses comes with more detailed inspections and scrutiny due to the significant number of rules necessary to engage in compounding safely. NAC 639.670(1)(c). When Respondent Pharmacy applied to the Board for a Nevada pharmacy license, they disclosed to the Board that they would not be engaged in compounding. At no point did Respondent Pharmacy ever notify the Board that they would be or were engaged in compounding.

249. Despite this, Respondent Pharmacy compounded, sold, and dispensed five (5) prescriptions to Nevada patients, including Tirzepatide Cyanoco 10MG/ML to patient T.R. under prescription number 00649160. Respondent Pharmacy never possessed the correct license to engage in compounding. Because of this, Respondent Pharmacy violated NRS 639.100(1). Respondent Pharmacy is subject to discipline for this violation pursuant to NRS 639.210(12).

250. Having violated state law as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(12); NRS 639.255; NAC 639.945; and NAC 639.955.

251. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FOURTY-SIX

Violations of State Law - Dispensing Compounded Drugs into Nevada without the Authority to do so (Respondent Pharmacy and Respondent Vo)

252. No person or entity may compound, sell, and dispense prescription drugs in this state without obtaining the proper license to do so. NRS 639.100(1). The Board has specific licenses related to compounding pharmacies. Obtaining these licenses comes with more detailed inspections and scrutiny due to the significant number of rules necessary to engage in compounding safely. NAC 639.670(1)(c). When Respondent Pharmacy applied to the Board for a Nevada pharmacy license, they disclosed to the Board that they would not be engaged in compounding. At no point did Respondent Pharmacy ever notify the Board that they would be or were engaged in compounding.

253. Despite this, Respondent Pharmacy compounded, sold, and dispensed five (5) prescriptions to Nevada patients, including Tirzepatide Cyanoco 10MG/ML to patient T.R. under prescription number 00649160 (dispensed on a different date than the previous Count). Respondent Pharmacy never possessed the correct license to engage in compounding. Because of this, Respondent Pharmacy violated NRS 639.100(1). Respondent Pharmacy is subject to discipline for this violation pursuant to NRS 639.210(12).

254. Having violated state law as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(12); NRS 639.255; NAC 639.945; and NAC 639.955.

255. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FOURTY-SEVEN

Unprofessional Conduct – Unlicensed Activity – Engaging in Wholesaling of Prescription Drugs without the Proper License to do so (Respondent Pharmacy and Respondent Vo)

256. Any person or entity engaged in wholesale distribution of drugs, restricted to sale by or on the order of a physician in this state must obtain a wholesale license. NRS 639.233. Respondent Pharmacy engaged in wholesale distribution when it shipped compounded medications to another pharmacy in Nevada that it did not share common ownership with. NRS 639.0155. Additionally, Respondent Pharmacy is not a registered outsourcing facility under Section 503B of the Federal Food Drug & Cosmetic Act. In order for Respondent Pharmacy to engage in wholesale distribution, they need to apply for and obtain a wholesale license from the Board. NRS 639.233.

257. The actions described above constitute unprofessional conduct. NRS 639.210(4). Unprofessional conduct includes a Respondent performing its duties as the holder of a license in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Respondent Pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it labeled a non-brand name drug as the brand name drug. NRS 639.210(4); NRS 639.233; NRS 639.0155; and NAC 639.945(1)(i).

258. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

259. Pharmacist Vo, as the Nevada registered pharmacist on staff, is responsible for Respondent Pharmacy's unregistered pharmacist's errors and omissions. NRS 639.2328(2)(d)(4).

COUNT FORTY-EIGHT

Violations of State Law –Dispensing Adulterated and/or Misbranded Drugs into Nevada (Respondent Pharmacy and Respondent Vo)

260. By dispensing adulterated and/or misbranded sterile drug products into Nevada as alleged herein, respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.351(1), NRS 585.520(1) and (2) and/or NRS 639.100(1), and are

therefore subject to discipline pursuant to NRS 639.210(12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificate of registration of these respondents.

DATED this 6th day of November 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **THU THI PHUONG VO, RPH,** **Registration No. 18661,** **Respondent.**	**Case No. 24-282-RPH-O** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file-stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 6th day of NOVEMBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **THU THI PHUONG VO, RPH** **Registration No. 18661,** **Respondent.**	**Case No. 24-282-RPH-O** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

THU THI PHUONG VO, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of Nov. 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Thu Thi Phuong Vo, RPH
[redacted]E Clubhouse CV
Fort Mohave, AZ 86426

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

5I

FILED
OCT 21 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

LAUGHLIN PHARMACY & WELLNESS CENTER, Pharmacy License No. PH04520,

YOUJIN SEO, RPH, Certificate of Registration No. 18704, and

THU VO, RPH, Certificate of Registration No. 18661,

Respondents.

Case Nos. 24-289-PH-S
24-289-RPH-A-S
24-289-RPH-B-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Youjin Seo, RPh (Seo), Certificate of Registration No. 18704, and Respondent Thu Vo, RPh (Vo), Certificate of Registration No. 18661, were pharmacists registered with the Board, and Respondent Laughlin Pharmacy & Wellness Center (Laughlin Pharmacy), Pharmacy License No. PH04520, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Seo and Vo co-owned Laughlin Pharmacy and Vo was managing pharmacist at the time of the events alleged herein.

3. Respondents dispensed and/or directly administered at least 51 syringes of sterile drug products as "weight loss injections" to five (5) different patients between January 3, 2024, and May 24, 2024.

4. The drug products included, without limitation, semaglutide 5mg and tirzepatide 10mg, purchased from and compounded by DeeFlat Pharmacy, Pharmacy License No. PH04171, located in Bullhead City, AZ, using non-sterile methods and adulterated and/or misbranded drugs.

5. The compounded drug products were purchased in vials and dispensed and/or administered in insulin use-only syringes.

6. Respondents maintained no records documenting the purchase of the compounded drug products from DeeFlat Pharmacy.

7. On or about June 5, 2024, Respondent Seo attempted to charge patient M.M-S. an additional cash charge of $90 beyond the required insurance co-pay to fill a prescription for a Dexcom G-7 Sensor.

APPLICABLE LAW

8. Any sterile drug products sold or dispensed by a pharmacy shall be compounded in compliance with NAC 639.6701-.6702, *inclusive*, NAC 639.6705 -.67079, *inclusive*, and related federal law, 21 U.S.C. § 353a and USP-797 standards. NRS 639.100; NRS 639.286.

9. Pursuant to NRS 585.520(1) and (2) it is unlawful to sell or dispense an adulterated or misbranded drug (as defined in NRS 585.380, NRS 585.400, NRS 585.410, NRS 585.420 and/or NRS 585.460). Pursuant to NRS 454.351(1) it is unlawful to sell or dispense any drug which may not be lawfully introduced into interstate commerce under the Federal Food, Drug, and Cosmetic Act.

10. Pursuant to 21 U.S.C. § 331(a), (b) and (c) it is unlawful to engage in the sale and/or distribution of an adulterated or misbranded drug in interstate commerce.

11. No person may administer a dangerous drug without specific statutory authority to do so. NRS 454.213.

12. A pharmacy shall maintain complete, accurate and readily retrievable records of all dangerous drugs purchased and those sold on prescription, dispensed, furnished or disposed of otherwise. NRS 454.286; NRS 454.291; NAC 639.487(2); NAC 639.510(2)(b).

13. Selling or dispensing or permitting to be sold or dispensed substandard drugs or preparations constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(a) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

14. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

15. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

16. The Board may suspend or revoke a license if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

17. The Board may suspend or revoke a license if the holder has violated any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

18. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy, including recordkeeping. NRS 639.210(15), NRS 639.220(1) and/or NAC 639.510(2)(b).

19. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the

pharmacy by the Board. NRS 639.230(5). Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Violations of Federal Law – Dispensing Adulterated or Misbranded Drugs

20. By dispensing adulterated and/or misbranded sterile drug products that were not compounded in compliance with 21 U.S.C. § 353a and USP-797 guidelines, as alleged in paragraphs 3-5 herein, respondents violated 21 U.S.C. § 331(a), (b) and/or (c), and are therefore subject to discipline pursuant to NRS 639.210(11) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

COUNT TWO

Violations of State Law – Dispensing Adulterated or Misbranded Drugs

21. By dispensing adulterated and/or misbranded sterile drug products that were not compounded in compliance with NAC 639.6701-.6702, *inclusive*, NAC 639.6705 -.67079, *inclusive*, as alleged in paragraphs 3-5 herein, respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.351(1), NRS 585.520(1) and (2) and/or NRS 639.100(1), and are therefore subject to discipline pursuant to NRS 639.210(12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

COUNT THREE

Violations of State Law – Unlawful Administration of Drug

22. By directly administering compounded drug products to patients as alleged in paragraphs herein, respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.213, and are therefore subject to discipline pursuant to NRS 639.210(12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

\\\

\\\

\\\

\\\

COUNT FOUR

Violations of State Law - Recordkeeping

23. By failing to keep and maintain complete, accurate and readily retrievable records accounting for all dangerous drugs as alleged in paragraph 6 herein, respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.286, NRS 454.291, NAC 639.487(2) and/or NAC 639.510(2)(b), and are therefore subject to discipline pursuant to NRS 639.210(12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

COUNT FIVE

Unprofessional Conduct – Selling or Dispensing Substandard Drugs

24. By dispensing and/or directly administering adulterated and/or misbranded sterile drug products to patients, as alleged herein, respondents sold or dispensed substandard drugs or preparations and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(a), and are subject to discipline pursuant to NRS 639.210(4).

COUNT SIX

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

25. By attempting to charge patient M.M-S. an additional cash charge of $90 beyond the required insurance co-pay to fill a prescription for a Dexcom G-7 Sensor, Respondent Seo was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and all respondents are therefore subject to discipline pursuant to NRS 639.210(4), NRS 639.230(5) and/or NAC 639.945(3).

COUNT SEVEN

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

26. By their conduct as alleged herein, respondents have performed their duties as licensees/registrants in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 639.210(4).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the license and registrations of these respondents.

Signed this 21 day of October 2024.

J. David Wuest, RPh, Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LAUGHLIN PHARMACY & WELLNESS CENTER** **License No. PH04520,** **Respondent.**	**Case No. 24-289-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 21st day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LAUGHLIN PHARMACY & WELLNESS CENTER, License No. PH04520,** **Respondent.**	**Case No. 24-289-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

AUTHORIZED REPRESENTATIVE FOR
Laughlin Pharmacy & Wellness Center

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 21st day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Laughlin Pharmacy & Wellness Center
3080 S Needles Hwy., Suite 1800
Laughlin, NV 89029

Youjin Seo, Rph
[redacted]Green Falls Ave
Henderson, NV 89052

Youjin Seo, Rph
Valley View Medical Center
5330 S Hwy 95
Fort Mohave, AZ 86426

Thu Vo, Rph
[redacted]E Clubhouse CV
Fort Mohave, AZ 86426

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT
BOARD COORDINATOR I

Docusign Envelope ID: 71245F8F-FCC5-451D-80D1-7E59F4C6E995

MICHAEL M LIN, ESQ.
Nevada Bar No. 010392
LIN LAW GROUP
5288 Spring Mtn. Rd, Ste 103
Las Vegas, Nevada 89146
(702) 871 9888
Attorneys for Respondent
Laughlin Pharmacy & Wellness Center

FILED
NOV 18 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, vs. LAUGHLIN PHARMACY & WELLNESS CENTER, Pharmacy License No. PH04520, Respondent.	Case No. 24-289-PH-S ANSWER AND NOTICE OF DEFENSE

Respondent, LAUGHLIN PHARMACY & WELLNESS CENTER, ("LPWC"), by and through its counsel, Michael M Lin, Esq of Lin Law Group, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. With respect to Board's Notice of Intended Action and Accusation and the allegations contained in Paragraphs 1, 2, 4, 5, and 6, Respondent admits said allegations.

2. With respect to Board's Notice of Intended Action and Accusation and the allegations contained in Paragraphs 3 and 7, Respondent denies said allegations.

3. With respect to Board's Notice of Intended Action and Accusation and the allegations contained in Paragraphs 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18 and 19, this Answering Respondent states that the allegations in these paragraphs appear to be an alleged statement of law as opposed to

LIN LAW GROUP
5288 Spring Mtn Rd., Ste 103
Las Vegas, NV 89146
(702) 871-9888 FAX: (702) 648-0888

Docusign Envelope ID: 71245F8F-FCC5-451D-80D1-7E59F4C6E995

factual allegations pertaining to this Answering Respondent, therefore, no answer by this Answering Respondent is required.

COUNT ONE

Violation of Federal Law- Dispensing Adulterated or Misbranded Drugs.

4. With respect to the Board's Notice of Intended Action and Accusation, and the allegations in Paragraph 20, the Respondent states and acknowledges that Laughlin Pharmacy began offering weight loss injections after repeated requests from local patients, many of whom had previously traveled to Deeflat Pharmacy in Bullhead City, AZ. With only a small number of patients, purchasing large quantities directly from a vendor was impractical. To address this need, Ms. Vo sourced a limited supply from Deeflat Pharmacy to minimize the inconvenience for patients in underserved areas. Unaware of the regulatory implications, she instructed her staff to dispense the medication into insulin syringes, not realizing it could be considered a compounding activity or result in labeling issues. Laughlin Pharmacy dispensed 41 syringes and 4 vials of sterile products as "weight loss injections" to five different patients between January 3, 2024 to May 24, 2024. As to all remaining allegations, this Answering Respondent respectfully denies each allegation therein.

COUNT TWO

Violations of State Law- Dispensing Adulterated or Misbranded Drugs

5. With respect to the Board's Notice of Intended Action and Accusation, and the allegations in Paragraph 21, the Respondent states and acknowledges that Laughlin Pharmacy began offering weight loss injections after repeated requests from local patients, many of whom had previously traveled to Deeflat Pharmacy in Bullhead City, AZ. With only a small number of patients, purchasing large quantities directly from a vendor was impractical. To address this need, Ms. Vo sourced a limited supply from Deeflat Pharmacy to minimize the inconvenience for patients in underserved areas. Unaware of the regulatory implications, she instructed her staff to dispense the medication into insulin syringes, not realizing it could be considered a compounding activity or result in labeling issues. Laughlin Pharmacy dispensed 41 syringes and

LIN LAW GROUP
5288 Spring Mtn Rd., Ste 103
Las Vegas, NV 89146
(702) 871-9888 FAX: (702) 648-0888

Docusign Envelope ID: 71245F8F-FCC5-451D-80D1-7E59F4C6E995

4 vials of sterile products as "weight loss injections" to five different patients between January 3, 2024 to May 24, 2024. As to all remaining allegations, this Answering Respondent respectfully denies each allegation therein.

COUNT THREE

Violations of State Law- Unlawful Administration of Drug

6. With respect to the Board's Notice of Intended Action and Accusation, and the allegations in Paragraph 22, the Respondent states and acknowledges that Laughlin Pharmacy provided direct administration of weight loss medications upon patient request, particularly when patients expressed discomfort with self-injection. Ms. Vo (PIC) did not provide specific instructions on administration; thus, these actions were taken based on the individual pharmacist's professional judgment and evaluation. As to all remaining allegations, this Answering Respondent respectfully denies each allegation therein.

COUNT FOUR

Violation of State Law- Recordkeeping

7. With respect to the Board's Notice of Intended Action and Accusation, and the allegations in Paragraph 23, the Respondent acknowledges that Laughlin Pharmacy does not have compounding logs for weight-loss injections. Both pharmacists were new to handling this compounded product and were unaware that dispensing the injection into a syringe qualified as compounding, leading to unintentional omissions in the required documentation. These omissions reflect a misunderstanding and lack of familiarity rather than any intentional non-compliance. Additionally, Laughlin Pharmacy does not possess purchase invoices for the weight-loss injection. At the time of the transaction, Ms. Vo served as the pharmacist in charge and was responsible for providing the invoices for each purchase from Deeflat Pharmacy. However, Ms. Vo failed to deliver these invoices to Laughlin Pharmacy, resulting in their unavailability. As to the remaining allegations, the Answering Respondent respectfully denies each and every allegation therein. As to all remaining allegations, this Answering Respondent respectfully denies each allegation therein.

COUNT FIVE

LIN LAW GROUP
5288 Spring Mtn Rd., Ste 103
Las Vegas, NV 89146
(702) 871-9888 FAX: (702) 648-0888

Docusign Envelope ID: 71245F8F-FCC5-451D-80D1-7E59F4C6E995

Unprofessional Conduct- Selling or Dispensing Substandard Drugs

8. With respect to the Board's Notice of Intended Action and Accusation, and the allegations in Paragraph 24, the Respondent acknowledges that at the time of dispensing, both pharmacists at Laughlin Pharmacy were unaware that the weight loss injections did not meet required standards. When concerns about medication quality arose, Laughlin Pharmacy immediately halted dispensing these products. Although no official recall was issued, Ms. Vo proactively decided to stop carrying the medication, informing staff accordingly. Affected patients were notified of the discontinuation by phone at the end of May 2024, and all compounding activities ceased as of May 25, 2024, with no affected products remaining at the pharmacy. Follow-up calls with updated quality information were conducted in July 2024, along with voluntary refunds beginning on July 12, 2024. In September 2024, a further risk assessment, prompted by the board investigator, confirmed no adverse effects among affected patients. All affected patients verbally confirmed no harm, with four of five providing written statements attesting to this and confirming no remaining medication in their possession. As to all remaining allegations, this Answering Respondent respectfully denies each allegation therein.

COUNT SIX

Unprofessional Conduct- Fraudulent/Deceitful Practice/Transaction

1. With respect to the Board's Notice of Intended Action and Accusation, and the allegations in Paragraph 25, the Respondent acknowledges the circumstances surrounding the unexpected closure of Deeflat Pharmacy. After Deeflat's closure, Laughlin Pharmacy faced a high volume of patient transfers, leading to the temporary hiring of Darren, a former Deeflat technician, for clerical support. Despite long hours and an extended commute, Ms. Seo, a dedicated pharmacist and co-owner, prioritized patient care over financial concerns. When Darren suggested that patient M.M-S cover part of the cost of Dexcom sensors, Ms. Seo immediately rejected the idea as unethical. Acting without her knowledge, Darren then attempted to charge the patient an additional $90, which led the patient to refuse the medication and request a transfer. On June 8th, Ms. Seo noticed the Dexcom boxes in the Return Bin and, upon confirming Darren's unauthorized action, promptly arranged to transfer the prescription to

LIN LAW GROUP
5288 Spring Mtn Rd., Ste 103
Las Vegas, NV 89146
(702) 871-9888 FAX: (702) 648-0888

Docusign Envelope ID: 71245F8F-FCC5-451D-80D1-7E59F4C6E995

Riverside Pharmacy by June 10th. Darren subsequently resigned. Given Ms. Seo's dedication to patient welfare in challenging circumstances, the Respondent respectfully requests the Board's understanding. As to all remaining allegations, this Answering Respondent respectfully denies each allegation therein.

COUNT SEVEN

Unprofessional Conduct- Incompetent, Unskillful or Negligent Performance of Duties

2. With respect to the Board's Notice of Intended Action and Accusation, and the allegations in Paragraph 26, the Respondent states and acknowledges that from January to May 2024, Laughlin Pharmacy provided weight loss injections to support local patients who previously received similar treatment from Deeflat Pharmacy. Laughlin Pharmacy never intended to compromise patient safety and regrets these procedural missteps. When quality concerns arose, the pharmacy promptly informed patients, ceased dispensing, and in July, offered full refunds to ensure transparency. Thankfully, no patients experienced adverse effects, and those affected chose to continue their care with Laughlin Pharmacy, reaffirming their trust in the pharmacy's dedication to patient well-being. As to all remaining allegations, this Answering Respondent respectfully denies each allegation therein.

WHEREFORE, Respondent prays this Board's understanding and compassion to take appropriate actions based on the facts and circumstances surrounding the responses.

11/18/2024 | 12:13:01 PM PST

DATED this _____ day of November, 2024

LIN LAW GROUP, PC

By: */s/ Michael M Lin*
MICHAEL M LIN, ESQ.
Nevada Bar No. 010392
5288 Spring Mtn. Rd, Ste 103
Las Vegas, Nevada 89146
(702) 871 9888
Attorneys for Respondent
Laughlin Pharmacy & Wellness Center

LIN LAW GROUP
5288 Spring Mtn Rd., Ste 103
Las Vegas, NV 89146
(702) 871-9888 FAX: (702) 648-0888

Docusign Envelope ID: 71245F8F-FCC5-451D-80D1-7E59F4C6E995

DECLARATION

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 11/18/2024 | 12:11:18 PM PST

LAUGHLIN PHARMACY &
WELLNESS CENTER

By: DocuSigned by: 748418E267FF438...

YOUJIN SEO, RPH, owner

///

///

///

LIN LAW GROUP
5288 Spring Mtn Rd., Ste 103
Las Vegas, NV 89146
(702) 871-9888 FAX: (702) 648-0888

Docusign Envelope ID: 71245F8F-FCC5-451D-80D1-7E59F4C6E995

CERTIFICATE OF SERVICE

11/18/2024 | 12:13:01 PM PST

I certify that I am an employee of Lin Law Group, and that on this _____ day of November, 2024, I served a true and correct copy of the foregoing document by emails below:

TeamBC@Pharmacy.nv.gov

And

bkandt@pharmacy.nv.gov

DS

DocuSigned by:
Michael
48BAED275F634E3...

An employee of Lin Law Group

LIN LAW GROUP
5288 Spring Mtn Rd., Ste 103
Las Vegas, NV 89146
(702) 871-9888 FAX: (702) 648-0888

5J

FILED
OCT 21 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

LAUGHLIN PHARMACY & WELLNESS CENTER, Pharmacy License No. PH04520,

YOUJIN SEO, RPH, Certificate of Registration No. 18704, and

THU VO, RPH, Certificate of Registration No. 18661,

Respondents.

Case Nos. 24-289-PH-S
24-289-RPH-A-S
24-289-RPH-B-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Youjin Seo, RPh (Seo), Certificate of Registration No. 18704, and Respondent Thu Vo, RPh (Vo), Certificate of Registration No. 18661, were pharmacists registered with the Board, and Respondent Laughlin Pharmacy & Wellness Center (Laughlin Pharmacy), Pharmacy License No. PH04520, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Seo and Vo co-owned Laughlin Pharmacy and Vo was managing pharmacist at the time of the events alleged herein.

3. Respondents dispensed and/or directly administered at least 51 syringes of sterile drug products as "weight loss injections" to five (5) different patients between January 3, 2024, and May 24, 2024.

4. The drug products included, without limitation, semaglutide 5mg and tirzepatide 10mg, purchased from and compounded by DeeFlat Pharmacy, Pharmacy License No. PH04171, located in Bullhead City, AZ, using non-sterile methods and adulterated and/or misbranded drugs.

5. The compounded drug products were purchased in vials and dispensed and/or administered in insulin use-only syringes.

6. Respondents maintained no records documenting the purchase of the compounded drug products from DeeFlat Pharmacy.

7. On or about June 5, 2024, Respondent Seo attempted to charge patient M.M-S. an additional cash charge of $90 beyond the required insurance co-pay to fill a prescription for a Dexcom G-7 Sensor.

APPLICABLE LAW

8. Any sterile drug products sold or dispensed by a pharmacy shall be compounded in compliance with NAC 639.6701-.6702, *inclusive*, NAC 639.6705 -.67079, *inclusive*, and related federal law, 21 U.S.C. § 353a and USP-797 standards. NRS 639.100; NRS 639.286.

9. Pursuant to NRS 585.520(1) and (2) it is unlawful to sell or dispense an adulterated or misbranded drug (as defined in NRS 585.380, NRS 585.400, NRS 585.410, NRS 585.420 and/or NRS 585.460). Pursuant to NRS 454.351(1) it is unlawful to sell or dispense any drug which may not be lawfully introduced into interstate commerce under the Federal Food, Drug, and Cosmetic Act.

10. Pursuant to 21 U.S.C. § 331(a), (b) and (c) it is unlawful to engage in the sale and/or distribution of an adulterated or misbranded drug in interstate commerce.

11. No person may administer a dangerous drug without specific statutory authority to do so. NRS 454.213.

12. A pharmacy shall maintain complete, accurate and readily retrievable records of all dangerous drugs purchased and those sold on prescription, dispensed, furnished or disposed of otherwise. NRS 454.286; NRS 454.291; NAC 639.487(2); NAC 639.510(2)(b).

13. Selling or dispensing or permitting to be sold or dispensed substandard drugs or preparations constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(a) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

14. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

15. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

16. The Board may suspend or revoke a license if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

17. The Board may suspend or revoke a license if the holder has violated any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

18. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy, including recordkeeping. NRS 639.210(15), NRS 639.220(1) and/or NAC 639.510(2)(b).

19. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the

pharmacy by the Board. NRS 639.230(5). Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Violations of Federal Law – Dispensing Adulterated or Misbranded Drugs

20. By dispensing adulterated and/or misbranded sterile drug products that were not compounded in compliance with 21 U.S.C. § 353a and USP-797 guidelines, as alleged in paragraphs 3-5 herein, respondents violated 21 U.S.C. § 331(a), (b) and/or (c), and are therefore subject to discipline pursuant to NRS 639.210(11) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

COUNT TWO

Violations of State Law – Dispensing Adulterated or Misbranded Drugs

21. By dispensing adulterated and/or misbranded sterile drug products that were not compounded in compliance with NAC 639.6701-.6702, *inclusive*, NAC 639.6705 -.67079, *inclusive*, as alleged in paragraphs 3-5 herein, respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.351(1), NRS 585.520(1) and (2) and/or NRS 639.100(1), and are therefore subject to discipline pursuant to NRS 639.210(12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

COUNT THREE

Violations of State Law – Unlawful Administration of Drug

22. By directly administering compounded drug products to patients as alleged in paragraphs herein, respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.213, and are therefore subject to discipline pursuant to NRS 639.210(12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

\\\

\\\

\\\

\\\

COUNT FOUR

Violations of State Law - Recordkeeping

23. By failing to keep and maintain complete, accurate and readily retrievable records accounting for all dangerous drugs as alleged in paragraph 6 herein, respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.286, NRS 454.291, NAC 639.487(2) and/or NAC 639.510(2)(b), and are therefore subject to discipline pursuant to NRS 639.210(12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

COUNT FIVE

Unprofessional Conduct – Selling or Dispensing Substandard Drugs

24. By dispensing and/or directly administering adulterated and/or misbranded sterile drug products to patients, as alleged herein, respondents sold or dispensed substandard drugs or preparations and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(a), and are subject to discipline pursuant to NRS 639.210(4).

COUNT SIX

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

25. By attempting to charge patient M.M-S. an additional cash charge of $90 beyond the required insurance co-pay to fill a prescription for a Dexcom G-7 Sensor, Respondent Seo was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and all respondents are therefore subject to discipline pursuant to NRS 639.210(4), NRS 639.230(5) and/or NAC 639.945(3).

COUNT SEVEN

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

26. By their conduct as alleged herein, respondents have performed their duties as licensees/registrants in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 639.210(4).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the license and registrations of these respondents.

Signed this 21 day of October 2024.

J. David Wuest, RPh, Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **YOUJIN SEO, RPH,** **Certificate of Registration No. 18704,** **Respondent.**	**Case No. 24-289-RPH-A-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 21st day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **YOUJIN SEO, RPH** **Certificate of Registration No. 18704,** **Respondent.**	**Case No. 24-289-RPH-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

YOUJIN SEO, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 21st day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Laughlin Pharmacy & Wellness Center
3080 S Needles Hwy., Suite 1800
Laughlin, NV 89029

Youjin Seo, Rph
[redacted] Green Falls Ave
Henderson, NV 89052

Youjin Seo, Rph
Valley View Medical Center
5330 S Hwy 95
Fort Mohave, AZ 86426

Thu Vo, Rph
[redacted] E Clubhouse CV
Fort Mohave, AZ 86426

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT
BOARD COORDINATOR I

Docusign Envelope ID: 71245F8F-FCC5-451D-80D1-7E59F4C6E995

FILED
NOV 18 2024
NEVADA STATE BOARD OF PHARMACY

MICHAEL M LIN, ESQ.
Nevada Bar No. 010392
LIN LAW GROUP
5288 Spring Mtn. Rd, Ste 103
Las Vegas, Nevada 89146
(702) 871 9888
Attorneys for Respondent
YOUJIN SEO, RPH

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, vs. YOUJIN SEO, RPH Certificate of Registration No. 18704 Respondent.	Case No. 24-289-RPH-A-S ANSWER AND NOTICE OF DEFENSE

Respondent, YOUJIN SEO ("SEO"), by and through her counsel, Michael M Lin, Esq of Lin Law Group, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. With respect to Board's Notice of Intended Action and Accusation and the allegations contained in Paragraphs 1, 2, 4, 5, and 6, Respondent admits said allegations.

2. With respect to Board's Notice of Intended Action and Accusation and the allegations contained in Paragraphs 3 and 7, Respondent denies said allegations.

3. With respect to Board's Notice of Intended Action and Accusation and the allegations contained in Paragraphs 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18 and 19, this Answering Respondent states that the allegations in these paragraphs appear to be an alleged statement of law as opposed to factual allegations pertaining to this Answering Respondent, therefore, no answer by this Answering Respondent is required.

LIN LAW GROUP
5288 Spring Mtn Rd., Ste 103
Las Vegas, NV 89146
(702) 871-9888 FAX: (702) 648-0888

Docusign Envelope ID: 71245F8F-FCC5-451D-80D1-7E59F4C6E995

LIN LAW GROUP
5288 Spring Mtn Rd., Ste 103
Las Vegas, NV 89146
(702) 871-9888 FAX: (702) 648-0888

COUNT ONE

Violation of Federal Law- Dispensing Adulterated or Misbranded Drugs.

4. With respect to the Board's Notice of Intended Action and Accusation, and the allegations in Paragraph 20, the Respondent states and acknowledges that at the time of dispensing, Ms. Vo was the Pharmacist in Charge, solely responsible for managing the purchase and inventory of compounded weight-loss medications. Although SEO held an ownership role, Ms. Vo did not involve SEO in the decision-making process regarding these purchases, and SEO was not informed of the medication's actual source until July 6, 2024. Given their longstanding mentor-student relationship from Valley View Medical Center, SEO regarded Ms. Vo as a trusted supervisor and mentor and had full faith in her clinical expertise. SEO thus had no reason to question Ms. Vo's professional judgment or the source of the medications. In light of SEO's sincere reliance on a trusted colleague and lack of knowledge regarding the details of these transactions, we respectfully ask for the Board's understanding and compassion. As to all remaining allegations, this Answering Respondent respectfully denies each allegation therein.

COUNT TWO

Violations of State Law- Dispensing Adulterated or Misbranded Drugs

5. With respect to the Board's Notice of Intended Action and Accusation, and the allegations in Paragraph 21, the Respondent states and acknowledges the extraordinary pressures SEO faced from the very beginning of the pharmacy's operations. As a single mother solely responsible for her son with serious emerging medical issues, SEO was stretched beyond her limits, balancing caretaking with a grueling three-hour daily commute. Understanding SEO's personal burdens, Ms. Vo offered to assume responsibility for major business decisions, easing SEO's heavy load. Consequently, Ms. Vo, as the Pharmacist in Charge, independently managed purchasing and inventory for compounded weight-loss injections, while SEO trusted her clinical judgment based on their mentor-student relationship from Valley View Medical Center. SEO looked up to Ms. Vo as both a superior and mentor, relying on her guidance without question. SEO was unaware that the instructed dispensing practices might unintentionally involve

Docusign Envelope ID: 71245F8F-FCC5-451D-80D1-7E59F4C6E995

compounding activity in a non-sterile environment. In light of SEO's sincere efforts to manage her many responsibilities under challenging circumstances, we ask for the Board's understanding and compassion. As to all remaining allegations, this Answering Respondent respectfully denies each allegation therein.

COUNT THREE

Violations of State Law- Unlawful Administration of Drug

6. With respect to the Board's Notice of Intended Action and Accusation, and the allegations in Paragraph 22, the Respondent states and acknowledges that an elderly patient expressed discomfort with self-administering a weight-loss injection, ultimately requesting SEO's assistance. Understanding the patient's struggles—having previously received injections at another pharmacy and continuing to face challenges with self-injection—SEO was genuinely concerned that self-administration posed a significant risk to the patient's well-being. Driven by empathy and a sincere desire to ensure the patient's safety, SEO made the decision to administer the injection, an action taken in a moment of human compassion but acknowledged as a lapse in judgment. In light of the circumstances and the patient-centered motivation behind this decision, we ask for the Board's understanding and consideration. As to all remaining allegations, this Answering Respondent respectfully denies each allegation therein.

COUNT FOUR

Violation of State Law- Recordkeeping

7. With respect to the Board's Notice of Intended Action and Accusation, and the allegations in Paragraph 23, the Respondent states and acknowledges that SEO was genuinely unaware that dispensing the weight-loss injection as directed constituted compounding. Ms. Vo independently managed the inventory and record for the weight-loss injection, without SEO's involvement in the recordkeeping process. Ms. Vo assured SEO she would generate the necessary invoices based on purchase history, but SEO never received them. Given this unintentional oversight and SEO's commitment to compliance, we respectfully request the Board's understanding and consideration. As to all remaining allegations, the Respondent respectfully denies each.

LIN LAW GROUP
5288 Spring Mtn Rd., Ste 103
Las Vegas, NV 89146
(702) 871-9888 FAX: (702) 648-0888

Docusign Envelope ID: 71245F8F-FCC5-451D-80D1-7E59F4C6E995

LIN LAW GROUP
5288 Spring Mtn Rd., Ste 103
Las Vegas, NV 89146
(702) 871-9888 FAX: (702) 648-0888

COUNT FIVE

Unprofessional Conduct- Selling or Dispensing Substandard Drugs

8. With respect to the Board's Notice of Intended Action and Accusation, and the allegations in Paragraph 24, the Respondent states and acknowledges that, at the time of dispensing, SEO was genuinely unaware that the compounded medication did not meet the necessary standards. Acting in good faith and with a commitment to patient care, SEO dispensed the medication, completely unaware that it was substandard. This action was taken without any intent to compromise quality or patient safety. Given SEO's sincere efforts to fulfill responsibilities and the unintentional nature of this oversight, we respectfully ask for the Board's understanding and consideration. As to all remaining allegations, this Answering Respondent respectfully denies each allegation therein.

COUNT SIX

Unprofessional Conduct- Fraudulent/Deceitful Practice/Transaction

9. With respect to the Board's Notice of Intended Action and Accusation, and the allegations in Paragraph 25, the Respondent acknowledges the circumstances that led to this unfortunate outcome. After Deeflat Pharmacy's sudden closure, SEO hired Darren, a former Deeflat technician, to handle the increased patient transfer volume as a clerk. Despite her demanding shifts and lengthy commute, SEO remained focused on patient care over financial concerns. When Darren proposed that patient M.M-S help cover additional costs for Dexcom sensors, SEO immediately deemed the idea unethical and declined. Unbeknownst to her, Darren later attempted to impose an extra charge, prompting the patient to request a transfer. On June 8th, SEO found the Dexcom boxes in the Return Bin and promptly arranged the patient's transfer to Riverside Pharmacy. Shortly afterward, Darren resigned. Given SEO's dedication to patient welfare during difficult conditions, the Respondent respectfully requests the Board's understanding. As to all remaining allegations, this Answering Respondent denies each allegation therein.

COUNT SEVEN

Unprofessional Conduct- Incompetent, Unskillful or Negligent Performance of Duties

Docusign Envelope ID: 71245F8F-FCC5-451D-80D1-7E59F4C6E995

10. With respect to the Board's Notice of Intended Action and Accusation, and the allegations in Paragraph 26, the Respondent asserts that since becoming a registered pharmacist in 2013, SEO has consistently adhered to state regulations and maintained high standards of professionalism. Over her nine-year tenure as a pharmacy manager in major retail chains, SEO has prioritized patient safety and had no prior concerns regarding medication sources or compounded injectable quality in a retail setting. Having observed her peers disciplined for non-compliance, SEO relied on her supervisor, Ms. Vo, for guidance on dispensing protocols, including those for weight-loss injections. When product quality concerns surfaced in late May, SEO promptly contacted affected patients, and upon discovering additional issues in July, she proactively reached out to each patient to provide full disclosure, a sincere apology, and offered full refunds to those who requested them. Many patients appreciated her transparency and expressed a desire to remain under her care. In light of SEO's genuine efforts to prioritize patient well-being and her swift response to concerns, she respectfully requests the Board's understanding and compassion. As to the remaining allegations, the Respondent denies each.

WHEREFORE, Respondent prays this Board's understanding and compassion to take appropriate actions based on the facts and circumstances surrounding the responses.

11/18/2024 | 12:13:01 PM PST

DATED this ____ day of November, 2024

LIN LAW GROUP, PC

By: */s/ Michael M Lin*
MICHAEL M LIN, ESQ.
Nevada Bar No. 010392
5288 Spring Mtn. Rd, Ste 103
Las Vegas, Nevada 89146
(702) 871 9888
Attorneys for Respondent
YOUJIN SEO, RPH

LIN LAW GROUP
5288 Spring Mtn Rd., Ste 103
Las Vegas, NV 89146
(702) 871-9888 FAX: (702) 648-0888

Docusign Envelope ID: 71245F8F-FCC5-451D-80D1-7E59F4C6E995

DECLARATION

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 11/18/2024 | 12:11:18 PM PST

DocuSigned by:

748418E257EFA38...

YOUJIN SEO, RPH

///

///

///

LIN LAW GROUP
5288 Spring Mtn Rd., Ste 103
Las Vegas, NV 89146
(702) 871-9888 FAX: (702) 648-0888

Docusign Envelope ID: 71245F8F-FCC5-451D-80D1-7E59F4C6E995

CERTIFICATE OF SERVICE

11/18/2024 | 12:13:01 PM PST

I certify that I am an employee of Lin Law Group, and that on this _____ day of November, 2024, I served a true and correct copy of the foregoing document by emails below:

TeamBC@Pharmacy.nv.gov

And

bkandt@pharmacy.nv.gov

DS

DocuSigned by:
Michael
48BAE5D276E834E5...

An employee of Lin Law Group

LIN LAW GROUP
5288 Spring Mtn Rd., Ste 103
Las Vegas, NV 89146
(702) 871-9888 FAX: (702) 648-0888

5K

FILED
OCT 2 1 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LAUGHLIN PHARMACY & WELLNESS CENTER, Pharmacy License No. PH04520,** **YOUJIN SEO, RPH, Certificate of Registration No. 18704, and** **THU VO, RPH, Certificate of Registration No. 18661,** **Respondents.**	**Case Nos. 24-289-PH-S** **24-289-RPH-A-S** **24-289-RPH-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Youjin Seo, RPh (Seo), Certificate of Registration No. 18704, and Respondent Thu Vo, RPh (Vo), Certificate of Registration No. 18661, were pharmacists registered with the Board, and Respondent Laughlin Pharmacy & Wellness Center (Laughlin Pharmacy), Pharmacy License No. PH04520, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Seo and Vo co-owned Laughlin Pharmacy and Vo was managing pharmacist at the time of the events alleged herein.

3. Respondents dispensed and/or directly administered at least 51 syringes of sterile drug products as "weight loss injections" to five (5) different patients between January 3, 2024, and May 24, 2024.

4. The drug products included, without limitation, semaglutide 5mg and tirzepatide 10mg, purchased from and compounded by DeeFlat Pharmacy, Pharmacy License No. PH04171, located in Bullhead City, AZ, using non-sterile methods and adulterated and/or misbranded drugs.

5. The compounded drug products were purchased in vials and dispensed and/or administered in insulin use-only syringes.

6. Respondents maintained no records documenting the purchase of the compounded drug products from DeeFlat Pharmacy.

7. On or about June 5, 2024, Respondent Seo attempted to charge patient M.M-S. an additional cash charge of $90 beyond the required insurance co-pay to fill a prescription for a Dexcom G-7 Sensor.

APPLICABLE LAW

8. Any sterile drug products sold or dispensed by a pharmacy shall be compounded in compliance with NAC 639.6701-.6702, *inclusive*, NAC 639.6705 -.67079, *inclusive*, and related federal law, 21 U.S.C. § 353a and USP-797 standards. NRS 639.100; NRS 639.286.

9. Pursuant to NRS 585.520(1) and (2) it is unlawful to sell or dispense an adulterated or misbranded drug (as defined in NRS 585.380, NRS 585.400, NRS 585.410, NRS 585.420 and/or NRS 585.460). Pursuant to NRS 454.351(1) it is unlawful to sell or dispense any drug which may not be lawfully introduced into interstate commerce under the Federal Food, Drug, and Cosmetic Act.

10. Pursuant to 21 U.S.C. § 331(a), (b) and (c) it is unlawful to engage in the sale and/or distribution of an adulterated or misbranded drug in interstate commerce.

11. No person may administer a dangerous drug without specific statutory authority to do so. NRS 454.213.

12. A pharmacy shall maintain complete, accurate and readily retrievable records of all dangerous drugs purchased and those sold on prescription, dispensed, furnished or disposed of otherwise. NRS 454.286; NRS 454.291; NAC 639.487(2); NAC 639.510(2)(b).

13. Selling or dispensing or permitting to be sold or dispensed substandard drugs or preparations constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(a) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

14. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

15. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

16. The Board may suspend or revoke a license if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

17. The Board may suspend or revoke a license if the holder has violated any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

18. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy, including recordkeeping. NRS 639.210(15), NRS 639.220(1) and/or NAC 639.510(2)(b).

19. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the

pharmacy by the Board. NRS 639.230(5). Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Violations of Federal Law – Dispensing Adulterated or Misbranded Drugs

20. By dispensing adulterated and/or misbranded sterile drug products that were not compounded in compliance with 21 U.S.C. § 353a and USP-797 guidelines, as alleged in paragraphs 3-5 herein, respondents violated 21 U.S.C. § 331(a), (b) and/or (c), and are therefore subject to discipline pursuant to NRS 639.210(11) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

COUNT TWO

Violations of State Law – Dispensing Adulterated or Misbranded Drugs

21. By dispensing adulterated and/or misbranded sterile drug products that were not compounded in compliance with NAC 639.6701-.6702, *inclusive*, NAC 639.6705 -.67079, *inclusive*, as alleged in paragraphs 3-5 herein, respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.351(1), NRS 585.520(1) and (2) and/or NRS 639.100(1), and are therefore subject to discipline pursuant to NRS 639.210(12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

COUNT THREE

Violations of State Law – Unlawful Administration of Drug

22. By directly administering compounded drug products to patients as alleged in paragraphs herein, respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.213, and are therefore subject to discipline pursuant to NRS 639.210(12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

\\\

\\\

\\\

\\\

COUNT FOUR

Violations of State Law - Recordkeeping

23. By failing to keep and maintain complete, accurate and readily retrievable records accounting for all dangerous drugs as alleged in paragraph 6 herein, respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.286, NRS 454.291, NAC 639.487(2) and/or NAC 639.510(2)(b), and are therefore subject to discipline pursuant to NRS 639.210(12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

COUNT FIVE

Unprofessional Conduct – Selling or Dispensing Substandard Drugs

24. By dispensing and/or directly administering adulterated and/or misbranded sterile drug products to patients, as alleged herein, respondents sold or dispensed substandard drugs or preparations and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(a), and are subject to discipline pursuant to NRS 639.210(4).

COUNT SIX

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

25. By attempting to charge patient M.M-S. an additional cash charge of $90 beyond the required insurance co-pay to fill a prescription for a Dexcom G-7 Sensor, Respondent Seo was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and all respondents are therefore subject to discipline pursuant to NRS 639.210(4), NRS 639.230(5) and/or NAC 639.945(3).

COUNT SEVEN

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

26. By their conduct as alleged herein, respondents have performed their duties as licensees/registrants in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 639.210(4).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the license and registrations of these respondents.

Signed this 21 day of October 2024.

J. David Wuest, RPh, Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **THU VO, RPH,** **Certificate of Registration No. 18661,** **Respondent.**	**Case No. 24-289-RPH-B-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 21st day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **THU VO, RPH** **Certificate of Registration No. 18661,** **Respondent.**	**Case No. 24-289-RPH-B-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

THU VO, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 21st day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Laughlin Pharmacy & Wellness Center
3080 S Needles Hwy., Suite 1800
Laughlin, NV 89029

Youjin Seo, Rph
[redacted] Green Falls Ave
Henderson, NV 89052

Youjin Seo, Rph
Valley View Medical Center
5330 S Hwy 95
Fort Mohave, AZ 86426

Thu Vo, Rph
[redacted] E Clubhouse CV
Fort Mohave, AZ 86426

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT
BOARD COORDINATOR I

5L

FILED
OCT - 7 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAFE CHAIN SOLUTIONS, LLC,** **Wholesaler License No. WH02131,** **Respondent.**	**CASE NO. 24-356-WH-O** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Safe Chain Solutions, LLC, Nevada Wholesaler License No. WH02131, located in Cambridge, MD, was a wholesaler licensed by the Board.

FACTUAL ALLEGATIONS

2. In March and April 2021, Respondent sold and/or distributed counterfeit drugs purportedly manufactured by Gilead Sciences, Inc. (Gilead), for the treatment of HIV-1 patients, including Biktarvy and Descovy, to no fewer than two pharmacies located in Las Vegas, Nevada, including ASP Cares Pharmacy, Nevada Pharmacy License No. PH03347, and Trinity Pharmacy, Nevada Pharmacy License No. PH03287.

3. Respondent falsified transaction records, including, without limitation, a statement of prior sales, for each bottle of counterfeit drugs that fraudulently represented that the drugs could be traced back through the supply chain to an authentic sale from Gilead.

4. On or about June 8, 2023, the U.S. Food and Drug Administration (FDA) issued warning letter no. 636044 to Respondent for the sale and/or distribution of counterfeit Biktarvy and other drugs in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act):

> FDA has observed that Safe Chain did not have adequate verification systems in place in violation of section 582(c)(4)(A) & (B) of the FD&C Act. FDA observed that Safe Chain failed to maintain records regarding suspect product investigations in violation of section 582(c)(4)(A)(iii) of the FD&C Act, and failed to respond to a notification of illegitimate product in violation of section 582(c)(4)(B)(iii) of the FD&C Act. In addition, Safe Chain engaged in transactions with unauthorized trading partners in violation of section 582(c)(3) of the FD&C Act. Failure to comply with any of the requirements under section 582 of the FD&C Act is a prohibited act under section 301(t) of the FD&C Act (21 U.S.C. § 331(t)).

(SEE EXHBIT A HERETO).

5. On or about September 30, 2024, the Board issued an order to Respondent pursuant to NRS 639.2895 to cease and desist engaging in the sale and/or distribution of counterfeit HIV-1 drugs purportedly manufactured by Gilead, including Biktarvy and Descovy, into Nevada.

APPLICABLE LAW

6. The Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54), enacted by Congress on November 27, 2013, added Section 582 to the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 582 of the FD&C Act (21 U.S.C. § 360eee-1) establishes the requirements that certain entities in the pharmaceutical distribution supply chain (including wholesale drug distributors) must follow related to product tracing, verification, and authorized trading partners. Failure to comply is a prohibited act under 21 U.S.C. § 331(t).

7. A wholesaler must comply with State law when engaging in the sale and/or distribution of drug products into Nevada, including the maintenance of accurate transaction records, including, without limitation, a statement of prior sales identifying each prior sale, purchase, or trade of a drug. NRS 639.595; NAC 639.599; NAC 639.602; NAC 639.603.

8. Pursuant to 21 U.S.C. § 331(a), (b) and (c) it is unlawful to engage in the sale and/or distribution of an adulterated or misbranded drug in interstate commerce.

9. Pursuant to NRS 585.520(1) and (2) it is unlawful to sell or distribute an adulterated or misbranded drug (as defined in NRS 585.380, NRS 585.400, NRS 585.410, NRS 585.420 and/or NRS 585.460) in Nevada, which shall be deemed a counterfeit drug under NAC 639.605(3)(b). Pursuant to NRS 454.351(1) it is unlawful to sell or distribute any drug which may not be lawfully introduced into interstate commerce under the FD&C Act. Pursuant to NRS 639.550 and NRS 639.555 it is unlawful for a wholesaler to falsify a statement of prior sales for a drug.

10. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license issued by the Board. NRS 453.236(1) and NRS 639.210(4).

11. Performing any duties as a license holder in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

12. The Board may suspend or revoke a license if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

13. The Board may suspend or revoke a license if the holder has violated any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

COUNT ONE

Violation of Federal Law – Sale/Distribution of Counterfeit Drugs

14. By engaging in the sale and/or distribution of counterfeit HIV-1 drugs purportedly manufactured by Gilead into Nevada, as alleged herein, Respondent violated 21 U.S.C. § 360eee-1 and/or 21 U.S.C. § 331(a), (b), (c) and/or (t), and is subject to discipline pursuant to NRS 639.210(11).

COUNT TWO

Violation of State Law – Sale/Distribution of Counterfeit Drugs

15. By engaging in the sale and/or distribution of counterfeit HIV-1 drugs purportedly manufactured by Gilead into Nevada, as alleged herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.351(1), NRS 585.520(1) and (2), and/or NRS 639.595, and is subject to discipline pursuant to NRS 639.210(12).

COUNT THREE

Violation of Federal Law – Falsification of Records

16. By falsifying transaction records, including, without limitation, a statement of prior sales for each bottle of counterfeit drugs that fraudulently represented that the drugs could be traced back through the supply chain to an authentic sale from Gilead, as alleged herein, Respondent violated 21 U.S.C. § 360eee-1 and/or 21 U.S.C. § 331(a), (b), (c) and/or (t), and is subject to discipline pursuant to NRS 639.210(11).

COUNT FOUR

Violation of State Law – Falsification of Records

17. By falsifying transaction records, including, without limitation, a statement of prior sales for each bottle of counterfeit drugs that fraudulently represented that the drugs could be traced back through the supply chain to an authentic sale from Gilead, as alleged herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.550, NRS 639.555, NAC 639.599, NAC 639.602 and/or NAC 639.603, and is subject to discipline pursuant to NRS 639.210(12).

COUNT FIVE

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

18. By its conduct as alleged herein, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 639.210(4).

\\\

\\\

COUNT SIX

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

19. By its conduct as alleged herein, Respondent has performed its duties as the holder of a wholesaler license in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 639.210(4).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the license of this Respondent.

Signed this 7th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAFE CHAIN SOLUTIONS, LLC,** **Wholesaler License No. WH02131,** **Respondent.**	**Case No. 24-356-WH-O** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 7th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SAFE CHAIN SOLUTIONS, LLC,** **Wholesaler License No. WH02131,** **Respondent.**	**Case No. 24-356-WH-O** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

AUTHORIZED REPRESENTATIVE FOR SAFE CHAIN SOLUTIONS, LLC

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Safe Chain Solutions
822 Chesapeake Drive
Cambridge, Maryland 21613

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

5M

FILED
SEP 3 1 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JOHN T. KATZEN, MD,** **Certificate of Registration No. CS24228,** **Respondent.**	**CASE NO. 24-389-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent John T. Katzen, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS24228, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about September 13, 2024, Respondent surrendered his License No. 15386 to practice medicine to the Nevada State Board of Medical Examiners (NSBME) pursuant to a settlement agreement in Case No. 24-34676-1.

3. On or about September 25, 2024, Board staff served Respondent with notice that the surrender of his NSBME License No. 15386 to practice medicine operated as an immediate suspension of his Certificate of Registration No. CS24228 with the Board pursuant to NRS 639.2107, and that Respondent must immediately cease and desist possessing, administering and/or prescribing controlled substances for Nevada patients.

APPLICABLE LAW

4. A practitioner must hold a license to practice his or her profession in this State and be registered with both the DEA and the Board to possess, administer, prescribe and/or otherwise dispense any controlled substance. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

5. The Board may suspend or revoke a registration to prescribe a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

6. The surrender, revocation or a suspension that has not been stayed of any certificate, license or registration of a practitioner, as defined in NRS 453.126, NRS 454.00958 or NRS 639.0125, by a licensing board or the Drug Enforcement Administration operates as an immediate suspension of a certificate, license, registration or permit issued by the Board pursuant to NRS chapters 453, 454 or 639 to possess, administer, prescribe or dispense drugs. NRS 639.2107.

7. The pre-hearing suspension of any certificate, license or registration of a practitioner pursuant to NRS 233B.127(3), NRS 453.241(3) and/or NRS 639.2107 is subject to review by the Board. *Barry v. Barchi*, 443 U.S. 55, 99 S. Ct. 2642 (1979); *Spiegel v. Ryan*, 946 F.2d 1435, 1439 (9th Cir. 1991).

COUNT ONE
Surrender of NSBME License for Cause

8. By his surrender of his NSBME License No. 15386 to practice medicine for cause, Respondent no longer qualifies as a practitioner for registration to dispense controlled substances under federal or state law and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

COUNT TWO

Commission of Acts that Render Registration Inconsistent with the Public Interest

9. As detailed in the NSBME Order entered an order in Case No. 24-34676-1, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 31st day of September 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JOHN T. KATZEN, MD** **Certificate of Registration No. CS24228,** **Respondent.**	**Case No. 24-389-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 31st day of SEPTEMBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JOHN T. KATZEN, MD,** **Certificate of Registration No. CS24228,** **Respondent.**	**Case No. 24-389-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

JOHN T. KATZEN, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

John T. Katzen, MD
[redacted] W Charleston Blvd.
Las Vegas, NV 89117

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **JOHN TIMOTHY KATZEN, M.D., Respondent.**	**Case No. 24-34676-1**

FILED
SEP 13 2024
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

SETTLEMENT AGREEMENT

The Investigative Committee (IC) of the Nevada State Board of Medical Examiners (Board), by and through Alexander J. Hinman, Deputy General Counsel for the Board and attorney for the IC, and John Timothy Katzen, M.D. (Respondent), a licensed physician in Nevada, hereby enter into this Settlement Agreement (Agreement) based on the following:[1]

A. BACKGROUND

1. Respondent is a medical doctor currently licensed in active status by the Board pursuant to Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC) (collectively, the Medical Practice Act) to practice medicine in Nevada. His license was originally issued on June 23, 2014 (License No. 15386).

2. On June 28, 2024, in Case No. 24-34676-1, the IC filed a formal Complaint (Complaint) charging Respondent with violating the Medical Practice Act. Specifically, the Complaint alleges one (1) violation of NRS 630.301(3), Disciplinary Action by Another Licensing Board (Count I). By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

///

[1] All agreements and admissions made by Respondent are solely for final disposition of this matter and any subsequent related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, Respondent's agreements and admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, state or federal civil or criminal proceeding, any state or federal court proceeding, or any credentialing or privileges matter.

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

3. Respondent was properly served with a copy of this Complaint, has reviewed and understands this Complaint, and has had the opportunity to consult with competent counsel concerning the nature and significance of this Complaint.

4. Respondent is hereby advised of his rights regarding this administrative matter, and of his opportunity to defend against the allegations in the Complaint. Specifically, Respondent has certain rights in this administrative matter as set out by the United States Constitution, the Nevada Constitution, the Medical Practice Act, the Nevada Open Meeting Law (OML), which is contained in NRS Chapter 241, and the Nevada Administrative Procedure Act (APA), which is contained in NRS Chapter 233B and 622A. These rights include the right to a formal hearing on the allegations in the Complaint, the right to representation by counsel, at his own expense, in the preparation and presentation of his defense, the right to confront and cross-examine the witnesses and evidence against him, the right to written findings of fact, conclusions of law and order reflecting the final decision of the Board, and the right to judicial review of the Board's order, if the decision is adverse to him.

5. Respondent understands that, under the Board's charge to protect the public by regulating the practice of medicine, the Board may take disciplinary action against Respondent's license, including license probation, license suspension, license revocation and imposition of administrative fines, as well as any other reasonable requirement or limitation, if the Board concludes that Respondent violated one or more provisions of the Medical Practice Act.

6. Respondent understands and agrees that this Agreement, by and between Respondent and the IC, is not with the Board, and that the IC will present this Agreement to the Board for consideration in open session at a duly noticed and scheduled meeting. Respondent understands that the IC shall advocate for the Board's approval of this Agreement, but that the Board has the right to decide in its own discretion whether or not to approve this Agreement. Respondent further understands and agrees that if the Board approves this Agreement, then the terms and conditions enumerated below shall be binding and enforceable upon him and the Board.

///

///

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

B. TERMS & CONDITIONS

NOW, THEREFORE, in order to resolve the matters addressed herein, i.e., the matters with regard to the Complaint, Respondent and the IC hereby agree to the following terms and conditions:

1. **Jurisdiction**. Respondent is, and at all times relevant to the Complaint has been, a physician licensed to practice medicine in Nevada subject to the jurisdiction of the Board as set forth in the Medical Practice Act.

2. **Representation by Counsel/Knowing, Willing and Intelligent Agreement**. Respondent acknowledges he is not represented by counsel, and wishes to resolve the matters addressed herein without counsel. Respondent agrees that if representation by counsel in this matter materially changes prior to entering into this Agreement and for the duration of this Agreement, that counsel for the IC will be timely notified of the material change. Respondent agrees that he knowingly, willingly and intelligently enters into this Agreement after deciding to forgo a full consultation with and upon the advice of legal counsel.

3. **Waiver of Rights**. In connection with this Agreement, and the associated terms and conditions, Respondent knowingly, willingly, and intelligently waives all rights in connection with this administrative matter. Respondent hereby knowingly, willingly, and intelligently waives all rights arising under the United States Constitution, the Nevada Constitution, the Medical Practice Act, the OML, the APA, and any other legal rights that may be available to him or that may apply to him in connection with the administrative proceedings resulting from the Complaint filed in this matter, including defense of the Complaint, adjudication of the allegations set forth in the Complaint, and imposition of any disciplinary actions or sanctions ordered by the Board. Respondent agrees to settle and resolve the allegations of the Complaint as set out by this Agreement, without a hearing or any further proceedings and without the right to judicial review.

4. **Acknowledgement of Reasonable Basis to Proceed**. As of the time of entering into this Settlement Agreement, the allegations of the Complaint remain unproven. Respondent acknowledges that the IC believes it has a reasonable basis to allege that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. The IC acknowledges

Respondent is not admitting that the IC's claims/counts as alleged in the Complaint have merit and Respondent is agreeing to resolve this matter to avoid the costs of hearing and potential subsequent litigation. Respondent asserts if this matter were to proceed to hearing, he has evidence, witnesses, expert witness(es) and defenses to the counts/claims alleged in the Complaint, but for the purposes of resolving the matter and for no other purpose, Respondent waives the presentation of evidence, witnesses, expert witnesses, and defenses in order to effectuate this Agreement.

5. **Consent to Entry of Order**. In order to resolve this Complaint pending against Respondent, Respondent hereby agrees that the Board may issue an order finding that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. Accordingly, the following terms and conditions are hereby agreed upon:

a. Respondent admits to Count I, violation of NRS 630.301(3), Disciplinary Action by Another Licensing Board.

b. Respondent shall immediately cease the practice of medicine and immediately, voluntarily, surrender his license to practice medicine within the State of Nevada pursuant to NAC 630.240.

c. Respondent shall not reinstate or reapply for licensure within the State of Nevada prior to September 13, 2027.

d. Respondent will pay the costs and expenses incurred in the investigation and prosecution of the above-referenced matter in the amount of six hundred sixty-seven dollars and ninety-eight cents ($667.98), within ninety (90) days of the Board's acceptance, adoption, and approval of this Agreement.

e. This Agreement shall be reported to the appropriate entities and parties as required by law, including, but not limited to, the National Practitioner Data Bank.

f. Respondent shall receive a Public Letter of Reprimand.

g. Any other claims arising from the Board's corresponding investigative case file(s), shall be dismissed with prejudice.

/ / /

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

h. **Release from Liability**. In execution of this Agreement, Respondent understands and agrees that the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents are immune from civil liability for any decision or action taken in good faith in response to information acquired by the Board. NRS 630.364(2)(a). Respondent agrees to release the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents from any and all manner of actions, causes of action, suits, debts, judgments, executions, claims and demands whatsoever, known and unknown, in law or equity, that Respondent ever had, now has, may have or claim to have, against any or all of the persons, government agencies or entities named in this paragraph arising out of, or by reason of, this investigation, this Agreement or the administration of the case referenced herein.

6. **Procedure for Adoption of Agreement**. The IC and counsel for the IC shall recommend approval and adoption of the terms and conditions of this Agreement by the Board in resolution of this Complaint. In the course of seeking Board acceptance, approval and adoption of this Agreement, counsel for the IC may communicate directly with the Board staff and the adjudicating members of the Board.

Respondent acknowledges that such contacts and communications may be made or conducted ex-parté, without notice or opportunity to be heard on his part until the public Board meeting where this Agreement is discussed, and that such contacts and communications may include, but may not be limited to, matters concerning this Agreement, the Complaint and any and all information of every nature whatsoever related to this matter. The IC and its counsel agree that Respondent and/or Counsel for the Respondent may appear at the Board meeting where this Agreement is discussed and, if requested, respond to any questions that may be addressed to the IC or the IC's counsel.

7. **Effect of Acceptance of Agreement by Board**. In the event the Board accepts, approves and adopts this Agreement, the Board shall issue a final order, making this Agreement an order of the Board, and, pending full compliance with the terms herein, the case shall be closed

and all remaining claims arising out of the Complaint shall be dismissed with prejudice.

8. **Effect of Rejection of Agreement by Board**. In the event the Board does not accept, approve and adopt this Agreement, this Agreement shall be null, void and of no force and effect except as to the following agreement regarding adjudications: (1) Respondent agrees that, notwithstanding rejection of this Agreement by the Board, nothing contained in this Agreement and nothing that occurs pursuant to efforts of the IC to seek the Board's acceptance of this Agreement shall disqualify any member of the adjudicating panel of the Board from considering this Complaint and from participating in disciplinary proceedings against Respondent, including adjudication of this case; and (2) Respondent further agrees that he shall not seek to disqualify any such member absent evidence of bad faith.

9. **Binding Effect**. If approved by the Board, Respondent understands that this Agreement is a binding and enforceable contract upon Respondent and the Board.

10. **Forum Selection Clause**. The parties agree that in the event either party is required to seek enforcement of this Agreement in district court, the party's consent to such jurisdiction and agree that exclusive jurisdiction shall be in the Second Judicial District Court, State of Nevada, Washoe County.

11. **Attorneys' Fees and Costs**. The parties agree that in the event an action is commenced in district court to enforce any provision of this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs.

12. **Failure to Comply with Terms**. Should Respondent fail to comply with any term or condition of this Agreement once the Agreement has been accepted, approved and adopted by the Board, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order to Show Cause Hearing, which will be duly noticed. Failure to comply with the terms of this Agreement, including failure to pay any fines, costs, expenses or fees owed to the Board, is a failure to comply with an order of the Board, which may result in additional disciplinary action being taken against Respondent. NRS 630.3065(2)(a).

///

///

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

Further, Respondent's failure to remit payment to the Board for monies agreed to be paid as a condition of this Agreement may subject Respondent to civil collection efforts.

DATED this 14th day of August, 2024.

INVESTIGATIVE COMMITTEE OF THE NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: Alexander J. Hinman

ALEXANDER J. HINMAN
Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: ahinman@medboard.nv.gov
Attorney for the Investigative Committee

AGREED TO AND UNDERSTOOD.

DATED this 9 day of AUGUST, 2024.

By: John Timothy Katzen M.D

JOHN TIMOTHY KATZEN, M.D.
License No. 15386

SUBSCRIBED and SWORN to before me by John Timothy Katzen, M.D. this _____ day of _____, 2024.

_____
NOTARY PUBLIC

PLEASE SEE THE ATTACHED UPDATED NOTARIAL CERTIFICATE
A.O. 08/09/2024
A.O.

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

08pgs

SETTLEMENT AGREEMENT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 9TH day of AUGUST, 2024, by JOHN TIMOTHY KATZENE,

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

ARGELIA ORTIZ
Notary Public · California
Los Angeles County
Commission # 2346628
My Comm. Expires Feb 12, 2025

(Seal)

Signature

ORDER

IT IS HEREBY ORDERED that, the foregoing Settlement Agreement (Case No. 24-34676-1) was approved and accepted by the Nevada State Board of Medical Examiners on the 13th day of September, 2024.

DATED this 13th day of September, 2024.

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

NICK M. SPIRTOS, M.D., F.A.C.O.G.
Board President

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 895521
(775) 688-2559

JOE LOMBARDO
Governor



HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

September 25, 2024

VIA CERTIFIED U.S. MAIL AND ELECTRONIC MAIL TO:

[redacted]**@timothykatzenmd.com**

John T. Katzen, MD
[redacted] W Charleston Blvd
Las Vegas NV 89117

Re: Notice of Suspension of Registration No. CS24228 (Case No. 24-389-CS-S)

Dear Dr. Katzen:

The Nevada State Board of Pharmacy (Board) has been notified that your License No. 15386 to practice medicine has been surrendered to the Nevada State Board of Medical Examiners pursuant to a settlement agreement entered September 13, 2024. Please be advised that pursuant to NRS 639.2107 this operates as an immediate suspension of your Certificate of Registration No. CS24228 with the Board.

You may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense a controlled substance until you petition the Board for reinstatement pursuant to NRS 639.2565 and the Board reinstates your certificate of registration. Your PMP account is also suspended pursuant to NAC 453.078.

You may request a hearing before the Board to contest the suspension of your registration by submitting a written request to the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

Regards,

Brett Kandt
General Counsel
Nevada State Board of Pharmacy

5N

FILED
SEP 3 1 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JON SIEMS, MD,** **Certificate of Registration No. CS09874,** **Respondent.**	**CASE NO. 24-390-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Jon Siems, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS09874, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about September 16, 2024, the Nevada State Board of Medical Examiners (NSBME) entered an order in Case No. 24-13009-1, suspending Respondent's NSBME License No. 9250 to practice medicine for cause.

3. On or about September 25, 2024, Board staff served Respondent with notice that the suspension of his NSBME License No. 9250 to practice medicine operated as an immediate suspension of his Certificate of Registration No. CS09874 with the Board pursuant to NRS 639.2107, and that Respondent must immediately cease and desist possessing, administering and/or prescribing controlled substances for Nevada patients.

APPLICABLE LAW

4. A practitioner must hold a license to practice his or her profession in this State and be registered with both the DEA and the Board to possess, administer, prescribe and/or otherwise dispense any controlled substance. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

5. The Board may suspend or revoke a registration to prescribe a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

6. The surrender, revocation or a suspension that has not been stayed of any certificate, license or registration of a practitioner, as defined in NRS 453.126, NRS 454.00958 or NRS 639.0125, by a licensing board or the Drug Enforcement Administration operates as an immediate suspension of a certificate, license, registration or permit issued by the Board pursuant to NRS chapters 453, 454 or 639 to possess, administer, prescribe or dispense drugs. NRS 639.2107.

7. The pre-hearing suspension of any certificate, license or registration of a practitioner pursuant to NRS 233B.127(3), NRS 453.241(3) and/or NRS 639.2107 is subject to review by the Board. *Barry v. Barchi*, 443 U.S. 55, 99 S. Ct. 2642 (1979); *Spiegel v. Ryan*, 946 F.2d 1435, 1439 (9th Cir. 1991).

COUNT ONE

Suspension of NSBME License for Cause

8. By the suspension of his NSBME License No. 9250 to practice medicine for cause, Respondent no longer qualifies as a practitioner for registration to dispense controlled substances under federal or state law and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

COUNT TWO

Commission of Acts that Render Registration Inconsistent with the Public Interest

9. As detailed in the NSBME Order entered an order in Case No. 24-13009-1, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 31st day of September 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JON SIEMS, MD** **Certificate of Registration No. CS09874,** **Respondent.**	**Case No. 24-390-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 31st day of SEPTEMBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY; **Petitioner,** **v.** **JON SIEMS, MD,** **Certificate of Registration No. CS09874,** **Respondent.**	**Case No. 24-390-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

JON SIEMS, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Jon Siems, MD
[redacted] Via Patito
Coto de Caza, CA 92679

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT
BOARD COORDINATOR I

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NEVADA

* * * * *

In the Matter of the Charges and Complaint Against: **JON LANE SIEMS, M.D.,** **Respondent.**	**Case No.: 24-13009-1**

FILED
SEP 16 2024
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

ORDER OF SUSPENSION AND NOTICE OF HEARING

The Investigative Committee[1] (IC) of the Nevada State Board of Medical Examiners (Board) hereby **IMMEDIATELY SUSPENDS** the license of Jon Lane Siems, M.D. (Respondent) from the practice of medicine, pursuant to the Board's authority to regulate the practice of medicine in the State of Nevada pursuant to Nevada Revised Statutes (NRS) Chapter 630.

The IC issues this Order of Suspension (Order) based on its determination that Respondent violated a Board Order when he did not satisfy all of the conditions contained in the discipline issued by the Board after adjudication at the Board meeting on December 1, 2023. *See* **Exhibit 1**.

Prior to the preparation of this Order, Board Staff presented to the IC the following:

1. Respondent is a medical doctor licensed to practice medicine in the State of Nevada (License No. 9250). The Board issued his license on December 20, 1999.

2. On December 27, 2022, in Case No. 19-13009-2, the IC suspended Respondent's license to practice medicine in the State of Nevada pending a show cause hearing regarding the subject of that summary suspension via an Order of Summary Suspension.

3. On January 30, 2023, the IC filed a formal Complaint against Respondent in Case No. 23-13009-1 which facts relate directly back to an Order issued in Case No. 19-13009-2.

///

[1] The Investigative Committee of the Nevada State Board of Medical Examiners is composed of Board members Bret W. Frey, M.D., Chairman, Carl N. Williams, Jr., M.D., and Col. Eric D. Wade, USAF (Ret.).

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

4. On February 2, 2023, a show cause hearing was held regarding Respondent's suspension.

5. After attempts to serve Respondent with the formal Complaint on a previous date, Respondent was served with the formal Complaint in Case 23-13009-1 on March 3, 2023.

6. On April 13, 2023, a formal hearing was held in Case No. 23-13009-1.

7. On December 1, 2023, the Board adjudicated the matter and found that Respondent did indeed violate the single count of Knowing or Willful Failure to Comply with a Board Order, as provided by NRS 630.3065(2)(a), and imposed discipline.

8. The discipline the Board imposed was a written public reprimand, that Respondent's license be suspended for a period of one (1) year from December 28, 2022 to December 27, 2023, and on December 28, 2023, Respondent's license status shall be reinstated to an active-probation status; Respondent shall complete the University of San Diego Physician Assessment and Competency Evaluation Program (PACE), Competency Assessment, or substantially similar assessment by another entity approved by the Board within six (6) months of issuance of the Order; that any continuing medical education received for attending the program shall be in addition to the requirements that are regularly imposed upon Respondent as a condition of licensure in the State of Nevada pursuant to NAC 630.153(1); and Respondent was required to reimburse the Board the reasonable and necessary costs and expenses actually incurred in the investigation and prosecution of this case in the amount of seven thousand four hundred and ninety-nine dollars, and twenty cents ($7,499.20) within six (6) months of service of the Order.

9. Respondent received a deadline of June 1, 2024, to pay the fines and costs in Case No. 23-13009-1.

10. Johnna LaRue, CMBI, Compliance Officer for the Board sent Respondent a letter dated December 19, 2023, containing helpful instructions and deadlines to assist Respondent in complying with the Board Order. *See* **Exhibit 2**.

11. As of today's date, Respondent has not paid the costs in the amount of seven thousand four hundred and ninety-nine dollars, and twenty cents ($7,499.20) and is therefore in violation of the Board's Order.

12. NRS 630.3065(2)(a) states in pertinent part that [e]xcept as otherwise provided in NRS 630.2672, knowingly or willfully failing to comply with: (a) [a] regulation, subpoena or order of the Board or a committee designated by the Board to investigate a complaint against a physician, constitutes grounds for initiating disciplinary action.

13. Based on the foregoing, the IC finds that Respondent has willfully and knowingly violated the Board Order and is immediately suspended from the practice of medicine in the State of Nevada. *See* NRS 630.326(1).

ORDER

IT IS HEREBY ORDERED that the License of Jon Lane Siems, M.D. (9250) is immediately **SUSPENDED** until further order of the IC or Board, and Respondent is prohibited from engaging in any acts that constitute the practice of medicine pursuant to NRS 630.020; and

IT IS FURTHER ORDERED that a hearing on this matter is set for the **18th day of October, 2024, at 9:00 a.m.,** at the Board's office located at 9600 Gateway Drive, Reno, Nevada 89521, with video conferencing to the Las Vegas office at 325 E. Warm Springs Road, Suite 225, Las Vegas, Nevada 89119 to determine whether this suspension may continue, unless the parties mutually agree in writing to a different date and/or time to hold the hearing. *See* NRS 630.326(2).

DATED this 16th day of September, 2024.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

BRET W. [illegible]REY, M.D.
Chairman of the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

CERTIFICATE OF SERVICE

I hereby certify that I am employed by the Nevada State Board of Medical Examiners and that on the 16th day of September, 2024, I served a file-stamped copy of the foregoing **ORDER OF SUSPENSION AND NOTICE OF HEARING**, via Fed Ex (priority overnight), postage pre-paid, to the following parties:

JON LANE SIEMS, M.D.
31852 Via Patito
Coto de Caza, CA 92679

Tracking No.: 778618923066

DATED this 16th day of September, 2024.

MEG BYRD
Legal Assistant
Nevada State Board of Medical Examiners

EXHIBIT 1

EXHIBIT 1

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against JON LANE SIEMS, M.D., Respondent.	**Case No. 23-13009-1**

FILED
DEC 19 2023
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER

This case was presented for adjudication and decision before the Nevada State Board of Medical Examiners (Board), during a regularly scheduled Board meeting on December 1, 2023, at 8:40 a.m., (Pacific Standard Time), located at 325 E. Warm Springs Road, Suite 225, Las Vegas, NV 89119, video conferenced to 9600 Gateway Drive, Reno, NV 89521. Jon Lane Siems, M.D., (Respondent), was properly served with a notice of the adjudication, including the date, time and location, and was present and not represented by counsel. The adjudicating members of the Board participating in these Findings of Fact, Conclusions of Law, and Order (FOFCOL) were: Nick M. Spirtos M.D., F.A.C.O.G., Ms. Maggie Arias-Petrel, Ms. Pamela Beal, Irwin B. Simon, M.D., FACS, Joseph Olivarez, P.A.-C, and Jason B. Farnsworth, RRT, MBA. Chricy E. Harris, Esq., Deputy Attorney General, served as legal counsel to the Board.

The Board, having received and read the Complaint and exhibits admitted at the hearing of this matter, the Hearing Officer's Findings and Recommendations[1], and the transcript of the hearing, made its decision pursuant to its authority and provisions of the Nevada Revised Statutes (NRS) Chapter 630 and Nevada Administrative Code (NAC) Chapter 630 (collectively, the Medical Practice Act), NRS Chapter 622A, and NRS Chapter 233B, as applicable.

///

///

[1] The Hearing Officer's Findings and Recommendations were prepared by Charles Woodman, Esq., who was appointed as Hearing Officer under NRS 630.106 in this matter and presided over the hearing.

The Board, after due consideration of the record, evidence, and law, and being fully advised in the premises, makes its FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER in this matter, as follows:

FINDINGS OF FACT

I.

Respondent held an Active-Probation license to practice medicine in the State of Nevada issued by the Board from December 3, 2021, until December 27, 2022. An Order for Summary Suspension of Respondent's license was filed on December 27, 2022, served on December 27, 2022, which immediately suspended Respondent's license until a show cause hearing could be held to determine if his medical license would be reinstated during the regular hearing process. On February 2, 2023, a show cause hearing was held at the office of the Nevada State Board of Medical Examiners and the Hearing Officer entered his order during the hearing that continued the suspension of Respondent's medical license throughout the hearing process.

II.

On January 30, 2022, the Investigative Committee filed its formal Complaint in Case No. 23-13009-1, alleging Respondent violated the Medical Practice Act. Respondent was personally served with the Complaint by a USPS Certified mail on March 3, 2023. The Complaint alleges as follows: Count I, a violation of NRS 630.3065(2)(a) Knowing or Willful Failure to Comply with a Board Order.

Respondent did not answer or file a response to the allegations set forth in the Complaint. Pursuant to NAC 630.460(4), the allegations of the Complaint are deemed generally denied if an answer is not filed.

III.

An Early Case Conference was held at the conclusion of the show cause hearing. Donald K. White, Senior Deputy General Counsel was present on behalf of the Investigative Committee (IC) of the Board, with Hearing Officer Charles Woodman, Esq., Respondent participated in the Early Case Conference and show cause hearing but was not represented by an attorney.

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

In compliance with NAC 630.465 an Order After Prehearing and Order Confirming Hearing Date was filed March 1, 2023, setting dates for the formal hearing calendared to commence on April 13, 2023, at the Office of the Nevada State Board of Medical Examiners, 9600 Gateway Drive, Reno, Nevada 89521 video conferenced to the Board's Las Vegas Office, located at 325 E. Warm Springs Road, Suite 225, Las Vegas, NV 89119. All documents intended to be introduced as evidence in the case were to be exchanged on or before March 13, 2023. Respondent was served this Order via USPS Certified Mail on March 6, 2023, at his address of record.

IV.

On April 13, 2023, as duly noticed and ordered, a hearing was held before the Hearing Officer to receive evidence and to hear arguments of both parties. Legal counsel for the Investigative Committee, Donald K. White, Senior Deputy General Counsel appeared, along with Respondent, without legal counsel, and Hearing Officer Charles Woodman, Esq. Mr. White presented the IC's case, offered documentary evidence, and presented witness testimony. Exhibits one (1) through (4) from the IC and several of Respondent's exhibits, were marked and admitted into evidence.

The Hearing Officer provided the Synopsis and Analysis of Record, filed May 9, 2023. This matter was scheduled for final adjudication on December 1, 2023, at a regularly scheduled Board meeting.

The notice of the adjudication was sent via USPS Certified Mail on October 30, 2023, and was delivered to Respondent on November 3, 2023, at 10:14 a.m.

A copy of the adjudication materials along with a copy of the Hearing Officer's Synopsis and Analysis of Record were mailed via Fed Ex 2-Day and were delivered to Respondent's address of record on November 10, 2023.

V.

Pursuant to NRS 622A.300(5)(a), the Findings and Recommendations of the Hearing Officer are hereby approved by the Board in their entirety, with modification to the discipline, and

///

are hereby specifically incorporated and made part of this Order by reference and are attached hereto as **Exhibit 1**.

VI.

In accordance with the Synopsis and Analysis of Record, the Board hereby finds that the count set forth in the Complaint, and as recapitulated in Paragraph II above, have been established by a preponderance of the evidence.

VII.

If any of the foregoing Findings of Fact is more properly deemed a Conclusion of Law, it may be so construed.

CONCLUSIONS OF LAW

I.

The Board has jurisdiction over Respondent and the Complaint, and an adjudication of this matter by the Board members as set forth herein is proper.

II.

Respondent was timely and properly served with the Complaint, and all notices and orders in advance of the hearing and adjudication thereon, in accordance with NRS and NAC Chapters 630, NRS Chapters 241, 622A and 233B, and all legal requirements of due process.

III.

With respect to the allegations of the Complaint, the Board concludes that Respondent has violated NRS 630.3065(2)(a) Knowing or Willful Failure to comply with a Board Order, as alleged in Count I. Accordingly, Respondent is subject to discipline pursuant to NRS 630.352.

IV.

The Board finds that, pursuant to NRS 622.400, recovery from Respondent of reasonable attorneys' fees and costs incurred by the Board as part of its investigation and disciplinary proceedings against Respondent is appropriate. The Board has reviewed the Investigative Committee's Memorandum of Costs and Disbursements and Attorneys' Fees, and the Board finds them to be the actual fees and costs incurred by the Board as part of its investigative, administrative and disciplinary proceedings against Respondent, and finds them to be reasonable,

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

necessary, and actually incurred based on: (1) the abilities, training, education, experience, professional standing and skill demonstrated by Board staff and attorneys; (2) the character of the work done, its difficulty, its intricacy, its importance, the time and skill required, the responsibility imposed and the prominence and character of the parties where, as in this case, they affected the importance of the litigation; (3) the work actually performed by the Board's attorneys and staff, and the skill, time and attention given to that work; and (4) the product of the work and benefits to the Board and the people of Nevada that were derived therefrom.

V.

If any of the foregoing Conclusions of Law is more properly deemed a Finding of Fact, it may be so construed.

ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law, and good cause appearing therefore,

IT IS HEREBY ORDERED that:

1. Respondent has violated the Medical Practice Act, as alleged in the Complaint, as follows: one (1) violation of NRS 630.3065(2)(a), Knowing or Willful Failure to comply with a Board Order.

2. Pursuant to NRS 630.352(4)(e), the Board shall administer a written public reprimand to Respondent.

3. Respondent's license shall be suspended for a period of one year, from December 28, 2022, to December 27, 2023.[2] On December 28, 2023, Respondent's license status shall be reinstated to an Active-Probation status.

4. Pursuant to NRS 630.352(4)(k), Respondent shall complete at the University of San Diego Physician Assessment and Competency Evaluation Program (PACE), Competency Assessment, or substantially similar assessment by another entity approved by the Board within six (6) months of issuance of this Order. Any aforementioned hours of Continuing Medical

[2] Pursuant to the Board's motion imposing discipline, the one-year suspension imposed upon Respondent shall take into account the time he has been suspended since the Order of Summary Suspension, which was served upon him on December 28, 2022.

Education received for attending the program that is substantially related to PACE shall be in addition to the requirements that are regularly imposed upon Respondent as a condition of licensure in the State of Nevada pursuant to NAC 630.153(1).

5. Respondent shall reimburse the Board the reasonable and necessary costs and expenses actually incurred in the investigation and prosecution of this case in the amount of seven thousand four hundred and ninety-nine dollars, and twenty cents ($7,499.20) within six (6) months of service of this Order. The Board, and/or its designee, are granted the authority to collect any and all funds due under this Order.

6. Investigation Case Nos. 18-18146, 19-18953, 20-19625, 20-19679, 20-19736, 21-20367, 22-21285, 22-21357, 23-22654, 23-22790, and 23-22844 shall be dismissed with prejudice.

IT IS SO ORDERED.

DATED this 19th day of December, 2023.

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

NICK M. SPIRTOS, M.D., F.A.C.O.G.
President of the Board

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

CERTIFICATION

I certify that the foregoing is the full and true original **FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER** on file in the office of the Board of Medical Examiners in the matter of **JON LANE SIEMS, M.D.**, Case No. 23-13009-1.

I further certify that Nick M. Spirtos, M.D., F.A.C.O.G., is the President of the Nevada State Board of Medical Examiners and that full force and credit is due to his official acts as such; and that the signature to the foregoing ORDER is the signature of said Nick M. Spirtos, M.D., F.A.C.O.G.

IN WITNESS THEREOF, I have hereunto set my hand in my official capacity as Secretary-Treasurer of the Nevada State Board of Medical Examiners.

DATED this 19th day of December, 2023.

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: Maggie Arias-Petrel

MAGGIE ARIAS-PETREL
Secretary-Treasurer and Public Member of the Board

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

EXHIBIT 1

EXHIBIT 1

BEFORE THE BOARD OF MEDICAL EXAMINERS

OF THE STATE OF NEVADA

FILED
MAY - 9 2023
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

In the Matter of Charges and Complaint Against JON L. SIEMS, M.D., Respondent.	Case No.: 23-13009-1 (Case No.:19-13009-2)

SYNOPSIS AND ANALYSIS OF THE RECORD

Hearing Officer Charles B. Woodman, having heard a formal pre-hearing conference, as well as the formal Hearing of this matter, hereby presents the Nevada State Board of Medical Examiners with his formal Analysis of this case. This Analysis is based upon all evidence adduced at the formal Hearing, this Hearing Officer's findings of facts and conclusions of law, which findings include the credibility of the witnesses who gave evidence.

RELEVANT BACKGROUND

This is a combined case as shown in the caption, whereby the Investigative Committee ("IC") of the Board of Medical Examiners of the State of Nevada ("Board") alleged that Dr. Jon Lane Siems, M.D., ("Dr. Siems") failed to comply with the Settlement Agreement he entered into as resolution to Board Case 19-13009-2. The final page of that Settlement Agreement contains the Board's order mandating compliance with the Agreement. A duly noticed formal hearing of the matter was held before the undersigned Hearing Officer on April 13, 2023 at the Northern Nevada office of the Board in Reno. Mr. Donald K. White, Esq., Senior Deputy General Counsel appeared on behalf of the Board's IC. Dr. Siems appeared via videoconference from the Board's Southern Nevada office representing himself in pro se. The matter was duly recorded by a licensed reporter and is a matter of public record.

The formal Complaint in Board Case 23-13009-1 alleges a single count of Knowing or Willful Failure to Comply with a Board Order, a violation of NRS 630.3065(2)(a), which states that:

> The following acts, among others, constitute grounds for initiating disciplinary action or denying licensure:
> * * *
> 2. Except as otherwise provided in NRS 630.2672, knowingly or willfully failing to comply with:
> (a) A regulation, subpoena or order of the Board or a committee designated by the Board to investigate a complaint against a physician;

More specifically, the IC alleges at paragraphs 8-9 of the Complaint that:

> 8. Respondent [Dr. Siems] knowingly or willfully failed to comply with an order of the Board when he failed to complete 20 hours of CMEs or the PACE Program by or within the deadline he agree to with the Board [in Case 19-13009-2].
> 9. Additionally, the Settlement Agreement [in Case 19-13009-2] that Respondent signed and was subsequently approved by the Board clearly states that Respondent agreed to be placed on stayed suspension and that if he violated any terms of the agreement that the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order to Show Cause hearing.

Accordingly, the two cases are inextricably linked inasmuch as Dr. Siems' alleged violation of the Order at the final page of the Settlement Agreement entered into in Case 19-13009-2 makes up the entirety of the basis for Case 23-13009-1. Further, it appears that the Board may determine to take formal action in both such cases.

At commencement of the formal Hearing of this matter, Dr. Siems was again advised of his right to be represented by counsel, as this Hearing Officer has so advised him in prior proceedings. The Hearing proceeded with Dr. Siems electing to represent himself. See Transcript at page 5 ("T.5").

It is noted very significantly here that the Board has already determined that Dr. Siems "willfully and knowingly violated his Settlement Agreement" via the Board's Order of Suspension And Notice of Hearing filed December 27, 2022. That Order was issued summarily based on evidence proffered by the IC. A duly noticed formal Order to Show

Cause hearing to determine whether that summary suspension should continue was heard before the undersigned on February 2, 2023, with Dr. Siems in attendance, also representing himself at that time. After that hearing and in light of evidence provided by the IC and by Dr. Siems, this Hearing Officer confirmed the suspension pending further decisions by the Board and pending adjudication of the new complaint in Case 23-13009-1. The April 13 hearing was held to formally adjudicate Case 23-13009-1. At the hearing, the IC's burden was to prove by a preponderance of the evidence that Dr. Siems committed the violation alleged in the Complaint in Case 23-13009-1, i.e. that he knowingly or willingly failed to comply with the Board's order confirming his Settlement Agreement.

THE EVIDENCE

The evidence adduced at the April 13 hearing is summarized as follows (bold and italics are inserted by the Hearing Officer):

The IC's Deputy Chief of Investigations and Compliance Officer Johnna LaRue testified that:

Following the Board's approval of the Settlement Agreement entered into between Dr. Siems and the IC, Ms. LaRue mailed notice of the Board's decision to Dr. Siems' then counsel on December 14, 2021. T.15-17;

Ms. LaRue's letter, including a copy of the Settlement Agreement, disclosed the specific requirements with which Dr. Siems would have to comply to meet his obligations under the Settlement Agreement, and the fact that he would have one year from the date of the Board hearing to so comply, which would allow Dr. Siems until December 3, 2022 to meet all the conditions outlined in the Settlement Agreement, and required by the Board's Order thereon. T.18-20;

Receipt of Ms. LaRue's letter containing the Settlement Agreement and Board Order by Dr. Siems' then counsel[1] was confirmed via documentary evidence showing that it was received on December 18, 2021. T.21-22, 26, IC Exhibit 4;

[1] As noted, Dr. Siems was not represented by counsel at the formal Hearing in Case 19-13009-2. However, he retained counsel after the Hearing which culminated in execution of the Settlement Agreement.

Dr. Siems and his counsel both signed the Settlement Agreement. T.28;

Via a November 18, 2022 email to the IC's counsel Mr. White, Dr. Siems' counsel advised Mr. White that he was no longer representing Dr. Siems. T.29-30;

At no time did Dr. Siems' counsel or any other person ever contact Ms. LaRue or anyone else at the Board to request an extension of time for Dr. Siems to complete his requirements under the Settlement Agreement. T.31-33;

Extensions of time to comply with settlement agreement conditions are routinely given under reasonable circumstances. T.33-34;

Dr. Siems did not complete all his CMEs required by the Settlement Agreement within the mandated one-year period, nor did he complete the PACE program. T.34-35. Rather, the last required CMEs were completed within a few days following the February 2, 2023 hearing on the license suspension, (which would have been approximately two months late) . T.35;

Dr. Siems pressed Ms. LaRue on whether the Board should have required him (Dr. Siems) to complete the PACE program when he discovered that the program could not accommodate him. However, Ms. LaRue responded by saying that the Board would have amended the Settlement Agreement had Dr. Siems contacted the Board within the one-year period to advise that PACE could not accommodate him. T.38-43;

In response to Dr. Siems raising the issue of possibly not receiving a copy of the Settlement Agreement from his counsel, Ms. LaRue advised that she had worked a number of times in the past with the same attorney who represented Dr. Siems, and she has never had any issues with practitioners not receiving documents from that attorney. T.45-46;

Had the IC known at any time prior to expiration of his one-year timeline that the PACE program could not presently accommodate Dr. Siems, arrangements would have been made to take the matter back to the Board to alter the terms of the Settlement Agreement. T.47-48;

Dr. Siems recognized a copy of the Settlement Agreement and acknowledged that he signed it. T.51-52;

Dr. Siems acknowledged that he knew his deadline for complying with the terms of the Settlement Agreement was December 3, 2022. T.54;

At some time during December, 2022, Dr. Siems had his manager Isabella call the IC to provide an update on his process of complying with the Settlement Agreement, but not to request an extension of time. T.55-56;

Dr. Siems confirmed that while he does not recall receiving the IC's letter via his counsel following the approval of the Settlement Agreement, that does not mean that he does not remember the "settlement demands." "That's not my claim. I was aware of what the settlement demands were." On questioning by Mr. White, Dr. Siems acknowledged he was aware of the settlement demands as of the date he signed the document, i.e. November 24, 2021. T.57;

Email correspondence between Dr. Siems and the PACE program showed that Dr. Siems was not yet enrolled with PACE as of December 20, 2022, as his outstanding balance due for participation was $10,000.00. The balance due check was dated December 30, 2022, three days after service of the suspension order. T.61, 63-65, Respondent's Exhibits p.0003, 00095;

The first time that Dr. Siems, or his office personnel, contacted the PACE program was October 31, 2022 (or approximately 33 days prior to the compliance deadline in the Settlement Agreement). T.63;

When asked directly if he complied with the terms of the Settlement Agreement, Dr. Siems answered "No." T.65;

Dr. Siems was advised that he had the opportunity to present a defense case, but as the Board and its IC have the burden of proof, he (Dr. Siems) had no obligation to do so. Dr. Siems chose to provide a defense case. T.67-68;

Beginning at page 75 of the transcript, Dr. Siems provided a quite thorough history of some highly traumatic personal crises which began happening in his life in November, 2022, i.e. approximately one month or less before the December 3, 2022 deadline for complying with the Settlement Agreement. Those circumstances include a November 22, 2022 trip to Europe for approximately two weeks due to family medical emergencies,

ongoing emergent care of a young man that Dr. Siems refers to as his step-son upon return to the United States from Europe, and the necessity of a restraining order on December 23, 2022. The undersigned Hearing Officer declines to include details of those matters here to protect the privacy of Dr. Siems' and his family members. Suffice it to say that circumstances involving the mother of his children, and the young man whom Dr. Siems refers to as his step-son, were in crisis stage, which, according to sworn testimony, were physically and emotionally consuming. T.75-141;

Dr. Siems received a letter from the PACE program advising that the program could not accommodate Dr. Siems. That letter was dated April 6, 2023. T.82, Respondent's Exhibits p.0147;

Dr. Siems believes it is the Board's responsibility to determine whether or not the PACE program could accommodate him. Dr. Siems does not feel it is his responsibility to make that determination. T.84;

Dr. Siems testified that he waited four months, i.e. until the PACE program letter of April 6, 2023, to discover / confirm that PACE could not accommodate him. T.89;

Dr. Siems asked his witness Amel Youssef, O.D., if the trauma they jointly experienced because of her son's medical emergencies could distract a person "enough that mundane parts of life, perhaps, were ignored and made oblivious?" She testified in the affirmative. T.114-115;

ANALYSIS

This Hearing Officer did not find any witness who testified at the hearing to have credibility issues. While the witnesses called by Dr. Siems could be argued to be self-serving, those witnesses presented as genuine and factual. This Hearing Officer takes their testimony, along with all of that elicited by the IC, at full face value.

Dr. Siems executed the Settlement Agreement on November 24, 2021. He soon thereafter learned that pursuant to an Order of the Board, he had until December 3, 2022, to complete the conditions of his resolution. He first contacted the PACE program on October 31, 2022, one month and three days before his deadline for full completion of all conditions. That deadline came and went without Dr. Siems handling his CME or PACE

obligations. On December 27, 2022, Dr. Siems' license was summarily suspended for his failure to comply with the conditions of the Settlement Agreement. A formal noticed hearing confirming the suspension was held February 2, 2023. It was after that hearing that Dr. Siems completed his CME requirements, which was more than two months out of compliance. Dr. Siems received a letter confirming that the PACE program could not accommodate him on or after April 6, 2023, just a week prior to the formal Hearing on the Complaint alleging his failure to comply. And while Dr. Siems had his office manager contact the IC with a status update on his compliance at some time in December, 2022, (most likely after his December 3 deadline), at no time – either before or after the deadline - did Dr. Siems or his staff ever request additional time to complete his requirements under the Settlement Agreement.

Dr. Siems offered what is genuinely a compassion-evoking explanation of a series of unfortunate and even tragic events in his life - not the results of his doing - and which no doubt required a great deal of his time and attention. The evidence is clear that he responded well to loved ones in need. His actions were indeed admirable.

Unfortunately, Dr. Siems' defense is measured against three harsh realities. First, as he readily acknowledged, Dr. Siems failed to comply with the terms of his Settlement Agreement and the Board's Order mandating such. Second, Dr. Siems made no contact with the PACE program till he was only thirty-three days away from his deadline. Third, Dr. Siems did not reach out to the IC until after his deadline passed, and even when he had his office manager call, it was to provide a status update and not to seek additional time to comply. Further, it is apparent from the record that the great majority of the challenges that occurred in Dr. Siems' personal life arose either just prior to his compliance deadline – and some even occurred thereafter (such as the necessity of obtaining a restraining order).

Dr. Siems also offers as part of his defense that it should have been the Board's responsibility to ensure that the PACE program could accommodate his area of specialty / expertise before including such in the Settlement Agreement. While not fully articulated in the record, it appears to the Hearing Officer that those involved in crafting the Settlement Agreement had ample cause to believe based on past experience that the PACE program

could serve a physician of Dr. Siems' specialty. It is also apparent from the record that Covid-19 had impacted the ability of the PACE program to accommodate some specialties. Accordingly, the Hearing Officer does not recognize a basis to leave upon the Board sole responsibility for the potential availability of the PACE program to function for Dr. Siems. As stated repeatedly by the IC's counsel Mr. White, had Dr. Siems not waited 333 days to initiate contact with PACE, this case could have been quite different. Ms. LaRue made sufficiently clear that timely notice of any deficiency in the ability of the PACE program to serve in this case would have allowed the Board to amend its requirements. Finally, there is the logical reality that the party on the hook, i.e. the one with his licensure at stake, ought to engage in sufficient due diligence to ensure he is doing all that is required to preserve his valuable practice. Dr. Siems offered no explanation as to why he did not reach out to PACE until October 31, 2022, or why he did not complete his CMEs from the time he signed the Settlement Agreement in November, 2021, until his personal challenges arose in late November 2022. Finally, it must be recognized that Dr. Siems' counsel – who was an extension of Dr. Siems, participated in the negotiating and crafting of the Settlement Agreement. And it was Dr. Siems who executed that Agreement. And accordingly, Dr. Siems shares responsibility for what that Agreement contains.

It is also significant that the statute at issue here is one of strict liability. While Dr. Siems argues that the statute does not prohibit consideration of extenuating circumstances, that does not obviate the plain language of the law that "knowingly or willfully failing to comply with . . . [an] order of the Board constitutes grounds for initiating disciplinary action. The Settlement Agreement became an Order of the Board when the Board approved it. The Order is the final page of the Agreement. Dr. Siems candidly admitted he knew that he did not comply with that Order. The knowing prong of the statute is thus satisfied. And while not a necessary finding or conclusion since either a knowing *or* willful violation will trigger the ramifications of the statute, it can reasonably be determined that Dr. Siems' failure to comply was willful considering the long delay before he took any action whatsoever. The Hearing Officer finds Dr. Siems' passive description of the Board's Order as a "mundane part of life" as a reflection of the amount of concern

he had for the Order, which is further reflected in the long delay before any action was taken whatsoever. In any event, the knowing violation is clear and convincing, thus exceeding the IC's burden of proving their case by a preponderance of the evidence.

CONCLUSION

This Hearing Officer, while readily acknowledging the significant trying life events experienced by Dr. Siems and his family, must recommend that the Board find that Respondent Dr. Jon Lane Siems, M.D., violated the statute as alleged in the Complaint, in that he knowingly failed to comply with the terms of the Order contained within the Settlement Agreement. There is no doubt room for compassion for Dr. Siems in all he experienced in his personal life right around the compliance deadline. But those extenuating circumstances do not negate the knowing failure to meet his mandated obligations, especially when he took no action to inform the Board of those circumstances and/or to seek additional time to comply, or to have the requirements duly amended.

Respectfully submitted this 8th day of May, 2023.



Charles B. Woodman, Hearing Officer

EXHIBIT 2

EXHIBIT 2

NEVADA STATE BOARD OF MEDICAL EXAMINERS
9600 Gateway Drive
Reno, NV 89521

Nick M. Spirtos, M.D., F.A.C.O.G.
Board President

Edward O. Cousineau, J.D.
Executive Director

December 19, 2023

Jon Lane Siems, M.D.
41493 Margarita Road, #G109
Temecula, CA 92591-5570

Re: Compliance Case #23-13009-1

Dear Dr. Siems:

On December 1, 2023, the Nevada State Board of Medical Examiners, approved and accepted the Findings of Fact, Conclusions of Law and Order regarding the complaint filed on Case No. 23-13009-1 finding the following:

- Respondent has violated the Medical Practice Act, as alleged in the Complaint, as follows: one (1) violation of NRS 630.3065(2)(a), Knowing or Willful Failure to comply with a Board Order.

As a result, the Board entered its **ORDER** as follows:

- Pursuant to NRS 630.352(4)(e), the Board shall administer a written public reprimand to Respondent;
- Respondent's license shall be suspended for a period of one year, from December 28, 2022 to December 27, 2023. On December 28, 2023, Respondent's license status shall be reinstated to Active-Probation status;
- Respondent shall complete at the University of San Diego Physician Assessment and Competency Evaluation Program (PACE), Competency Assessment, or substantially similar assessment by another entity approved by the Board within six (6) months of issuance of this Order. Any aforementioned hours of Continuing Medical Education received for attending the program that is substantially related to PACE shall be in addition to the requirements that are regularly imposed upon Respondent as a condition of licensure in the State of Nevada pursuant to NAC 630.153(1);
- Respondent shall reimburse the Board the reasonable and necessary costs and expenses actually incurred in the investigation and prosecution of this case in the amount of seven thousand four hundred and ninety-nine dollars, and twenty cents ($7,499.20) within six (6) months of service of this Order. The Board, and/or its designee, are granted the authority to collect any and all funds due under this Order;
- Investigation Case Nos. 18-18146, 19-18953, 20-19625, 20-19679, 20-19736, 21-20367, 22-21285, 22-21357, 23-22654, 23-22790, and 23-22844 shall be dismissed with prejudice.

Your compliance with the terms and conditions pertaining to **CME's** will be monitored by Johnna S. LaRue, CMBI, Compliance Officer. Please contact me at (775) 324-9377 for any questions or concerns regarding CME's.

Your compliance with the terms and conditions pertaining to **Administrative Costs and Fines** will be monitored by Donya Jenkins, Chief of Finance and Human Resources. Please contact Ms. Jenkins at (775) 324-9354 for any questions or concerns regarding payment of costs and fines.

Please make note of the Board's new policies for making payments, credit cards, cashier's checks and money orders are the only form of payment accepted.

Payment can be made online at https://nsbme.us.thentiacloud.net/webs/nsbme/service/#/login.

Included in the Order are mandatory actions that you must fulfill some of which include:

1.) The costs in the amount of $7,499.20 are due by **June 1, 2024**.

2.) The University of San Diego Physician Assessment and Competency Evaluation Program (PACE), Competency Assessment, or substantially similar assessment by another entity is due by **June 1, 2024**.

Please contact me, in writing, **within 30 days** and provide the most expeditious method of contacting you. Thereafter, please update me immediately upon any change in your contact information. You may mail the information to the address below, fax it to 775-688-2553 or e-mail it to me at jlarue@medboard.nv.gov. In addition, any additional information required from you should be submitted to the same contact numbers and address.

If you have any questions, please call, or write. Thank you for your cooperation on this matter.

Respectfully,

Johnna S. LaRue, CMBI
Deputy Chief of Investigations/Compliance Officer
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, NV 89521
(775) 324-9377

JOE LOMBARDO
Governor



HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

September 25, 2024

VIA CERTIFIED U.S. MAIL AND ELECTRONIC MAIL TO:

[redacted]**@siemslasik.com**

Jon Siems, MD
[redacted] W Sahara Avenue [redacted]
Las Vegas NV 89117

Re: Notice of Suspension of Registration No. CS09874 (Case No. 24-390-CS-S)

Dear Dr. Siems:

The Nevada State Board of Pharmacy (Board) has been notified that your License No. 9250 to practice medicine was summarily suspended by the Nevada State Board of Medical Examiners pursuant to an order entered September 16, 2024. Please be advised that pursuant to NRS 639.2107 this operates as an immediate suspension of your Certificate of Registration No. CS09874 with the Board.

You may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense a controlled substance until you petition the Board for reinstatement pursuant to NRS 639.2565 and the Board reinstates your certificate of registration. Your PMP account is also suspended pursuant to NAC 453.078.

You may request a hearing before the Board to contest the suspension of your registration by submitting a written request to the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

Regards,

Brett Kandt
General Counsel
Nevada State Board of Pharmacy

50

FILED
SEP 28 2023
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW OKEKE, M.D.,** **Certificate of Registration No. CS10935,** **Respondent.**	**Case No. 19-013-CS-S** **FIRST AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a first amended notice of intended action under NRS 233B.127(3) and a first amended accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over Respondent Matthew Okeke, M.D. (Respondent), because Respondent, at the time of the violations alleged herein, held a Nevada controlled substance registration, Certificate of Registration No. CS10935.

2. Respondent is a physician licensed by the Nevada State Board of Medical Examiners to practice psychiatry in Nevada. During the time periods discussed herein, Respondent was a "practitioner" as that term is defined at NRS 453.126.

FACTUAL ALLEGATIONS

3. Between February 28, 2017, and November 21, 2018, Respondent maintained a psychiatric practice in Las Vegas, Nevada. During that time frame, while engaged at various times in overseas travel, Respondent issued or caused to be issued at least one hundred twenty (120) prescriptions for controlled substances. These included prescriptions for alprazolam, clonazepam, diazepam, lacosamide, pregabalin, lisdexamfetamine, and buprenorphine.

4. Respondent was located outside of the United States during the periods from: 1) February 26 to March 11, 2017; 2) September 27 to October 2, 2017; 3) June 30 to July 17, 2018; and 4) November 9 to November 23, 2018.

5. While engaged in overseas travel as alleged above, Respondent employed the following methods of issuing prescriptions for controlled substances: 1) Respondent pre-signed certain of the prescriptions and supplied then to persons under his supervision or control for subsequent distribution to consumers; 2) Respondent authorized or directed one or more persons under his supervision or control to issue prescriptions to consumers by affixing Respondent's signature to those prescriptions via a rubber stamp imprinted with Respondent's signature; and 3) Respondent authorized or directed one or more persons under his supervision or control to telephonically issue prescriptions for consumers using Respondent's name and controlled substances registration number.

6. During the periods described herein, Respondent intentionally failed to maintain patient treatment charts and/or records from which a person could reasonably determine whether Respondent had a bona fide therapeutic relationship with the persons to whom prescriptions for controlled substances were issued under Respondent's name and controlled substances registration number.

7. Respondent caused, directed, or permitted one or more persons under his supervision or control to issue prescriptions for controlled substances even though such person(s) were not licensed or registered under state or federal law to prescribe controlled substances. Respondent knew or should have known that such person(s) were not licensed or registered under state or federal law to prescribe controlled substances.

8. On or about March 9, 2020, the Nevada State Board of Medical Examiners disciplined Respondent for malpractice and for failure to maintain proper medical records.

9. On or about September 7, 2022, Respondent entered a guilty plea pursuant to a plea agreement of committing the offense of intentional failure to maintain adequate records, a gross misdemeanor violation of NRS 422.510(1).

10. On or about September 7, 2022, Discovery Mind Center Ltd. (Discovery Mind Center), a Nevada limited-liability company, entered a guilty plea pursuant to a plea agreement of submitting false claims to defraud Medicaid, a felony violation of NRS 422.540; and of using the identifying information of an older person for unlawful purposes, a felony violation of NRS 205.463.

11. At the time of the offenses described in paragraph 10 above, Respondent owned, controlled, and/or managed Discovery Mind Center. Respondent entered guilty pleas on behalf of Discovery Mind Center.

12. On or about December 8, 2022, the Nevada State Board of Medical Examiners disciplined Respondent for failure to maintain proper medical records.

13. On or about January 17, 2023, Respondent and Discovery Mind Center were sentenced for the criminal offenses described in paragraph 10 above. Discovery Mind Center was ordered to pay $330,000 in restitution, and Respondent was sentenced to probation and ordered to pay $300,000 in costs and penalties.

14. On or about February 21, 2023, Matthew Okeke, M.D., Ltd., a Nevada limited-liability company, was convicted pursuant to a plea agreement of one count of submitting false claims: Medicaid fraud, a category D felony in violation of NRS 422.540(1)(a) and NRS 422.540(2)(a), and one count of obtaining and using personal identifying information of an older person for unlawful purposes, a category D felony in violation of NRS 205.463(1) and NRS 205.463(3)(a).

15. At the time of the offenses described in paragraph 14 above, Respondent owned, controlled, and/or managed Matthew Okeke, M.D., Ltd., a Nevada limited-liability company. Respondent entered guilty pleas on behalf of the company.

16. On or about February 21, 2023, Matthew Okeke, M.D., Ltd., a Nevada limited-liability company, was sentenced for the offenses described in paragraph 14 above. The company was ordered to pay a fine of $100,000, among other fees and assessments.

17. Respondent was charged individually with the offenses described in paragraphs 9, 10, and 14 above. However, Respondent entered into plea agreements whereby he avoided individual convictions for all offenses except the gross misdemeanor offense described in paragraph 9 above.

18. On or about October 25, 2022, Respondent submitted to the Board his application to renew his certificate of registration to prescribe controlled substances. The application specifically directed Respondent to disclose any charges, arrests, or convictions. Respondent disclosed the

conviction described in paragraph 9 above, referring to it as a "misdemeanor for record keeping," but he did not disclose the individual charges and/or arrests related to the felony fraud charges mentioned in paragraphs 10 and 14 above.

APPLICABLE LAW

19. In Nevada, it is unlawful to dispense a controlled substance except as authorized by NRS Chapter 453. *See* NRS 453.321(1)(a). "Dispense" is defined to include the act of prescribing a controlled substance. *See* NRS 453.056.

20. Every practitioner who prescribes controlled substances in Nevada must secure and maintain a certificate of registration from the Board. NRS 453.226(1)(a); NRS 453.231(3). A practitioner who fails to secure and maintain such a registration is subject to criminal and/or civil penalties for prescribing controlled substances without a registration. *See* NRS 453.232; NRS 453.553; NRS 453.5531.

21. In addition to any criminal or civil penalties that may apply, the Board may revoke or suspend the existing registration of any practitioner who has been guilty of unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4).

22. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner: 1) performs, without the required registration, any task or operation for which registration is required; 2) performs his or her duties in an incompetent, unskillful, or negligent manner; 3) performs or engages in any fraudulent or deceitful transaction; or, 4) prescribes a drug as a prescribing practitioner to a patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship. *See* NAC 639.945(1)(h)-(o).

23. Additionally, the Board may revoke or suspend the registration of any practitioner who has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to controlled substances, *see* NRS 639.210(11), or who has violated any Nevada statute or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, *see* NRS 639.210(12).

24. Further, the Board may revoke or suspend the registration of any practitioner who has been convicted of a crime involving moral turpitude, dishonesty or corruption. *See* NRS 639.210(7)(c).

25. Finally, the Board may revoke or suspend the registration of any practitioner who "[h]as willfully made to the Board or its authorized representative any false statement which is material to the administration or enforcement of any of the provisions of [NRS chapter 639]." *See* NRS 639.210(9).

26. In addition to or in lieu of revoking or suspending a practitioner's certificate of registration due to any violation described herein, the Board may impose an administrative fine upon such practitioner. The fine may not exceed $10,000 for each offense. *See* NRS 639.255(1)(f) and (3).

COUNT ONE

Failure to Comply with Federal Registration Requirements

27. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribed controlled substances in Nevada without their having obtained a registration from the Drug Enforcement Division of the U.S. Department of Justice. This constitutes a violation of federal law relating to controlled substances. *See* 21 U.S.C. 822(a)(2); 21 C.F.R. § 1306.03(a)(1). It also constitutes a violation of NRS 639.210(11), an offense for which the Board may impose administrative discipline.

COUNT TWO

Failure to Comply with State Registration Requirements

28. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada without their having obtained a registration from the Board. This violates state law relating to controlled substances. *See* NRS 453.321(1); NRS 453.226. It also constitutes a violation of NRS 639.210(12), an offense for which the Board may impose administrative discipline.

COUNT THREE
Participating in Deceitful Transactions

29. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada.

30. Respondent engaged in the conduct described herein as part of a scheme to bill Medicaid for services that Respondent did not provide. In this regard, Respondent used prescriptions to falsely document patient visits that never occurred.

31. By causing prescriptions to be issued in the manner described herein, Respondent engaged in unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(h).

COUNT FOUR
Issuing Pre-signed Prescriptions

32. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada by supplying patients with written prescriptions that Respondent had signed or stamped in advance of his overseas travel.

33. By causing prescriptions to be issued in the manner described herein, Respondent violated NRS 639.2353 by issuing pre-signed prescriptions. This constitutes a violation of state law for which the Board may impose administrative discipline. *See* NRS 639.210(12). Through his conduct, Respondent has potentially subjected other persons to administrative discipline. *See* NAC 639.295(15). (a physician assistant is subject to discipline for supplying patients with pre-signed prescriptions).

COUNT FIVE
Issuing Prescriptions from Unauthorized Locations

34. Between May 18, 2022, and January 22, 2023, while located outside the United States, Respondent caused prescriptions for controlled substances to be issued in his name and under his controlled substances registration number.

35. By engaging in the conduct described herein, Respondent prescribed controlled substances from locations other than his office and/or a location properly registered with the Board. This constitutes a violation of state law for which the Board may impose administrative discipline. *See* NRS 453.226; NRS 639.210(12); NAC 453.130(3).

COUNT SIX

Performing Duties in an Incompetent, Unskillful, or Negligent Manner

36. Respondent failed to maintain patient charts and records from which the Board and/or a member of the Board's staff could reasonably ascertain whether Respondent maintained bona fide therapeutic relationships with the persons to whom prescriptions for controlled substances were issued between May 18, 2022, and January 22, 2023. Pursuant to NRS 453.246 and NAC 639.945(1)(o), Respondent had a legal duty to maintain such records.

37. By failing to maintain records as required by NRS 453.246 and NAC 639.945(1)(o), Respondent violated state law relating to controlled substances and/or performed his duties in an incompetent, unskillful and/or negligent manner. This is conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4) and (12); NAC 639.945(1)(i).

38. By subjecting persons under his supervision or control to potential disciplinary action, Respondent performed his duties in an incompetent, unskillful and/or negligent manner. This too is conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(i).

COUNT SEVEN

Failure to Establish Bona Fide Patient Relationships

39. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances for persons whom Respondent identified as his patients. Respondent did not establish bona fide therapeutic relationship with one or more of these ostensible patients.

40. Respondent's conduct as described above constitutes unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(o).

COUNT EIGHT
Conviction of Crime Involving Dishonesty

41. As described above, Respondent was convicted of intentional failure to maintain adequate records, a gross misdemeanor.

42. Respondent's conviction for intentional failure to maintain adequate records, a gross misdemeanor, was directly related to a fraudulent billing scheme involving the Discovery Mind Center and Matthew Okeke, M.D., Ltd., both limited-liability companies under the ownership and control of Respondent.

43. Respondent's conviction for intentional failure to maintain adequate records, a gross misdemeanor, amounted to a conviction for a crime involving dishonesty. The Board may impose administrative discipline based upon that conviction. *See* NRS 639.210(7)(c).

COUNT NINE
Willfully Making False Statements in Connection with Renewal Application

44. As alleged above, on or about October 25, 2022, Respondent submitted to the Board his application to renew his certificate of registration to prescribe controlled substances. On the application, Respondent falsely represented that he had never been charged with or arrested for a criminal offense other than a misdemeanor offense related to record keeping. When he made this representation, Respondent had recently been charged with and/or arrested for multiple felony offenses related to a scheme to defraud Medicaid.

45. When he made the above false representation, Respondent knew that he had recently been charged with and/or arrested for multiple felony offenses related to a scheme to defraud Medicaid.

46. Respondent's false statement was material to the Board's determination whether to renew Respondent's certificate of registration to prescribe controlled substances.

47. Having willfully made a false representation as alleged above, Respondent is subject to discipline pursuant to NRS 639.210(9).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 26th day of September 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the First Amended Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this First Amended Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW OKEKE, MD,** **Certificate of Registration No. CS10935,** **Respondent.**	**CASE NO. 19-013-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a First Amended Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the First Amended Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the First Amended Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the First Amended Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has rescheduled your hearing on this matter for Wednesday, December 6, 2023, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 26th day of September, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW OKEKE, MD,** **Certificate of Registration No. CS10935,** **Respondent.**	**CASE NO. 19-013-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the First Amended Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the First Amended Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the First Amended Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

MATTHEW OKEKE, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 29th day of September 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Liborius Agwara, JD, PhD
Law Offices of Libo Agwara, LTD
2785 E. Desert Inn Road, Suite 280
Las Vegas, NV 89121

Matthew Okeke, MD
[redacted] S. Las Vegas Blvd., [redacted]
Las Vegas, NV 89101

SHIRLEY HUNTING

5P

FILED
OCT 2 2 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JACK KELTON THOMAS, JR., DVM, Certificate of Registration Nos. CS08932 and DV00496,** **Respondent.**	**Case Nos. 22-187-CS-S** **FIRST AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), files the following document that will serve as both notice of the Board's intended action under NRS 233B.127(3) and a FIRST AMENDED accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Jack Kelton Thomas, Jr., DVM ("Respondent"). At the time of the events alleged below, Respondent held: i) a certificate of registration to prescribe controlled substances in Nevada; and ii) a certificate of registration to dispense dangerous drugs and controlled substances in Nevada. These certificates of registration are identified as Certificate of Registration No. CS08932 and Certificate of Registration No. DV00496, respectively, and they were issued by the Board pursuant to NRS 453.226, NRS 453.231, NRS 454.215, and NAC 639.7423.

2. The Board has jurisdiction over the subject matter of this accusation because the allegations below concern the procurement, possession, storage, and distribution of dangerous drugs and/or controlled substances. *See* NRS 639.070.

FACTUAL ALLEGATIONS

3. Between 2015 and June 2022, Respondent was a Doctor of Veterinary Medicine licensed by the Nevada Board of Veterinary Medical Examiners. As such, Respondent was a "practitioner" as that term is defined at NRS 639.0125 and NRS 453.126.

4. Between 2015 and June 2022, Respondent practiced veterinary medicine at the Animal Care Center of Pahrump, located at 6981 North Highway 160, in Pahrump, Nevada. Respondent owned and managed the practice until November 2019, at which time he transferred ownership and management responsibilities to AmeriVet Veterinary Partners ("AmeriVet").

5. Between November 2019 and June 2022, Respondent practiced veterinary medicine as an employee of AmeriVet. Respondent signed an employment contract with AmeriVet that purportedly relieved Thomas of any responsibility for managing the business of Animal Care Center of Pahrump.

6. Between November 2019 and June 2022, Kristin Rastella ("Rastella"), a veterinary technician, routinely ordered and/or accepted delivery of controlled substances that were administered and/or dispensed by Respondent within the scope of his veterinary practice. Drugs ordered by Rastella included buprenorphine, a Schedule III controlled substance. Rastella ordered buprenorphine using Respondent's credentials.

7. In May and June 2022, AmeriVet audited the books and records of Animal Care Center of Pahrump. The auditors were unable to reconcile purchase records and dispensing records. The auditors estimate that during the 24-month period covered by the audit, approximately 270 10ml vials of buprenorphine were diverted from the Animal Care Center of Pahrump. Ultimately, the auditors concluded that Rastella had diverted the missing buprenorphine. Rastella denied having diverted the missing buprenorphine.

8. On or about July 11, 2022, Kenneth R. Merrell, a senior management employee with AmeriVet, submitted to the Board a report of loss or theft of controlled substances. Respondent did not assist with the preparation, drafting, and/or submission of the report.

9. In a written statement to Board Investigator Kenneth Scheuber, Respondent denied any responsibility to supervise Rastella and/or to ensure the secure storage and tracking of controlled substances. Respondent stated that his employment contract with AmeriVet relieved him of management responsibilities.

10. Between November 2019 and June 2022, Respondent failed to designate or otherwise identify another practitioner with the responsibility to supervise Rastella and/or to ensure the secure storage and tracking of controlled substances at the Animal Care Center of Pahrump.

11. Between November 2019 and June 2022, Respondent was one of only three licensed veterinarians at the Animal Care Center of Pahrump with authority to procure and dispense controlled substances.

12. Between November 2019 and June 2022, as the former owner of the Animal Care Center of Pahrump, Respondent was the person most knowledgeable about the facility's practices and procedures related to the procurement, possession, storage, and dispensing of buprenorphine.

13. In November 2019, Respondent abdicated any responsibility for supervising the procurement, possession, storage, and dispensing by others of dangerous drugs and controlled substances.

14. In November 2019, upon abdicating his supervisory responsibilities at the Animal Care Center of Pahrump, Respondent failed to take reasonable steps to ensure that another practitioner assumed responsibility for supervising the procurement, possession, storage, and dispensing of dangerous drugs and controlled substances.

15. In November 2019, upon abdicating his supervisory responsibilities at the Animal Care Center of Pahrump, Respondent failed to take reasonable steps to notify Amerivet management that Rastella was ordering and handling controlled substances without meaningful supervision.

16. Despite his knowledge and familiarity with operations at the Animal Care Center of Pahrump, and despite having abdicated his supervisory responsibilities at the facility, Respondent did

not take reasonable steps to ensure that buprenorphine was ordered under some other practitioner's credentials.

17. As a result of Respondent's acts and/or omissions as described above, Amerivet failed to adequately supervise the receipt, possession, storage, and/or distribution of dangerous drugs and/or controlled substances at or from the Animal Care Center of Pahrump.

18. As a result of Respondent's acts and/or omissions as described above, Amerivet failed to adequately supervise non-practitioner employees with access to dangerous drugs and/or controlled substances at the Animal Care Center of Pahrump.

19. As a result of Respondent's acts and/or omissions as described above, Amerivet failed to properly secure dangerous drugs and/or controlled substances at the Animal Care Center of Pahrump.

20. As a result of Respondent's acts and/or omissions as described above, Amerivet failed to maintain accurate and/or complete inventory records of dangerous drugs and/or controlled substances at the Animal Care Center of Pahrump.

21. As a result of Respondent's acts and/or omissions as described above, one or more persons diverted approximately 270 10ml vials of buprenorphine from the Animal Care Center of Pahrump.

22. When Respondent became aware of the diversion as described above, Respondent advised, directed, and/or encouraged other AmeriVet employees to delay reporting the diversion to the Board and/or to the federal Drug Enforcement Administration (DEA). Respondent informed them that he would handle the reporting himself.

23. Respondent never reported the loss or theft of controlled substances to the Board and/or to the DEA.

24. Given his position, tenure, and responsibilities at the Animal Care Center of Pahrump, Respondent knew or reasonably should have known as early as February 2022 that one or more persons were diverting buprenorphine from the facility. Yet, Respondent failed to take reasonable steps to prevent the continued diversion of controlled substances from the Animal Care Center of Pahrump.

APPLICABLE LAW

25. The Board may revoke or suspend the registration of any practitioner who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the provisions of NRS chapter 639 or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. *See* NRS 639.210(12); NRS 453.231(1)(b); NRS 453.236(1)(e).

26. Additionally, the Board may revoke or suspend the registration of any practitioner who is guilty of unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4); NRS 453.231(1)(h); NRS 453.236(1)(e).

27. In lieu of, or in addition to revoking or suspending a practitioner's registration for violating the law or engaging in unprofessional conduct, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

28. A practitioner must establish and maintain effective controls and procedures to prevent or guard against theft and misuse of controlled substances. NAC 453.400.

29. All loss or theft of controlled substances must be reported within 10 days after the date of discovery of the theft or loss. NRS 453.568.

30. A practitioner's conduct is deemed unprofessional if the practitioner performs his or her duties in an incompetent, unskillful or negligent manner. *See* NAC 639.945(1)(i).

31. A practitioner's conduct is deemed unprofessional if the practitioner performs or in any way participates in any fraudulent or deceitful practice or transaction. *See* NAC 639.945(1)(h).

32. It is unlawful for a practitioner to dispense a controlled substance or dangerous drug in violation of any regulation adopted by the Board. *See* NRS 453.381(8); NRS 454.215; NRS 455.301. Further, it is unlawful for a veterinary technician to dispense controlled substances except at the direction of his or her supervising veterinarian. *See* NRS 453.375(1)(h).

33. A veterinarian may not allow veterinary assistants to prepare controlled substances for dispensing. *See* NAC 639.7423(2)(b). This function must be performed by the veterinarian or a veterinary technician.

34. A veterinarian must keep controlled substances and dangerous drugs in a secure container and must maintain a log of activity related to the acquisition, possession, storage, administration, and dispensing of the dangerous drugs and controlled substances contained therein. The log must include: i) the name of the veterinarian or veterinary technician who accessed the secure container and the date that he or she accessed the secure container; ii) the name, strength and quantity of the controlled substance or dangerous drug removed from or placed into the secure container and the total amount of all quantities of that particular controlled substance or dangerous drug remaining inside the secure container; iii) the name and quantity of any controlled substance or dangerous drug that will be destroyed and the date and time that the controlled substance or dangerous drug will be destroyed. *See* NAC 639.7423(5)(d) and (e). *See also* NRS 453.246; NAC 453.400; NAC 453.410.

35. A veterinarian must ensure that all controlled substances and dangerous drugs received by the veterinary facility are verified by a veterinarian or with the knowledge of the veterinarian. *See* NAC 639.7423(5)(g).

36. A veterinarian must maintain records and logs for at least 4 years and make those records and logs available for inspection by the Board or its representative or any authorized federal, state, or local regulatory agency or law enforcement agency. *See* NAC 639.7423(6).

\\\

\\\

\\\

\\\

COUNT ONE

Unprofessional Conduct by a Practitioner (Negligence)

37. Between November 2019 and June 2022, Respondent engaged in unprofessional conduct because he performed his duties in an incompetent, unskillful or negligent manner. Respondent's duties to his patients and others included those identified below.

38. Respondent had a duty to establish and maintain effective controls and procedures to prevent or guard against theft and misuse of controlled substances. NAC 453.400.

39. Respondent had a duty to report the loss or theft of controlled substances within 10 days after the date of discovery of the theft or loss. NRS 453.568.

40. Respondent had a duty to ensure that veterinary assistants and technicians did not enjoy unsupervised access to dangerous drugs and/or controlled substances. *See* NRS 453.375; NAC 639.7423; NAC 453.400.

41. Respondent had duty to ensure that all controlled substances and dangerous drugs received by the veterinary facility were verified by a veterinarian or with the knowledge of the veterinarian. *See* NAC 639.7423(5)(g).

42. Respondent had a duty to investigate credible allegations of diversion once those allegations came to his attention. *See* NAC 639.7423; NAC 453.400; NAC 453.410.

43. Respondent had a duty to adopt and/or implement reasonable procedures, protocols, and/or safeguards to prevent the unauthorized use of his credentials for the purpose of acquiring dangerous drugs and/or controlled substances. *See* NRS 453.246; NAC 639.7423; NAC 453.400; NAC 453.410.

44. Respondent had the duty to maintain accurate inventory and dispensing logs from which one could reasonably determine the name, strength, and quantity of dangerous drugs and controlled substances in Respondent's possession, and the dates upon which dangerous drugs and/or controlled substances were added to or removed from inventory. *See* NRS 453.246; NAC 639.7423(5)(d) and (e).

45. Respondent had the duty to maintain medical records, inventory logs, and/or dispensing logs for at least four years. *See* NAC 639.7423(6).

46. Respondent had the duty to report the loss or theft of controlled substances to the Board within 10 days after the date of discovery of the loss or theft. *See* NRS 453.568

47. Respondent failed to perform one or more of the duties listed above and/or performed one or more of said duties in an incompetent, unskillful or negligent manner. This amounts to unprofessional conduct for which the Board may discipline Respondent. NRS 453.236; NRS 453.241; NRS 639.210(4); NRS 639.255, NAC 639.945(1)(i); NAC 639.955.

COUNT TWO

Unprofessional Conduct by a Practitioner

48. As alleged above, Respondent knew or reasonably should have known that one or more persons had been diverting dangerous drugs and/or controlled substances from the Animal Care Center of Pahrump.

49. Respondent thereafter advised, directed, and/or encouraged other AmeriVet employees to delay reporting the diversion to the Board and/or to the DEA.

50. The conduct described above was deceitful.

51. The conduct described above caused Amerivet to violate the 10-day reporting requirement set forth at NRS 453.568.

52. By having committed any one or more of the acts or omissions described above, Respondent is subject to discipline by the Board. *See* NRS 453.236; NRS 453.241; NRS 639.210(4); NRS 639.255, NAC 639.945(1)(h); NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of Respondent Jack Kelton Thomas, Jr., DVM.

DATED this 22nd day of October 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JACK KELTON THOMAS, JR., DVM, Certificate of Registration Nos. CS08932 and DV00496,** **Respondent.**	**Case No. 22-187-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a First Amended Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 22nd day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JACK KELTON THOMAS, JR., DVM, Certificate of Registration Nos. CS08932 and DV00496,** **Respondent.**	**Case No. 22-187-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the First Amended Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the First Amended Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the First Amended Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

JACK KELTON THOMAS, JR., DVM

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 22nd day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Jack K. Thomas, Jr., DVM
c/o Animal Care Center of Pahrump
6981 N Hwy 160
Pahrump, NV 89060

Jack K. Thomas, Jr
[redacted] County Road [redacted]
Green Forest, AR 72638

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

FILED
OCT - 7 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **Jack Kelton Thomas, Jr., DVM, Certificate of Registration Nos. CS08932 and DV00496,** **Respondent.**	**Case No. 22-187-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

See attached.

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

See attached.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

JACK KELTON THOMAS, JR., DVM

FILED
OCT – 7 2024
NEVADA STATE BOARD
OF PHARMACY

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy
Suite 206
Reno, Nevada 89521

Subj: Response to Notice Of Intended Action and Accusation regarding Jack Thomas, Jr and Case No. 22-187-CS-S.

To: Nevada State Board of Pharmacy,

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: Incorrect, incomplete, and/or false allegations.

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies, and alleges as follows:

On Thursday September 19, 2024, I was advised by the current Practice Manager at Animal Care Center of Pahrump that an employee had signed for certified mail addressed to me. I personally paid to have this sent to my current mailing address and received the mail approximately 6 days later. I was not advised of the date of the signing by the employee. I strongly object to this action being delivered to my former place of employment when this office had my current mailing address per my 2022 interview with the board investigator. This action was mailed to Animal Care Center of Pahrump in Pahrump, Nevada. I have not worked or lived in Pahrump, Nevada since mid 2022 as was discussed during my conversation with the Nevada State Board of Pharmacy investigator in mid 2022. In response to the above listed action, I submit the following:

1. Under Factual Allegations, the following are not factual or are misleading:

   A. (8) I was never contacted nor given the opportunity to "cooperate with the.....of the report."
   B. (9) Between November of 2019 and June of 2022, there was "another practitioner with the responsibility of supervising Rastella.....Animal Care Center of Pahrump." This allegation is false.
   C. (10) Between November of 2019 and June of 2022, Respondent was not the only practitioner who regularly practiced veterinary medicine at the Animal Care Center of Pahrump. Respondent was not "the only employee on site.....without supervision. " This allegation is false.
   D. (16) (17) Respondent never advised, directed, and/or encouraged other Amerivet employees not to report the loss of theft of the controlled substances to the Board and/or DEA. Respondent recollection is these two bodies were never discussed with employees. The allegations regarding "the Board and/or DEA" are false.

2. In response to Count One:

   A. (34) All veterinarians at Animal Care Center of Pahrump "ensured that all controlled substances and dangerous drugs received by the veterinary facility were verified by a veterinarian or with knowledge of the veterinarian". The diversion was apparently done during the ordering and prior to the receiving of the products by the veterinarian. No product was diverted after verification by the veterinarian. Kristin Rastella, apparently, removed the product prior to verification.

   B. (36) As in my previous statement, I had no knowledge that my license or credientials were being used to purchase or maintain buprinorphine from an Amerivet distributer for Animal Care Center of Pahrump. That information was never advised to me in either verbal or written form. Amerivet Veterinary Partners purchased Animal Care Center of Pahrump in November 2019 and removed the entirety of my management or administrative duties per my employment contract at that time.

   C. (37) I maintained impeccable records in my duties as an employed veterinarian at Animal Care Center of Pahrump. Each of my uses of dangerous or controlled drugs was noted in both patient medical records and in applicable controlled substance logs. This was done in great detail in both medical and surgical records.

   D. (38) I was meticulous, as with any other veterinarians working at Animal Care Center of Pahrump, in "maintaining accurate inventory and dispensing logs.....added or removed from inventory".

   E. (39) I was not responsible for maintaining all "medical records, inventory logs, and/or dispensing logs for at least 4 years". Amerivet Veterinary Partners purchased Animal Care Center of Pahrump as a business and the facility in which it was located in November 2019. Per my employment contract, I was relieved of any and all management and administrative duties. It was reported to me that Kristin Rastella had destroyed some or all paperwork and records shortly after I retired or while I was on vacation prior to my retirement.

3. In response to Count Two:

   A. (43) (44) I never "advised, directed, and/or encouraged other AmeriVet employees to "conceal the diversion" or "not report the theft of controlled substances to the Board and/or the DEA." Those are both false.

I am unable to attend the hearing scheduled on October 16, 2024, and submit this statement as my response. Amerivet Veterinary Partners is the company that owned Animal Care Center of Pahrump (business and facility) and was responsible for all protocols. I had no management or administrative responsibilities from November 2019 to my retirement in July 2022. I retired my Nevada State Board of Veterinary Examiners license and my Nevada State Board of Pharmacy license shortly after my retirement in July of 2022.

I, hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated are true and correct to the best of my knowledge.

Dated this third day of October 2024.

Please contact me at this email address regarding any further communication.

Respectfully submitted,

Dr. Jack K Thomas, Jr BS, DVM

5Q

FILED
OCT 2 8 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WILSON F. BERNALES, M.D.,** **Certificate of Registration No. CS27754,** **Respondent.**	**CASE NO. 23-015-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (the "Board") has personal jurisdiction over Respondent Wilson F. Bernales, M.D. ("Respondent"), because Respondent holds a certificate of registration issued by the Board that authorizes him to prescribe controlled substances in Nevada.

2. The Board has jurisdiction over the subject matter of this accusation because it implicates Respondent's fitness to hold a certificate of registration authorizing him to prescribe controlled substances in Nevada.

FACTUAL ALLEGATIONS

3. Since 2011, Respondent has been licensed by the Nevada State Board of Medical Examiners to practice medicine in Nevada.

4. Respondent is a "practitioner" as that term is defined at NRS 453.126(2).

5. Respondent currently holds Certificate of Registration No. CS27754, which was issued by the Board pursuant to NRS 453.226 and NRS 453.231. Certificate of Registration No. CS27754 authorizes Respondent to prescribe controlled substances in Nevada.

6. Respondent applied for and obtained Certificate of Registration No. CS27754 in September 2018. Respondent submitted an initial application dated September 12, 2018, and renewal applications dated September 18, 2020, and October 5, 2022.

7. In 2012, Respondent first applied for a certificate of registration to prescribe controlled substances in Nevada. Between 2012 and 2016, Respondent held certificate no. CS20454. That certificate expired on November 1, 2016, due to non-renewal.

8. In 1991, Respondent received a degree from the Divine Word College of Medicine in Tacloban, Philippines.

9. During some period of time between 1991 and 2002, Respondent served in the United States Army.

10. On information and belief, Respondent was dismissed, discharged, or administratively separated from the U.S. Army under other than honorable conditions.

11. On or about January 24, 2002, Respondent was dismissed from the Floyd Medical Center Residency Program in Rome, Georgia (the "Floyd Program").

12. On or about December 27, 2002, proctors for Step 3 of the United States Medical Licensing Examination ("USMLE") reported that Respondent brought a cellular telephone and a pager into the testing room during the examination in violation of testing protocols.

13. In 2005, Respondent applied for and obtained a license to practice medicine in New York.

14. In 2006, Respondent participated in the Obstetric Fellowship in the Department of Family Medicine of the Louisiana State University ("LSU Program").

15. In February 2006, Respondent was placed on probation by, and then summarily dismissed from the LSU Program. Respondent reportedly interacted with staff in an unprofessional manner and failed to discuss with the attending physician the management of a labor and delivery unit patient.

16. In 2006, Respondent applied for and obtained a license to practice medicine in Delaware.

17. In 2007, Respondent applied for and obtained a license to practice medicine in Wyoming.

18. In January 2012, Respondent applied for and obtained a license to practice medicine in New Mexico.

19. In 2012, Respondent applied for and obtained a license to practice medicine in Pennsylvania.

20. On October 2, 2012, Respondent applied for a license to practice medicine in Virginia.

21. In support of his application for a license to practice medicine in Virginia, Respondent submitted two letters of recommendation that were ostensibly drafted and signed by supervisors for whom he had allegedly worked while practicing medicine in Wyoming. The letters of recommendations were fakes and/or forgeries.

22. In 2014, Respondent applied for and obtained a license to practice medicine in Connecticut.

23. In 2015, Respondent applied for and obtained a license to practice medicine in Florida.

24. On July 15, 2015, after investigating Respondent's background, the Virginia Board of Medicine denied Respondent's application for a license to practice medicine in Virginia.

25. In support of its decision to deny licensure, the Virginia Board of Medicine noted Respondent's dismissal from the Floyd Program, his dismissal from the LSU Program, the incident at the USMLE testing center, and his submission of fake and/or forged letters of recommendation in support of his application for licensure.

26. The 2015 action by the Virginia Board of Pharmacy prompted regulators to initiate administrative disciplinary actions in the various jurisdictions where Respondent was then licensed to practice medicine.

27. For example, after having been denied licensure in Virginia, Respondent was formally disciplined by medical licensing authorities in New York, Pennsylvania, New Mexico, Florida, Connecticut, Delaware, Nevada, and Wyoming. In some cases, Respondent's license to practice medicine was revoked or suspended. In other cases, Respondent was reprimanded and/or fined.

28. Generally, in any given jurisdiction, the discipline was related to one or more of the following factors: i) Respondent's dismissal from the Floyd Program and/or his failure to disclose the same; ii) Respondent's dismissal from the LSU program and/or his failure to disclose the same; iii) the incident at the USMLE testing center and/or Respondent's failure to disclose the same; iv) Respondent's submission of fake and/or forged letters of recommendation in support of his application for licensure in Virgina; v) Respondent's failure to disclose that he was denied licensure in Virginia; and, vi) Respondent's failure to disclose that he was disciplined by one or more medical licensing authorities due to the foregoing.

29. The disciplinary actions taken against Respondent by New York, Pennsylvania, New Mexico, Florida, Connecticut, Delaware, Nevada, and Wyoming became final and enforceable at various points in time between March 2016 and January 2018; Respondent did not file any licensure applications with the Board during that time frame.

30. On or about September 12, 2018, Respondent filed with the Board his application for Certificate of Registration No. CS27754. In that application, Respondent disclosed the disciplinary actions taken against him by New York, Pennsylvania, New Mexico, Florida, Connecticut, Delaware, Nevada, and Wyoming.

31. In March 2022, Respondent was disciplined in Oklahoma for one or more of the same reasons that he was disciplined in New York, Pennsylvania, New Mexico, Florida, Connecticut, Delaware, Nevada, and Wyoming. Respondent disclosed the Oklahoma discipline in his 2022 renewal application for Certificate of Registration No. CS27754. The 2022 disclosure prompted an investigation by the Board.

32. In his renewal applications dated September 18, 2020, and October 5, 2022, Respondent stated that he had never served on active duty in the military. The application forms submitted by Respondent prior to 2020 did not pose questions about military service.

APPLICABLE LAW

33. Every practitioner who intends to prescribe controlled substances in Nevada must first apply for and obtain a certificate of registration from the Board. NRS 453.226(1)(a); NRS 453.231(3). A practitioner who fails to register may be subject to criminal and/or civil penalties for prescribing controlled substances without a certificate of registration. *See* NRS 453.232; NRS 453.553; NRS 453.5531; NRS 639.100.

34. A certificate of registration to prescribe controlled substances expires on October 31 of each even-numbered year. NAC 453.210. The registration must be renewed on a form prescribed by the Board. NAC 453.220. The Board may deny a renewal application if it determines that registration would be inconsistent with the public interest. *See* NRS 453.231; NRS 453.241; NRS 639.241-.257.

35. The holder of any certificate, license, or permit issued by the Board must report to the Executive Secretary of the Board any "administrative action taken against the holder by any professional licensing board or any state or federal agency not later than 30 days after the final disposition of the administrative action and provide any documentation of the administrative action requested by the Executive Secretary." NAC 639.229.

36. The Board may revoke or suspend the registration of any practitioner who "[h]as had a certificate, license or permit suspended or revoked in another state on grounds which would cause suspension or revocation of a certificate, license or permit in this State." NRS 639.210(14).

37. The Board may revoke or suspend the registration of any practitioner who has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent. NRS 453.236(1)(a); NRS 639.210(9)-(10).

38. The Board may revoke or suspend the registration of any practitioner who is guilty of unprofessional conduct or conduct contrary to the public's interest. *See* NRS 639.210(4); NRS 453.231(1)(h); NRS 453.236(1)(e). A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner performs or is in any way a party to any fraudulent or deceitful practice or transaction. NAC 639.945(1)(h).

COUNT ONE
Engaging in Deceitful Transactions

39. As noted above, on October 2, 2012, Respondent applied for a license to practice medicine in Virginia. In support of his application, Respondent submitted two letters of recommendation that were ostensibly drafted and signed by supervisors for whom he had allegedly worked while practicing medicine in Wyoming. The letters of recommendations were fakes and/or forgeries.

40. By submitting faked and/or forged letters of recommendation in support of his application for licensure in Virginia, Respondent engaged in a deceitful or fraudulent practice or transaction.

41. By virtue of his misconduct in Virginia as described above, Respondent is subject to discipline in Nevada for unprofessional conduct and/or conduct contrary to the public interest. *See* NRS 639.210(4), (9)-(10); NRS 453.236(1)(e): NAC 639.945(1)(h).

COUNT TWO
Suspension or Revocation of License in Another Jurisdiction

42. As noted above, on October 2, 2012, Respondent applied for a license to practice medicine in Virginia. In support of his application, Respondent submitted two letters of recommendation that were ostensibly drafted and signed by supervisors for whom he had allegedly worked while practicing medicine in Wyoming. The letters of recommendations were fakes and/or forgeries.

43. On the basis of the conduct described above, Respondent's licenses to practice medicine were either revoked or suspended in New Mexico, Connecticut, Delaware and/or Wyoming.

44. Respondent's licenses to practice medicine in New Mexico, Connecticut, Delaware and/or Wyoming were suspended or revoked on grounds which would cause suspension or revocation of a certificate, license or permit in Nevada. *See* NRS 453.231(1)(f); NRS 453.236(1)(a).

45. Respondent is subject to discipline in Nevada by virtue of the suspension and/or revocation actions in New Mexico, Connecticut, Delaware and/or Wyoming. NRS 639.210(14); NRS 453.231(1)(f); NRS 453.236(1)(a).

COUNT THREE
Making False Statements on Renewal Applications

46. For Certificate of Registration No. CS27754, Respondent submitted renewal applications dated September 18, 2020, and October 5, 2022. In those renewal applications, Respondent falsely stated that he had never served on active duty in the military.

47. As noted above, Respondent served in the U.S. Army during some unknown period of time between 1991 and 2002.

48. On information and belief, Respondent was dismissed, discharged, or administratively separated from the U.S. Army under other than honorable conditions.

49. On information and belief, Respondent denied having served in the military in order to conceal the facts and circumstances surrounding his discharge, dismissal, or administrative separation from the U.S. Army. These facts and circumstances were material to the Board's decision whether to renew Certificate of Registration No. CS27754.

50. By falsely stating that he had never served in the military, Respondent submitted renewal applications to the Board that were false or fraudulent.

51. By falsely stating that he had never served in the military, Respondent engaged in fraudulent or deceitful practices or transactions.

52. Respondent may be disciplined for any one or more of the acts and/or omissions described above. NRS 453.236(1)(a); NRS 639.210(4), (9) and (10); NAC 639.945(1)(h).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate

disciplinary action with respect to the certificate of registration of Respondent Wilson F. Bernales.

DATED this 28th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WILSON F. BERNALES, M.D.,** **Certificate of Registration No. CS27754,** **Respondent.**	**Case No. 23-015-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file-stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 18th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WILSON F. BERNALES, M.D.,** **Certificate of Registration No. CS27754,** **Respondent.**	**Case No. 23-015-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

WILSON F. BERNALES, M.D.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 29th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Wilson F. Bernales, MD
c/o Red Rock Medical Center
5701 W Charleston Blvd., Suite 207
Las Vegas, NV 89146

Kristina Holman, Esq.
Holman Law Office
8275 S Eastern Ave #215
Las Vegas, NV 89123

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

5R

FILED
OCT 04 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARCY HANSON, RPH,** **Registration No. 09550,** **Respondent.**	**Case No. 24-193-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Marcy Hanson, RPh (Respondent), because Respondent, at the time of the violations alleged herein, held a Certificate of Registration issued by the Board pursuant to NRS 639.100 and NRS 639.127, authorizing Respondent to work as a pharmacist. Since September 2, 1987, Respondent has held Certificate of Registration No. 09550, allowing her to work as a pharmacist issued by the Board pursuant to NRS 639.100 and NRS 639.127.

2. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the issuance of Certificates of Registration as required by Nevada law and the regulation of the practice of pharmacy. NRS 639.070.

FACTUAL ALLEGATIONS

3. Respondent held a license allowing her to work in the State of Nevada as a pharmacist during the biannual renewal period from November 1, 2021, to October 31, 2023.

4. Respondent's renewal application for the 2021-2023 biannual renewal period lists that she resided at an address in Las Vegas, NV. This address is the last known address for this licensee that the Board has.

5. Respondent failed to submit the 30 required continuing education (CE) hours required by Nevada law by the October 31, 2023, deadline.

6. Respondent was issued a Citation-and-Fine Order by the Board for not completing her CE hours in a timely manner. The Citation-and-Fine Order required Respondent to pay an administrative fine of $500.00 and to submit the required CE hours by July 31, 2024, or to appeal the Order by submitting a written request for appeal to the Board within 30 days.

7. Respondent failed to pay the administrative fine and submit the required 30 CE hours by the July 31, 2024, deadline.

8. Respondent also failed to submit a request for an appeal of the Order within the statutorily prescribed 30 days. NRS 639.2895(2).

9. Respondent continues to hold a pharmacist certificate of registration with the Board despite not having completed the requirements prescribed by Nevada law to keep the registration.

10. Respondent has also failed to comply with the Citation-and-Fine Order issued by the Board on May 22, 2024.

APPLICABLE LAW

11. In Nevada, the Board may discipline the holder of any registration if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

12. Conduct contrary to the public interest includes, "performing any duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

13. The Board may issue a Citation-and-Fine Order to individuals and/or entities that fail to comply with regulations adopted by the Board. NRS 639.100(1); NRS 639.2895.

14. "The Board shall adopt regulations necessary to carry out the purposes of NRS 639.2171 to 639.2176, inclusive, which must include the methods of determining accredited programs, the number of hours of continuing professional education necessary to constitute a continuing education unit, the number of units required of each pharmacist during the period for which a certificate is issued

and such other regulations consistent with NRS 639.2171 to 639.2176, inclusive, as the Board may determine to be necessary." NRS 639.2176.

15. "The Board will not issue a certificate as a registered pharmacist to any person pursuant to NRS 639.127, or renew the certificate of any registered pharmacist, until the applicant submits proof to the Board of receipt of 30 continuing education units within the biennium immediately preceding the current renewal period." NAC 639.330(1).

16. The Board may impose a fine of up to $10,000 for each violation committed. NRS 639.255(1)(f) and (3).

COUNT ONE

Unprofessional Conduct – Failure to Comply with a Board Citation-and-Fine Order

17. Respondent failed to comply with a Board Citation-and-Fine Order in a timely manner. NRS 639.2895(2). The Citation-and-Fine Order was lawfully issued pursuant to NRS 639.2895 and NRS 639.100(1)(b). NRS 639.2176; NAC 639.330(1). Respondent was required to either pay the $500.00 fine and submit the required CE hours or submit a written appeal request within 30 days of the issuance of the letter. NRS 639.2895(2). Respondent failed to do either.

18. Because of these actions, Respondent performed her duties as the holder of a registration issued by the Board in an incompetent, unskillful or negligent manner. Respondent performed her duties in an incompetent, unskillful, or negligent manner because she failed to comply with a Board Citation-and-Fine Order. NRS 639.210(4); NAC 639.945(1)(i).

19. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent.

DATED this 4th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARCY HANSON, RPH,** **Registration No. 09550,** **Respondent.**	**Case No. 24-193-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **gvanderdonck@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 4th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARCY HANSON, RPH** **Registration No. 09550,** **Respondent.**	**Case No. 24-193-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

MARCY HANSON, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Marcy Hanson, RPH
[redacted] Harvest Green Way
Las Vegas, NV 89135

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

24-193-RPH-S
Exhibit 1
Marcy Hanson

Marcy Hanson, RPH
[redacted] Harvest Green Way
Las Vegas, NV 89135
24-193-RPH-S. NIAA

9171 9690 0935 0313 8184 05

MAILED
10/8/24

Cert. - $10.72

Reg. - $2.04

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Marcy Hanson, RPH
[redacted] Harvest Green Way
Las Vegas, NV 89135

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

USPS Tracking®

FAQs >

Remove ×

Tracking Number:

9171969009350313818405

Copy Add to Informed Delivery (https://informeddelivery.usps.com/)

Latest Update

Your item arrived at our USPS facility in PHOENIX AZ DISTRIBUTION CENTER on October 28, 2024 at 11:00 pm. The item is currently in transit to the destination.

Get More Out of USPS Tracking:

USPS Tracking Plus®

Feedback

Moving Through Network

Arrived at USPS Regional Facility
PHOENIX AZ DISTRIBUTION CENTER
October 28, 2024, 11:00 pm

Unclaimed/Being Returned to Sender
LAS VEGAS, NV 89134
October 25, 2024, 2:25 pm

Reminder to Schedule Redelivery of your item
October 16, 2024

Notice Left (No Authorized Recipient Available)
LAS VEGAS, NV 89135
October 11, 2024, 3:07 pm

Departed USPS Regional Facility
LAS VEGAS NV DISTRIBUTION CENTER
October 11, 2024, 9:03 am

Arrived at USPS Regional Facility

LAS VEGAS NV DISTRIBUTION CENTER
October 10, 2024, 12:05 pm

In Transit to Next Facility
October 9, 2024

Arrived at USPS Regional Facility
RENO NV DISTRIBUTION CENTER
October 8, 2024, 11:43 pm

Accepted at USPS Origin Facility
RENO, NV 89521
October 8, 2024, 10:28 pm

Pre-Shipment, USPS Awaiting Item
October 8, 2024

Hide Tracking History

What Do USPS Tracking Statuses Mean? (https://faq.usps.com/s/article/Where-is-my-package)

Text & Email Updates

USPS Tracking Plus®

Product Information

See Less

Track Another Package

Enter tracking or barcode numbers

Need More Help?

Contact USPS Tracking support for further assistance.

FAQs

24-193-RPH-S
Exhibit 2
Marcy Hanson

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
Email: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

October 31, 2024

Marcy Hanson
[redacted]Harvest Green Way
Las Vegas, NV 89135

Re: Marcy Hanson and Case No. 24-193-RPH-S

Dear Marcy Hanson,

The hearing for case number **24-193-RPH-S** has been scheduled for **12/4/2024** at **9:00 AM PST** or soon thereafter at the following location:

Hilton Garden Inn
7830 S Las Vegas
Las Vegas, NV 89123

This is an in-person hearing; all respondents, witnesses and counsel must appear in person before the Board.

Pursuant to NRS 241.033, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

If you have any questions, please feel free to contact the board staff.

Sincerely,

Board Coordination
Nevada State Board of Pharmacy

9171 9690 0935 0314 1112 53

5S

FILED
OCT 04 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **XU ZHANG, RPH,** **Registration No. 19417,** **Respondent.**	**Case No. 24-196-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Xu Zhang, RPh (Respondent), because Respondent, at the time of the violations alleged herein, held a Certificate of Registration issued by the Board pursuant to NRS 639.100 and NRS 639.127, authorizing Respondent to work as a pharmacist. Since September 15, 2016, Respondent has held Certificate of Registration No. 19417, allowing him to work as a pharmacist issued by the Board pursuant to NRS 639.100 and NRS 639.127.

2. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the issuance of Certificates of Registration as required by Nevada law and the regulation of the practice of pharmacy. NRS 639.070.

FACTUAL ALLEGATIONS

3. Respondent held a license allowing him to work in the State of Nevada as a pharmacist during the biannual renewal period from November 1, 2021, to October 31, 2023.

4. Respondent's renewal application for the 2021-2023 biannual renewal period lists that he resided at an address in Las Vegas, NV. This address is the last known address for this licensee that the Board has.

5. Respondent failed to submit the 30 required continuing education (CE) hours required by Nevada law by the October 31, 2023, deadline.

6. Respondent was issued a Citation-and-Fine Order by the Board for not completing his CE hours in a timely manner. The Citation-and-Fine Order required Respondent to pay an administrative fine of $500.00 and to submit the required CE hours by July 31, 2024, or to appeal the Order by submitting a written request for appeal to the Board within 30 days.

7. Respondent failed to pay the administrative fine and submit the required 30 CE hours by the July 31, 2024, deadline.

8. Respondent also failed to submit a request for an appeal of the Order within the statutorily prescribed 30 days. NRS 639.2895(2).

9. Respondent continues to hold a pharmacist certificate of registration with the Board despite not having completed the requirements prescribed by Nevada law to keep the registration.

10. Respondent has also failed to comply with the Citation-and-Fine Order issued by the Board on May 22, 2024.

APPLICABLE LAW

11. In Nevada, the Board may discipline the holder of any registration if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

12. Conduct contrary to the public interest includes, "performing any duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

13. The Board may issue a Citation-and-Fine Order to individuals and/or entities that fail to comply with regulations adopted by the Board. NRS 639.100(1); NRS 639.2895.

14. "The Board shall adopt regulations necessary to carry out the purposes of NRS 639.2171 to 639.2176, inclusive, which must include the methods of determining accredited programs, the number of hours of continuing professional education necessary to constitute a continuing education unit, the number of units required of each pharmacist during the period for which a certificate is issued

and such other regulations consistent with NRS 639.2171 to 639.2176, inclusive, as the Board may determine to be necessary." NRS 639.2176.

15. "The Board will not issue a certificate as a registered pharmacist to any person pursuant to NRS 639.127, or renew the certificate of any registered pharmacist, until the applicant submits proof to the Board of receipt of 30 continuing education units within the biennium immediately preceding the current renewal period." NAC 639.330(1).

16. The Board may impose a fine of up to $10,000 for each violation committed. NRS 639.255(1)(f) and (3).

COUNT ONE

Unprofessional Conduct – Failure to Comply with a Board Citation-and-Fine Order

17. Respondent failed to comply with a Board Citation-and-Fine Order in a timely manner. NRS 639.2895(2). The Citation-and-Fine Order was lawfully issued pursuant to NRS 639.2895 and NRS 639.100(1)(b). NRS 639.2176; NAC 639.330(1). Respondent was required to either pay the $500.00 fine and submit the required CE hours or submit a written appeal request within 30 days of the issuance of the letter. NRS 639.2895(2). Respondent failed to do either.

18. Because of these actions, Respondent performed his duties as the holder of a registration issued by the Board in an incompetent, unskillful or negligent manner. Respondent performed his duties in an incompetent, unskillful, or negligent manner because he failed to comply with a Board Citation-and-Fine Order. NRS 639.210(4); NAC 639.945(1)(i).

19. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent.

DATED this 4th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **XU ZHANG, RPH,** **Registration No. 19417,** **Respondent.**	**Case No. 24-196-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **gvanderdonck@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 4th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **XU ZHANG, RPH,** **Registration No. 19417,** **Respondent.**	**Case No. 24-196-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

XU ZHANG, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Xu Zhang, RPH
[redacted] Railroad River Ave.
Las Vegas, NV 89139

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

24-196-RPH-S
Exhibit 1
Xu Zhang

Xu Zhang, RPH
[redacted] Railroad River Ave.
Las Vegas, NV 89139
24-193-RPH-S. NIAA

9171 9690 0935 0313 8184 12

MAILED
10/8/24

Cert. - $10.72

Reg. - $2.04

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Xu Zhang, RPH
[redacted]Railroad River Ave.
Las Vegas, NV 89139

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

USPS Tracking®

FAQs >

Remove ×

Tracking Number:

9171969009350313818412

Copy Add to Informed Delivery (https://informeddelivery.usps.com/)

Latest Update

Your item was picked up at a postal facility at 12:21 pm on October 17, 2024 in LAS VEGAS, NV 89113.

Get More Out of USPS Tracking:

USPS Tracking Plus®

Delivered

Delivered, Individual Picked Up at Postal Facility
LAS VEGAS, NV 89113
October 17, 2024, 12:21 pm

Reminder to Schedule Redelivery of your item
October 16, 2024

Available for Pickup
WESTRIDGE
7925 W RUSSELL RD
LAS VEGAS NV 89113-9998
M-F 0830-1700; SAT 0900-1500
October 15, 2024, 9:11 am

Notice Left (No Authorized Recipient Available)
LAS VEGAS, NV 89139
October 11, 2024, 7:11 pm

Departed USPS Regional Facility
LAS VEGAS NV DISTRIBUTION CENTER
October 11, 2024, 9:03 am

Feedback

3303

Arrived at USPS Regional Facility
LAS VEGAS NV DISTRIBUTION CENTER
October 10, 2024, 12:05 pm

In Transit to Next Facility
October 9, 2024

Arrived at USPS Regional Facility
RENO NV DISTRIBUTION CENTER
October 8, 2024, 11:43 pm

Accepted at USPS Origin Facility
RENO, NV 89521
October 8, 2024, 10:28 pm

Pre-Shipment, USPS Awaiting Item
October 8, 2024

Hide Tracking History

What Do USPS Tracking Statuses Mean? (https://faq.usps.com/s/article/Where-is-my-package)

Text & Email Updates

USPS Tracking Plus®

Product Information

See Less

Track Another Package

Enter tracking or barcode numbers

Need More Help?

Contact USPS Tracking support for further assistance.

24-196-RPH-S
Exhibit 2
Xu Zhang

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521

(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444

Email: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

October 31, 2024

Xu Zhang
9050 W Warm Springs Rd
Las Vegas, NV 89148

Re: Xu Zhang and Case No. 24-196-RPH-S

Dear Xu Zhang,

The hearing for case number **24-196-RPH-S** has been scheduled for **12/4/2024** at **9:00 AM PST** or soon thereafter at the following location:

Hilton Garden Inn
7830 S Las Vegas
Las Vegas, NV 89123

This is an in-person hearing; all respondents, witnesses and counsel must appear in person before the Board.

Pursuant to NRS 241.033, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

If you have any questions, please feel free to contact the board staff.

Sincerely,

Board Coordination
Nevada State Board of Pharmacy

9171 9690 0935 0314 1112 60

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
Email: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

October 31, 2024

Xu Zhang
[redacted] Pirates Delight Ave
Las Vegas, NV 89139

Re: Xu Zhang and Case No. 24-196-RPH-S

Dear Xu Zhang,

The hearing for case number **24-196-RPH-S** has been scheduled for **12/4/2024** at **9:00 AM PST** or soon thereafter at the following location:

Hilton Garden Inn
7830 S Las Vegas
Las Vegas, NV 89123

This is an in-person hearing; all respondents, witnesses and counsel must appear in person before the Board.

Pursuant to NRS 241.033, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

If you have any questions, please feel free to contact the board staff.

Sincerely,

Board Coordination
Nevada State Board of Pharmacy

9171 9690 0935 0314 1112 77

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
Email: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

October 31, 2024

Xu Zhang
[redacted]Railroad River Ave
Las Vegas, NV 89139

Re: Xu Zhang and Case No. 24-196-RPH-S

Dear Xu Zhang,

The hearing for case number **24-196-RPH-S** has been scheduled for **12/4/2024** at **9:00 AM PST** or soon thereafter at the following location:

Hilton Garden Inn
7830 S Las Vegas
Las Vegas, NV 89123

This is an in-person hearing; all respondents, witnesses and counsel must appear in person before the Board.

Pursuant to NRS 241.033, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

If you have any questions, please feel free to contact the board staff.

Sincerely,

Board Coordination
Nevada State Board of Pharmacy

9171 9690 0935 0314 1112 84

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
Email: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

October 31, 2024

Xu Zhang
[redacted] Boulder Hwy
Las Vegas, NV 89122

Re: Xu Zhang and Case No. 24-196-RPH-S

Dear Xu Zhang,

The hearing for case number **24-196-RPH-S** has been scheduled for **12/4/2024** at **9:00 AM PST** or soon thereafter at the following location:

Hilton Garden Inn
7830 S Las Vegas
Las Vegas, NV 89123

This is an in-person hearing; all respondents, witnesses and counsel must appear in person before the Board.

Pursuant to NRS 241.033, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

If you have any questions, please feel free to contact the board staff.

Sincerely,

Board Coordination
Nevada State Board of Pharmacy

9171 9690 0935 0314 1112 91

USPS Tracking®

FAQs >

Remove ×

Tracking Number:

9171969009350314111260

Copy Add to Informed Delivery (https://informeddelivery.usps.com/)

Latest Update

Your item has been delivered to the original sender at 2:43 pm on November 12, 2024 in RENO, NV 89521.

Get More Out of USPS Tracking:

USPS Tracking Plus®

Feedback

Delivered

Delivered, To Original Sender

RENO, NV 89521
November 12, 2024, 2:43 pm

Arrived at USPS Regional Facility

RENO NV DISTRIBUTION CENTER
November 10, 2024, 9:41 pm

Departed USPS Regional Facility

LAS VEGAS NV DISTRIBUTION CENTER
November 8, 2024, 9:09 am

Insufficient Address

LAS VEGAS, NV 89148
November 4, 2024, 5:56 pm

In Transit to Next Facility

November 3, 2024

Arrived at USPS Regional Facility

LAS VEGAS NV DISTRIBUTION CENTER
November 2, 2024, 11:28 pm

Arrived at USPS Regional Facility
RENO NV DISTRIBUTION CENTER
November 1, 2024, 12:14 am

Accepted at USPS Origin Facility
RENO, NV 89521
October 31, 2024, 10:59 pm

Pre-Shipment, USPS Awaiting Item
October 31, 2024

Hide Tracking History

What Do USPS Tracking Statuses Mean? (https://faq.usps.com/s/article/Where-is-my-package)

Text & Email Updates

USPS Tracking Plus®

Product Information

See Less

Remove ×

Tracking Number:

9171969009350314111277

Copy **Add to Informed Delivery (https://informeddelivery.usps.com/)**

Latest Update

Your item has been delivered to the original sender at 2:43 pm on November 12, 2024 in RENO, NV 89521.

Get More Out of USPS Tracking:

USPS Tracking Plus®

Delivered
Delivered, To Original Sender
RENO, NV 89521
November 12, 2024, 2:43 pm

Arrived at USPS Regional Facility
RENO NV DISTRIBUTION CENTER
November 9, 2024, 12:30 pm

Departed USPS Regional Facility
LAS VEGAS NV DISTRIBUTION CENTER
November 8, 2024, 9:09 am

Forward Expired
LAS VEGAS, NV 89139
November 4, 2024, 4:36 pm

Arrived at USPS Regional Facility
LAS VEGAS NV DISTRIBUTION CENTER
November 2, 2024, 11:28 pm

Arrived at USPS Regional Facility
RENO NV DISTRIBUTION CENTER
November 1, 2024, 12:14 am

Accepted at USPS Origin Facility
RENO, NV 89521
October 31, 2024, 10:59 pm

Pre-Shipment, USPS Awaiting Item
October 31, 2024

Hide Tracking History

What Do USPS Tracking Statuses Mean? (https://faq.usps.com/s/article/Where-is-my-package)

See More

Remove ✕

Tracking Number:

9171969009350314111284

Copy **Add to Informed Delivery (https://informeddelivery.usps.com/)**

Latest Update

Your item was delivered to an individual at the address at 7:20 pm on November 4, 2024 in LAS VEGAS, NV 89139.

Get More Out of USPS Tracking:

USPS Tracking Plus®

Delivered

Delivered, Left with Individual

LAS VEGAS, NV 89139
November 4, 2024, 7:20 pm

Notice Left (No Authorized Recipient Available)

LAS VEGAS, NV 89139
November 4, 2024, 6:32 pm

In Transit to Next Facility

November 4, 2024

Arrived at USPS Regional Facility

LAS VEGAS NV DISTRIBUTION CENTER
November 2, 2024, 11:28 pm

Arrived at USPS Regional Facility

RENO NV DISTRIBUTION CENTER
October 31, 2024, 11:13 pm

Accepted at USPS Origin Facility

RENO, NV 89521
October 31, 2024, 9:58 pm

Pre-Shipment, USPS Awaiting Item

October 31, 2024

Hide Tracking History

What Do USPS Tracking Statuses Mean? (https://faq.usps.com/s/article/Where-is-my-package)

See More ⌄

Tracking Number:

Remove ✕

9171969009350314111291

Copy **Add to Informed Delivery (https://informeddelivery.usps.com/)**

Latest Update

Your package is moving within the USPS network and is on track to be delivered to its final destination. It is currently in transit to the next facility.

Get More Out of USPS Tracking:

USPS Tracking Plus®

Moving Through Network

In Transit to Next Facility
November 12, 2024

Departed USPS Regional Facility
LAS VEGAS NV DISTRIBUTION CENTER
November 8, 2024, 9:09 am

Forwarded
LAS VEGAS, NV
November 4, 2024, 9:58 am

Arrived at USPS Regional Facility
LAS VEGAS NV DISTRIBUTION CENTER
November 2, 2024, 11:28 pm

Arrived at USPS Regional Facility
RENO NV DISTRIBUTION CENTER
November 1, 2024, 12:14 am

Accepted at USPS Origin Facility
RENO, NV 89521
October 31, 2024, 10:59 pm

Pre-Shipment, USPS Awaiting Item
October 31, 2024

Hide Tracking History

What Do USPS Tracking Statuses Mean? (https://faq.usps.com/s/article/Where-is-my-package)

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206 • Reno, Nevada 89521
ADDRESS SERVICE REQUESTED

CERTIFIED MAIL™

9171 9690 0935 0314 1112 77

Xu Zhang
[redacted] Pirates Delight Ave
Las Vegas, NV 89139

Re: Xu Zhang and Case No. 24-196-RPH-S

NIXIE 891 FE 1 0011/06/24
RETURN TO SENDER
NOT DELIVERABLE AS ADDRESSED
UNABLE TO FORWARD
BC: 895214881566 *2941-19912-31-44

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206 • Reno, Nevada 89521
ADDRESS SERVICE REQUESTED

CERTIFIED MAIL

9171 9690 0935 0314 1112 60

ober 31, 2024

Zhang
[redacted] W Warm Springs Rd
s Vegas, NV 89148

NIXIE 891 SE 1 2211/08/24
RETURN TO SENDER
UNDELIVERABLE AS ADDRESSED
UNABLE TO FORWARD

5T

FILED
SEP 11 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ORTHOPEDIC MOTION, INC.,** **License No. MP00772,** **Respondent.**	**CASE NO. 24-281-MP-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Orthopedic Motion, Inc. ("Respondent"), held a Nevada Medical Products Provider License No. MP00772, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about July 2, 2024, the Board conducted an inspection of Respondent's facility located at 3233 W. Charleston Blvd., Las Vegas, NV 89102, and discovered that Respondent was operating without an approved administrator for its Medical Products Wholesaler facility.

3. Respondent failed to notify the Board of the departure of its facility administrator within three (3) business days.

4. Respondent continued its Medical Products Provider operations for more than ten (10) business days without an approved facility administrator.

\\

\\

APPLICABLE LAW

5. The Board may suspend or revoke any certificate, license, registration or permit issued pursuant to this chapter, and deny the application of any person for a certificate, license, registration or permit, if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

6. The Board may suspend or revoke any certificate, license, registration or permit issued pursuant to this chapter, and deny the application of any person for a certificate, license, registration or permit, if the holder or applicant has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy committed by the holder of a certificate, license, registration or permit. NRS 639.210(12).

7. Except as otherwise provided in subsection 4, each medical products provider or medical products wholesaler shall employ an administrator at all times. The administrator must be approved by the Board. NAC 639.694(1)(e).

8. A medical products provider or medical products wholesaler shall notify the staff of the Board of the cessation of employment of an administrator within 3 business days after the cessation of the employment. A medical products provider or medical products wholesaler shall notify the staff of the Board of the employment of a new administrator within 3 business days after the beginning of the employment. NAC 639.694(3).

9. A medical products provider or medical products wholesaler may not operate for more than 10 business days without an administrator. The Board may summarily suspend the operation of a business or facility that operates without an administrator. NAC 639.694(4).

10. A medical products wholesaler shall employ a facility administrator and other employees sufficient to operate, set up, repair, maintain and service all medical products sold, leased or otherwise provided by the medical products wholesaler. NAC 639.6957(1)(a).

11. Any violation of these regulations or violation of any applicable federal, state or local laws related to the practices of the medical products provider or medical products wholesaler is unprofessional conduct. NAC 639.6941(1)(a).

12. It is unprofessional conduct to perform any of his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

FIRST CAUSE OF ACTION

Failure to Employ Facility Administrator – Violation of State Law(s)

13. Respondent failed to comply with NAC 639.694(1)(e); NAC 639.694(3) and (4); as well as NAC 639.6957(1)(a) when it neglected to timely notify the Board of the departure of its facility administrator and continued its operations as a Medical Products Provider without timely obtaining approval of a qualified facility administrator; therefore, Respondent is subject to discipline pursuant to NRS 639.210(12).

SECOND CAUSE OF ACTION

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

14. By violating NAC 639.694(3) and (4) and NAC 639.6957(1)(a), as detailed above, Respondent engaged in unprofessional conduct and conduct contrary to the public interest, as set forth in NAC 639.6941(1)(a), and performed its duties as the holder of a Medical Products Provider license in an incompetent, unskillful, or negligent manner in violation of NAC 639.945(1)(i); therefore, Respondent subject to discipline pursuant NRS 639.210(4).

\\

\\

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 11th day of September 2024.

J. David Wuest, Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ORTHOPEDIC MOTION, INC.,** **License No. MP00772,** **Respondent.**	**Case No. 24-281-MP-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 16, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** gvanderdonck@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of SEPTEMBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ORTHOPEDIC MOTION, INC.,** **License No. MP00772,** **Respondent.**	**Case No. 24-281-MP-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

TYPE OR PRINT NAME

_____

AUTHORIZED REPRESENTATIVE FOR ORTHOPEDIC MOTION, INC.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 11th day of Sept. 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Orthopedic Motion, Inc.
3233 W Charleston Blvd. #111
Las Vegas, NV 89102

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

5U

FILED
OCT 07 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JOHN DEVILBISS, RPH,** **Certificate of Registration No. 19345,** **Respondent.**	**Case No. 24-243-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent John Devilbiss, RPh (Respondent), because Respondent, at the time of the violations alleged herein, held a Certificate of Registration issued by the Board pursuant to NRS 639.100 and NRS 639.127, authorizing Respondent to work as a pharmacist. Since July 26, 2016, Respondent has held Certificate of Registration No. 19345, allowing him to work as a pharmacist issued by the Board pursuant to NRS 639.100 and NRS 639.127.

2. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the issuance of Certificates of Registration as required by Nevada law and the regulation of the practice of pharmacy. NRS 639.070.

FACTUAL ALLEGATIONS

3. Respondent held a license allowing him to work in the State of Nevada as a pharmacist during the biannual renewal period from November 1, 2021, to October 31, 2023.

4. Respondent's renewal application for the 2021-2023 biannual renewal period lists that he resided at an address in Las Vegas, NV. This address is the last known address for this licensee that the Board has.

5. Respondent failed to submit the 30 required continuing education (CE) hours required by Nevada law by the October 31, 2023, deadline.

6. Respondent was issued a Citation-and-Fine Order by the Board for not completing his CE hours in a timely manner. The Citation-and-Fine Order required Respondent to pay an administrative fine of $500.00 and to submit the required CE hours by July 31, 2024, or to appeal the Order by submitting a written request for appeal to the Board within 30 days.

7. Respondent failed to pay the administrative fine and submit the required 30 CE hours by the July 31, 2024, deadline.

8. Respondent also failed to submit a request for an appeal of the Order within the statutorily prescribed 30 days. NRS 639.2895(2).

9. Respondent continues to hold a pharmacist certificate of registration with the Board despite not having completed the requirements prescribed by Nevada law to keep the registration.

10. Respondent has also failed to comply with the Citation-and-Fine Order issued by the Board on June 10, 2024.

APPLICABLE LAW

11. In Nevada, the Board may discipline the holder of any registration if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

12. Conduct contrary to the public interest includes, "performing any duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

13. The Board may issue a Citation-and-Fine Order to individuals and/or entities that fail to comply with regulations adopted by the Board. NRS 639.100(1); NRS 639.2895.

14. "The Board shall adopt regulations necessary to carry out the purposes of NRS 639.2171 to 639.2176, inclusive, which must include the methods of determining accredited programs, the number of hours of continuing professional education necessary to constitute a continuing education unit, the number of units required of each pharmacist during the period for which a certificate is issued

and such other regulations consistent with NRS 639.2171 to 639.2176, inclusive, as the Board may determine to be necessary." NRS 639.2176.

15. "The Board will not issue a certificate as a registered pharmacist to any person pursuant to NRS 639.127, or renew the certificate of any registered pharmacist, until the applicant submits proof to the Board of receipt of 30 continuing education units within the biennium immediately preceding the current renewal period." NAC 639.330(1).

16. The Board may impose a fine of up to $10,000 for each violation committed. NRS 639.255(1)(f) and (3).

COUNT ONE

Unprofessional Conduct – Failure to Comply with a Board Citation-and-Fine Order

17. Respondent failed to comply with a Board Citation-and-Fine Order in a timely manner. NRS 639.2895(2). The Citation-and-Fine Order was lawfully issued pursuant to NRS 639.2895 and NRS 639.100(1)(b). NRS 639.2176; NAC 639.330(1). Respondent was required to either pay the $500.00 fine and submit the required CE hours or submit a written appeal request within 30 days of the issuance of the letter. NRS 639.2895(2). Respondent failed to do either.

18. Because of these actions, Respondent performed his duties as the holder of a registration issued by the Board in an incompetent, unskillful or negligent manner. Respondent performed his duties in an incompetent, unskillful, or negligent manner because he failed to comply with a Board Citation-and-Fine Order. NRS 639.210(4); NAC 639.945(1)(i).

19. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

\\

\\

\\

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent.

DATED this 7th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JOHN DEVILBISS, RPH** **Certificate of Registration No. 19345,** **Respondent.**	**Case No. 24-243-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **gvanderdonck@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 7th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JOHN DEVILBISS, RPH** **Certificate of Registration No. 19345,** **Respondent.**	**Case No. 24-243-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

JOHN DEVILBISS, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

John Devilbiss, RPH
[redacted] Pacific Sageview Ln
Las Vegas, NV 89144

John Devilbiss, RPH
[redacted] Corsica Mist Ave
Las Vegas, NV 89135

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT
BOARD COORDINATOR I

24-243-RPH-S
Exhibit 1
John Devilbiss

FILED
OCT 08 2024
NEVADA STATE BOARD OF PHARMACY

John Devilbiss
[redacted] Pacific Sageview Ln
Las Vegas, NV 89144
24-243-RPH-S. NIAA

MAILED
10/8/24

9171 9690 0935 0313 8183 68

certified : $10.72

standard : $1.25

FILED
OCT 08 2024
NEVADA S[illegible]ARD OF PHARMACY

John Devilbiss
[redacted] Corsica Mist Ave
Las Vegas, NV 89135
24-243-RPH-S. NIAA

MAILED
10/8/24

9171 9690 0935 0313 8183 75

certified : $10.72

standard : $1.25

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

John Devilbiss, RPH
[redacted] Pacific Sageview Ln
Las Vegas, NV 89144

John Devilbiss, RPH
[redacted] Corsica Mist Ave
Las Vegas, NV 89135

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT
BOARD COORDINATOR I

ALERT: HURRICANES HELENE AND MILTON, FLOODING, AND SEVERE WEATHER IN THE SOU...

USPS Tracking®

FAQs >

Remove ×

Tracking Number:

9171969009350313818368

Copy Schedule a Redelivery (https://tools.usps.com/redelivery.htm)

Latest Update

We attempted to deliver your item at 4:40 pm on October 12, 2024 in LAS VEGAS, NV 89144 and a notice was left because an authorized recipient was not available. You may arrange redelivery by using the Schedule a Redelivery feature on this page or may pick up the item at the Post Office indicated on the notice beginning October 15, 2024. If this item is unclaimed by October 27, 2024 then it will be returned to sender.

Feedback

Get More Out of USPS Tracking:

USPS Tracking Plus®

Delivery Attempt: Action Needed
Notice Left (No Authorized Recipient Available)
LAS VEGAS, NV 89144
October 12, 2024, 4:40 pm

Departed USPS Regional Facility
LAS VEGAS NV DISTRIBUTION CENTER
October 11, 2024, 9:03 am

Arrived at USPS Regional Facility
LAS VEGAS NV DISTRIBUTION CENTER
October 10, 2024, 12:06 pm

In Transit to Next Facility
October 9, 2024

Arrived at USPS Regional Facility
RENO NV DISTRIBUTION CENTER

October 8, 2024, 11:43 pm

Accepted at USPS Origin Facility
RENO, NV 89521
October 8, 2024, 10:28 pm

Pre-Shipment, USPS Awaiting Item
October 8, 2024

Hide Tracking History

What Do USPS Tracking Statuses Mean? (https://faq.usps.com/s/article/Where-is-my-package)

Text & Email Updates

Schedule Redelivery

USPS Tracking Plus®

Product Information

See Less

Remove ✕

Tracking Number:

9171969009350313818375

Copy **Add to Informed Delivery (https://informeddelivery.usps.com/)**

Latest Update

Your item was delivered to an individual at the address at 2:04 pm on October 11, 2024 in LAS VEGAS, NV 89135.

Get More Out of USPS Tracking:

USPS Tracking Plus®

Delivered

Delivered, Left with Individual
LAS VEGAS, NV 89135
October 11, 2024, 2:04 pm

Out for Delivery
LAS VEGAS, NV 89135
October 11, 2024, 10:31 am

Departed USPS Regional Facility
LAS VEGAS NV DISTRIBUTION CENTER
October 11, 2024, 9:03 am

Arrived at USPS Regional Facility
LAS VEGAS NV DISTRIBUTION CENTER
October 10, 2024, 12:06 pm

In Transit to Next Facility
October 9, 2024

Arrived at USPS Regional Facility
RENO NV DISTRIBUTION CENTER
October 8, 2024, 11:43 pm

Accepted at USPS Origin Facility
RENO, NV 89521
October 8, 2024, 10:28 pm

Pre-Shipment, USPS Awaiting Item
October 8, 2024

Hide Tracking History

What Do USPS Tracking Statuses Mean? (https://faq.usps.com/s/article/Where-is-my-package)

See More

Track Another Package

Enter tracking or barcode numbers

24-243-RPH-S
Exhibit 2
John Devilbliss

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
Email: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

October 31, 2024

John Devilbiss
[redacted] Pacific Sageview Ln
Las Vegas, NV 89144

Re: John Devilbiss and Case No. 24-243-RPH-S

Dear John Devilbiss,

The hearing for case number **24-243-RPH-S** has been scheduled for **12/4/2024** at **9:00 AM PST** or soon thereafter at the following location:

Hilton Garden Inn
7830 S Las Vegas
Las Vegas, NV 89123

This is an in-person hearing; all respondents, witnesses and counsel must appear in person before the Board.

Pursuant to NRS 241.033, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

If you have any questions, please feel free to contact the board staff.

Sincerely,

Board Coordination
Nevada State Board of Pharmacy

9171 9690 0935 0314 1113 14

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
Email: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

October 31, 2024

John Devilbiss
[redacted] Corsica Mist Ave
Las Vegas, NV 89135

Re: John Devilbiss and Case No. 24-243-RPH-S

Dear John Devilbiss,

The hearing for case number **24-243-RPH-S** has been scheduled for **12/4/2024** at **9:00 AM PST** or soon thereafter at the following location:

Hilton Garden Inn
7830 S Las Vegas
Las Vegas, NV 89123

This is an in-person hearing; all respondents, witnesses and counsel must appear in person before the Board.

Pursuant to NRS 241.033, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

If you have any questions, please feel free to contact the board staff.

Sincerely,

Board Coordination
Nevada State Board of Pharmacy

9171 9690 0935 0314 1113 21

USPS Tracking®

FAQs >

Remove ×

Tracking Number:

9171969009350314111314

Copy Add to Informed Delivery (https://informeddelivery.usps.com/)

Latest Update

This is a reminder to arrange for redelivery of your item or your item will be returned to sender.

Get More Out of USPS Tracking:

USPS Tracking Plus®

Delivery Attempt

Reminder to Schedule Redelivery of your item
November 12, 2024

Notice Left (No Authorized Recipient Available)
LAS VEGAS, NV 89144
November 7, 2024, 2:44 pm

In Transit to Next Facility
November 6, 2024

Arrived at USPS Regional Facility
LAS VEGAS NV DISTRIBUTION CENTER
November 2, 2024, 11:28 pm

Arrived at USPS Regional Facility
RENO NV DISTRIBUTION CENTER
November 1, 2024, 12:10 am

Accepted at USPS Origin Facility
RENO, NV 89521

Feedback

3347

October 31, 2024, 10:55 pm

Pre-Shipment, USPS Awaiting Item
October 31, 2024

Hide Tracking History

What Do USPS Tracking Statuses Mean? (https://faq.usps.com/s/article/Where-is-my-package)

Text & Email Updates

USPS Tracking Plus®

Product Information

See Less

Remove ×

Tracking Number:

9171969009350314111321

Copy **Add to Informed Delivery (https://informeddelivery.usps.com/)**

Latest Update

Your item has been delivered to the original sender at 2:43 pm on November 12, 2024 in RENO, NV 89521.

Get More Out of USPS Tracking:

USPS Tracking Plus®

Delivered

Delivered, To Original Sender
RENO, NV 89521
November 12, 2024, 2:43 pm

Arrived at USPS Regional Facility
RENO NV DISTRIBUTION CENTER
November 9, 2024, 2:29 pm

3348

In Transit to Next Facility
November 8, 2024

Addressee Unknown
LAS VEGAS, NV 89135
November 7, 2024, 8:51 am

Departed USPS Regional Facility
LAS VEGAS NV DISTRIBUTION CENTER
November 6, 2024, 9:30 am

Forwarded
LAS VEGAS, NV
November 4, 2024, 12:00 pm

Arrived at USPS Regional Facility
LAS VEGAS NV DISTRIBUTION CENTER
November 2, 2024, 11:28 pm

Arrived at USPS Regional Facility
RENO NV DISTRIBUTION CENTER
November 1, 2024, 12:10 am

Accepted at USPS Origin Facility
RENO, NV 89521
October 31, 2024, 10:55 pm

Pre-Shipment, USPS Awaiting Item
October 31, 2024

Hide Tracking History

What Do USPS Tracking Statuses Mean? (https://faq.usps.com/s/article/Where-is-my-package)

See More

Track Another Package

Enter tracking or barcode numbers

6

6A

Heath DeHart
[redacted] S 900 E
St. George, UT 84790
[redacted]

03/20/2024

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, suite 206
Reno, NV 89521

Subject: Appeal of Citation for Prescribing Controlled Substances
Heath G. DeHart, PA (CS33956) Case No. 22-351-CS-N

Dear Members of the Nevada Board of Pharmacy,

I am writing to appeal the decision to issue a citation to me, Heath Gabriel DeHart, Physician Assistant, for prescribing controlled substances between January 10, 2022, and June 3, 2022. I am a licensed physician assistant, and I believed that my prescribing authority for controlled substances had been transferred to fully approved status during the timeframe mentioned above.

As you are aware, I was initially approved under COVID-19 status, and my license was later converted to a fully approved physician assistant license. Unfortunately, I was not fully aware of the intricacies of Nevada State Board of Pharmacy approval process, and I mistakenly believed that my prescribing authority for controlled substances had also been transferred to fully approved status.

I want to emphasize that I did not intend to prescribe controlled substances without proper authorization or maliciously. My sole intention was to provide adequate pain management to patients who were experiencing traumatic injuries, or severe conditions causing pain. There was no monetary gain for me in prescribing these medications, and the only benefit was to ensure the well-being and comfort of my patients.

I deeply regret any misunderstanding , or oversight on my part. and I immediately took steps to rectify the situation and ensure compliance with all regulations and guidelines once I was made aware of the situation. I am committed to upholding the highest standards of healthcare and serving the people of Nevada with integrity and professionalism.

I respectfully request that you reconsider the decision to issue a citation to me and take into account the circumstances outlined in this appeal. I am willing to provide any additional information or documentation that may assist in your review of this matter.

Thank you for your attention to this appeal, and I look forward to a favorable resolution.

Sincerely,

Heath DeHart, PA-C

From:	Darlene Nases
To:	Gus Vanderdonck; Erin Miller; Jessette Phaynarikone
Cc:	David Wuest
Subject:	RE: 22-351-CS-N Heath DeHart
Date:	Tuesday, September 10, 2024 10:22:00 AM

Thanks. Added him for December.

Regards,

Darlene Nases
Board Coordinator
Custodian of Records
Nevada State Board of Pharmacy
(775) 850-1440
dnases@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

From: Gus Vanderdonck <gvanderdonck@pharmacy.nv.gov>
Sent: Tuesday, September 10, 2024 9:35 AM
To: Darlene Nases <dnases@pharmacy.nv.gov>; Erin Miller <emiller@pharmacy.nv.gov>; Jessette Phaynarikone <jphaynarikone@pharmacy.nv.gov>
Cc: David Wuest <dwuest@pharmacy.nv.gov>
Subject: FW: 22-351-CS-N Heath DeHart

Darlene,

Please put Mr. DeHart on the December agenda. This will be a hearing for reconsideration.

Best,

Gustaf Vanderdonck
General Counsel
Nevada State Board of Pharmacy
(775)-850-1440 Ext. 132
gvanderdonck@pharmacy.nv.gov

From: Heath DeHart <[redacted]>
Sent: Monday, September 9, 2024 6:41 PM
To: Gus Vanderdonck <gvanderdonck@pharmacy.nv.gov>
Subject: Re: 22-351-CS-N Heath DeHart

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

To whom it may concern:

I am writing to formally request that the Nevada Board of Pharmacy reconsider the decision rendered against me regarding the alleged prescribing without a controlled substance certificate. I believe that there is new, relevant evidence that was not previously taken into account and may directly affect the outcome of my case.

The new information pertains to the Board's responsibility to provide timely notice to practitioners about any controlled substance licensing restrictions imposed on them. In my case, I did not receive such notice, which I believe is a significant procedural oversight. Additionally, there may be applicable provisions under Nevada law concerning emergency dispensing of medications and the licensure requirements for locum tenens practitioners, which were not fully explored. The provisionary Covid license had overlap until May 2022. I also hold a valid DEA license in other states, that was active at the time of this occurrence, which may have bearing on my case. In exploring other options, I found in the bylaws, the board also has power to retroactively date the effective date of my controlled substance certificate to reflect the date the certificate was applied for, this would allow for compliance.

In light of this new evidence, I respectfully request the opportunity to have my case reheard and to provide this additional information for your review.

I am confident that a reconsideration of the facts, with the inclusion of this new evidence, will result in a more accurate and fair decision.

Thank you for your time and attention to this matter. I look forward to your favorable response and am available at your convenience to discuss any further details or to provide documentation as needed.

Sincerely,
Heath DeHart

Sent from my iPhone

> On Aug 20, 2024, at 2:32 PM, Heath DeHart <[redacted]> wrote:
>
> I accept the factual allegations 1-5 contained within “The Statement to the Respondent”
>
> Sent from my iPhone
>
> > On Aug 20, 2024, at 2:06 PM, Gus Vanderdonck <gvanderdonck@pharmacy.nv.gov> wrote:
> >
> > P.A. DeHart,
> >
> > Attached is the Statement to the Respondent and Notice of Hearing. If you decide to stipulate to the facts for this hearing, you would only be stipulating to paragraphs 1-5 of this document. Please let me know if you have any questions.
> >
> > Best Regards,
> >
> > Gustaf Vanderdonck
> > General Counsel
> > Nevada State Board of Pharmacy
> > (775)-850-1440 Ext. 132
> > gvanderdonck@pharmacy.nv.gov
> >
> > ---
> >
> > **From:** Heath DeHart <heath@routinefitness.com>
> > **Sent:** Tuesday, August 20, 2024 12:01 PM

To: Gus Vanderdonck <gvanderdonck@pharmacy.nv.gov>
Subject: Re: 22-351-CS-N

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

I have time today.

Sent from my iPhone

> On Aug 20, 2024, at 10:19 AM, Gus Vanderdonck <gvanderdonck@pharmacy.nv.gov> wrote:
>
> P.A. DeHart,
>
> Let me know if you have some time to call today or this week regarding your citation and fine appeal. Thanks!
>
> Best,
>
> Gustaf Vanderdonck
> General Counsel
> Nevada State Board of Pharmacy
> (775)-850-1440 Ext. 132
> gvanderdonck@pharmacy.nv.gov
>
> <image001.gif>
>
> NOTICE: This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not establish an attorney-client relationship. This information does not override the specific provisions of Nevada law as applied to a particular set of facts.
>
> CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the

use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

<Case No. 22-351-CS-N DeHart STRNOH.docx>

Heath DeHart
[redacted] E 2840 S Cir.
St. George, UT 84790
[redacted]

11/18/2024

Dear Members of the Nevada State Board of Pharmacy,

I am writing to formally request the board to vacate and amend the citation and fine imposed upon me regarding a violation related to the expiration of the COVID-19 controlled substance waiver.

The citation and fine of $5,000, along with the associated reporting to the National Provider Data Bank, are penalties, I respectfully believe are disproportionately severe given the circumstances of this case. I would like to present new evidence demonstrating that I did, in fact, complete the COVID-19 Prescribing Registration Waiver for controlled substance. Furthermore, I unknowingly prescribed one controlled substance prescription outside of the waiver period, and this error was not due to negligence, but rather the absence of any notification from the Nevada State Board of Pharmacy that the waiver had expired.

Throughout my career, I have been committed to upholding the highest standards of medical practice, particularly in my prescribing practices. I have a conservative approach when prescribing controlled substances and only prescribe when absolutely necessary and in small quantities. I have consistently adhered to all laws and regulations governing controlled substances. This singular incident was an unintentional oversight, and I humbly ask the Board to consider my exemplary track record and dedication to my patients.

Given the extraordinary challenges and rapid changes brought about by the COVID-19 pandemic, the expiration of the waiver occurred without proper notification. The board did not have on file my COVID-19 Prescribing Registration Waiver for controlled substance, even though I had completed the form and had been approved by the board to prescribe controlled substances, this may be why I was not properly notified of expiration of the waiver; however, this was an error on the part of the Nevada board of Pharmacy, as I have provided the completed waiver and provided email confirmation that it was approved by the Nevada board of Pharmacy. I was relying on the waiver to address patients' needs in good faith. I am confident that had I been made aware of its expiration, I would have promptly discontinued prescribing controlled substances. While applying for permanent licensing I had sent several emails to the board asking to know the status of my controlled substance prescribing, and at no time was I given a response that I was not registered and that I did not have controlled substance prescribing authority.

I respectfully request that the Board vacate and amend the citation and fine in light of this new evidence and the mitigating circumstances. Reporting this incident to the National Provider Data Bank will unjustly impact my professional reputation, credentialing, and employment opportunities.

I deeply regret any oversight on my part and assure the Board that I have since implemented additional measures to ensure such a situation does not occur again. My sole intent has always been to provide the highest standard of care to my patients while fully adhering to all legal and professional guidelines.

Sincerely,

Heath DeHart

22-351-CS-N
Exhibit 1
Heath DeHart

State of Nevada

Executive Department

DECLARATION OF EMERGENCY

DIRECTIVE 011

WHEREAS, on March 12, 2020, I, Steve Sisolak, Governor of the State of Nevada issued a Declaration of Emergency to facilitate the State's response to the COVID-19 pandemic; and

WHEREAS, on March 13, 2020, Donald J. Trump, President of the United States declared a nationwide emergency pursuant to Sec. 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the "Stafford Act"); and

WHEREAS, pursuant to NRS 414.070(6), the Governor may exercise the power "[t]o authorize providers of emergency medical services and providers of mental health services who are not licensed, certified or registered, as applicable, in this State but hold a license, certificate, registration or similar credential in good standing in another state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or any territory or insular possession subject to the jurisdiction of the United States to practice their profession within their scope of practice as if they were licensed, certified or registered, as applicable, in this State for the amount of time necessary to assist in responding to the emergency or disaster;" and

WHEREAS, pursuant to NRS 414.070(7), the Governor may perform and exercise such other functions, powers and duties as are necessary to promote and secure the safety and protection of the civilian population; and

WHEREAS, NRS 414.110(1) provides that all functions under Chapter 414 and all other activities relating to emergency management are hereby declared to be governmental functions. Neither the State nor any political subdivision thereof nor other agencies of the State or political subdivision thereof, nor except in cases of willful misconduct, gross negligence, or bad faith, any worker complying with or reasonably attempting to comply with this chapter, or any order or regulation adopted pursuant to the provisions of this chapter, or pursuant to any ordinance relating to any necessary emergency procedures or other precautionary measures enacted by any political subdivision of the State, is liable for the death of or injury to persons, or for damage to property, as a result of any such activity.

WHEREAS, NRS 414.110(2) provides that any requirement for a license to practice any professional, mechanical or other skill does not apply to any authorized worker who, in the course of performing

his or her duties as such, practices that professional, mechanical or other skill during an emergency or disaster.

WHEREAS, NRS 414.110(3) defines "worker" to include without limitation any full-time or part-time paid, volunteer or auxiliary employee of this State, of any political subdivision thereof, of other states, territories, possessions or the District of Columbia, of the Federal Government, of any neighboring country, or of any political subdivision thereof, or of any agency or organization, performing services for emergency management at any place in this State subject to the order or control of, or pursuant to a request of, the State Government or any political subdivision thereof; and

WHEREAS, Nevada must be prepared to expand its health care workforce to protect its citizens who require emergency care and services and ensure all critical medical resources are available to identify and treat those impacted by COVID-19 during this emergency;

WHEREAS, Article 5, Section 1 of the Nevada Constitution provides: "The supreme executive power of this State, shall be vested in a Chief Magistrate who shall be Governor of the State of Nevada;" and

NOW THEREFORE, by the authority vested in me as Governor by the Constitution and the laws of the State of Nevada and the United States, and pursuant to the March 12, 2020, Emergency Declaration,

IT IS HEREBY ORDERED THAT:

SECTION 1: The waiver of licensing provision of NRS 414.110 is hereby invoked. Professional licensing boards regulating providers of medical services shall temporarily waive certain licensing requirements to allow the practice of currently unlicensed skilled medical professionals during the pendency of the COVID-19 crisis. For the purposes of this Directive, a provider of medical services includes all categories of skilled personnel deemed necessary by the Governor's COVID-19 Medical Advisory Team to augment and bolster Nevada's healthcare workforce to the levels necessary to combat this pandemic, including without limitation, medical doctors, physician assistants, nurse practitioners, advanced practice registered nurses, registered nurses, licensed practical nurses, emergency medical technicians, advanced emergency medical technicians, respiratory care practitioners, paramedics, pharmacists, pharmacy technicians, medical students, nursing students, medical laboratory directors or technicians, and licensed or certified behavioral health professionals.

SECTION 2: The waiver and exemption of professional licensing requirements shall apply to qualified providers of medical services during this declared emergency who currently hold a valid license in good standing in another state, providers of medical services whose licenses currently stand suspended for licensing fee delinquencies, providers of medical services whose licenses currently stand suspended for failure to meet continuing medical education requirements, and providers of medical services who have retired from their practice in any state with their license in good standing. These waivers and exemptions shall not apply to persons whose licenses have been revoked or voluntarily surrendered as a result of disciplinary proceedings.

SECTION 3: The Chief Medical Officer is authorized to approve the wavier and exemption of professional licensing requirements for any provider of medical services who has received training in another country but is not currently licensed in the United States, subject to verification of their credentials.

SECTION 4: Individuals seeking waiver and exemption of professional licensing requirements are required to notify the applicable Nevada licensing board or agency and provide any requested information. Any medical facility as defined by NRS 449.0151, laboratory, or pharmacy employs or contracts with a provider of emergency medical services who is not licensed in Nevada during this declared emergency must ensure that the provider has notified the applicable Nevada license board or agency.

SECTION 5: The Chief Medical Officer and, to the extent necessary, the appropriate professional licensing board shall expedite the processing and final disposition of all applications to practice under the terms of this Directive.

SECTION 6: A provider of medical services during this emergency is authorized to supervise students in their profession to provide any emergency medical services as is appropriate to the student's knowledge and skill level without further licensure or certification.

SECTION 7: All providers of medical services in the State of Nevada are authorized to practice outside the scope of their specialization, within the limits of their competency, to the extent necessary to augment and bolster Nevada's healthcare system during the COVID-19 crisis.

SECTION 8: The Governor authorizes the Chief Medical Officer or his designee to review and approve the Crisis Standards of Care Guidance for COVID-19 promulgated by the State of Nevada Department of Health and Human Services, Division of Public and Behavioral Health, and the Governor's COVID-19 Medical Advisory Team.

SECTION 9: All regulatory requirements for providers of medical services that are not compatible with the applicable Crisis Standards of Care approved by the Chief Medical Officer during this declared emergency will be suspended.

SECTION 10: All providers of medical services related to COVID-19 are performing services for emergency management subject to the order or control of and at the request of State Government and shall be afforded the immunities and protections set forth in NRS 414.110, subject to the same exclusions therein.

SECTION 11: All licensing fees assessed on providers of medical services by the State of Nevada or professional licensing boards shall be waived for all persons applying to practice in the State of Nevada pursuant to this Directive, for the duration that this Directive shall be in effect. Providers of medical services currently licensed by the State of Nevada may, at their election, delay submission of outstanding licensing fees for the period this Directive shall be in effect, except that no person who has paid the fee prior to the date of this Directive shall be entitled to a refund thereof by virtue of this order. No

license for a provider of medical services shall be suspended for nonpayment of licensing fees while this Directive is in effect, and for a period of 60 days thereafter.

SECTION 12: No license for a provider of medical services shall be suspended for any administrative reasons, including without limitation, continuing education requirements while this Directive is in effect, and for a period of 60 days thereafter. This restriction shall not be construed to prohibit the suspension or revocation of licenses for reasons that jeopardize patient health, including without limitation, incompetency or malpractice.

SECTION 13: This Directive shall remain in effect until specifically modified or terminated by a subsequent Directive promulgated pursuant to the March 12, 2020 Declaration of Emergency to facilitate the State's response to the COVID-19 pandemic.

IN WITNESS WHEREOF, I have hereunto set my hand and caused the Great Seal of the State of Nevada to be affixed at the State Capitol in Carson City, this 1st day of April, in the year two thousand twenty.

Governor of the State of Nevada

Barbara K. Cegavske

Secretary of State

Deputy Secretary of State

22-351-CS-N
Exhibit 2
Heath DeHart

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Advanced Nurse Practitioner and Physician Assistant– Prescribing Registration Waiver Request
Governor Sisolak's COVID-19 Declaration of Emergency Directive 011

Rev 1/21/2022

On April 1, 2020, Governor Sisolak issued Emergency Directive 011 ("Directive") to temporarily waive licensing requirements. The waiver applies to qualified APRNs or PAs who hold licenses that are active, expired, or inactive, in good standing in Nevada or another state. Ineligible APRNs and PAs include those who have licenses that are currently revoked or have been surrendered as a result of disciplinary proceedings. All APRNs and PAs who wish to prescribe under this Directive must complete and return this form to the Nevada State Board of Pharmacy. Once this form has been approved, you are eligible to prescribe under the Directive. Please note, this is a waiver of licensure. You will not be issued a license in Nevada, but may prescribe in Nevada upon approval of this form and only for the duration of the Directive. If you wish to apply for licensure, you must complete the appropriate form and pay the required fee at www.bop.nv.gov

You may fax this completed form to 775-850-1444, mail to 985 Damonte Ranch Parkway, Ste. 206, Reno, Nevada 89521 or email to pharmacy@pharmacy.nv.gov.

Personal Information

First: _____ Middle: _____ Last: _____

Date of Birth: _____ SSN or ITIN:_____ License Type: ☐ APRN ☐ PA

Home Address: _____

City: _____ State: _____ Zip: _____

Email Address: _____ Contact Number: _____

Nevada Employer Information

Practice Name: _____

Practice Address:_____

City: _____ State: _____ Zip: _____

Name of Facility Director/Supervising Physician (if PA must be the Supervising Physician):_____

List your license(s), including DEA number(s), in all jurisdictions and provide proof of licensure (use another sheet if additional space is needed)

State	License number	License Status					License in Good Standing?	
		Active	Inactive	Expired	Revoked	Surrendered	Yes	No

Waiver Information	Yes	No
Have you been granted a waiver pursuant to Governor Sisolak's COVID-19 Declaration of Emergency Directive 011 from the Nevada State Board of Nursing, Board of Medical Examiners, or Board of Osteopathic Medicine?		

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		
3. Have you been the subject of an administrative action whether completed or pending in any state?		
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		

If you marked YES to any of the number questions (1-4) above, include the following information and provide documentation:

Board Administrative Action:	State:	Date:	Case #

Criminal Action:	State	Date:	Case#:	County:	Court:

Types of Drugs you may Prescribe under this Waiver

You may prescribe **Dangerous Drugs** under this waiver if you have provided proof as requested above that:

1. All of your practice licenses are active, expired, or inactive, and in good standing in Nevada or another state; and
2. You have you been granted a waiver pursuant to Governor Sisolak's COVID-19 Declaration of Emergency Directive 011 from the Nevada State Board of Nursing, Board of Medical Examiners, or Board of Osteopathic Medicine.

You may also prescribe and administer **Controlled Substances** under this waiver if you have provided proof as requested above that:

1. You have an active **DEA license in Good Standing** in another state; and none of your DEA licenses were revoked or suspended.

Please check that you certify to the following:

☐ I hereby certify that I am directly performing essential healthcare services in Nevada in response to the COVID-19 pandemic; I understand that if I perform healthcare services in Nevada not directly related to the COVID-19 pandemic response I can be cited for unlicensed practice pursuant to NRS 639.2895.

☐ I hereby certify, under penalty of perjury, that the information on this application is true, accurate and correct. I further agree to abide by all statutes, rules or regulations governing the prescribing in Nevada and understand that a violation of any such statute, rules or regulations may be grounds for suspension or revocation of this permit of authorization.

_____ _____

Signature of Applicant (Electronic Signature Permitted) Date

_____ _____

Signature of Facility Director/Supervising Physician
(If PA must be the Supervising Physician)
(Electronic Signature Permitted)

Date

Board Use Only	Date Received: _____ ☐Approved on _____ ☐Denied on _____
	Approved for: ☐ Dangerous Drugs Only ☐ Dangerous Drugs and Controlled Substances Approval Signature: _____

22-351-CS-N
Exhibit 3
Heath DeHart

From:	Mark I. Sedar
To:	Gregory Zunino
Subject:	FW: NV Board of Pharmacy Form - Heath DeHart, PA & Lindsay Allen, PA
Date:	Monday, November 18, 2024 10:02:11 AM
Attachments:	image002.jpg image003.jpg image001.png

Kind Regards,

Mark Sedar
COO
Nevada State Board of Pharmacy
(775) 850-1440
msedar@pharmacy.nv.gov



This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

From: Mark I. Sedar
Sent: Friday, October 15, 2021 10:09 AM
To: Credentialing-RPG <credentialing-RPG@ruralphysiciansgroup.com>
Subject: RE: NV Board of Pharmacy Form - Heath DeHart, PA & Lindsay Allen, PA

Hi Corine,

The waiver for Mr, DeHart is approved.

Regards,

Mark Sedar
COO
Nevada State Board of Pharmacy
(775) 850-1440
msedar@pharmacy.nv.gov



This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

From: Credentialing-RPG <credentialing-RPG@ruralphysiciansgroup.com>
Sent: Thursday, October 14, 2021 1:18 PM
To: Mark I. Sedar <msedar@pharmacy.nv.gov>
Subject: RE: NV Board of Pharmacy Form - Heath DeHart, PA & Lindsay Allen, PA

CAUTION: This email originated from outside your organization. Exercise caution when opening attachments or clicking links, especially from unknown senders.

South Lyon Medical Center
213 Whitacre Street
Yerington, NV 89447

Logo



Corine Borbon
Licensing & Credentialing Coordinator

10624 S. Eastern Avenue, Suite A263, Henderson, NV 89052
c: 760-684-0407 | f: 866-439-0227|
w:ruralphysiciansgroup.com

Warning: This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or employee/agent responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you receive this communication in error, please notify me immediately.

From: Mark I. Sedar <msedar@pharmacy.nv.gov>
Sent: Thursday, October 14, 2021 8:59 AM
To: Credentialing-RPG <credentialing-RPG@ruralphysiciansgroup.com>
Subject: RE: NV Board of Pharmacy Form - Heath DeHart, PA & Lindsay Allen, PA

Corine, is Dehart at the South Meadows facility?

Mark Sedar
COO
Nevada State Board of Pharmacy
(775) 850-1440
msedar@pharmacy.nv.gov



This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

From: Credentialing-RPG <credentialing-RPG@ruralphysiciansgroup.com>
Sent: Thursday, October 14, 2021 8:53 AM
To: Mark I. Sedar <msedar@pharmacy.nv.gov>

Subject: RE: NV Board of Pharmacy Form - Heath DeHart, PA & Lindsay Allen, PA

CAUTION: This email originated from outside your organization. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Great thank you and Heath DeHart is still processing?

Logo

Corine Borbon
Licensing & Credentialing Coordinator

10624 S. Eastern Avenue, Suite A263, Henderson, NV 89052
c: 760-684-0407 | f: 866-439-0227|
w:ruralphysiciansgroup.com

Warning: This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or employee/agent responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you receive this communication in error, please notify me immediately.

From: Mark I. Sedar <msedar@pharmacy.nv.gov>
Sent: Wednesday, October 13, 2021 4:24 PM
To: Credentialing-RPG <credentialing-RPG@ruralphysiciansgroup.com>
Subject: RE: NV Board of Pharmacy Form - Heath DeHart, PA & Lindsay Allen, PA

Hi Corine,

Please note that the Waiver for Dr. Allen is approved.

Mark Sedar
COO
Nevada State Board of Pharmacy
(775) 850-1440
msedar@pharmacy.nv.gov



This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

From: Credentialing-RPG <credentialing-RPG@ruralphysiciansgroup.com>
Sent: Monday, October 11, 2021 2:18 PM
To: Mark I. Sedar <msedar@pharmacy.nv.gov>
Subject: RE: NV Board of Pharmacy Form - Heath DeHart, PA & Lindsay Allen, PA

The Employer is Rural Physicians Group, the providers work for us at South Lyon Medical Center and Mount Grant General Hospital.

Logo



Corine Borbon
Licensing & Credentialing Coordinator

10624 S. Eastern Avenue, Suite A263, Henderson, NV 89052
c: 760-684-0407 | f: 866-439-0227|
w:ruralphysiciansgroup.com

Warning: This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or employee/agent responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you receive this communication in error, please notify me immediately.

From: Mark I. Sedar <msedar@pharmacy.nv.gov>
Sent: Monday, October 11, 2021 1:45 PM
To: Credentialing-RPG <credentialing-RPG@ruralphysiciansgroup.com>
Cc: Dr. Sandra Guidry <drguidry@ruralphysiciansgroup.com>

Subject: RE: NV Board of Pharmacy Form - Heath DeHart, PA & Lindsay Allen, PA

Corine, who is the employer? The information was left blank on the application?

Thank you,

Mark Sedar
COO
Nevada State Board of Pharmacy
(775) 850-1440
msedar@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

From: Credentialing-RPG <credentialing-RPG@ruralphysiciansgroup.com>
Sent: Monday, October 11, 2021 1:09 PM
To: Mark I. Sedar <msedar@pharmacy.nv.gov>; Credentialing-RPG <credentialing-RPG@ruralphysiciansgroup.com>
Cc: Dr. Sandra Guidry <drguidry@ruralphysiciansgroup.com>
Subject: RE: NV Board of Pharmacy Form - Heath DeHart, PA & Lindsay Allen, PA

CAUTION: This email originated from outside your organization. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Hello, yes I sent these last week after the Aten debacle but I have attached them again
They actually came from cborbon@ruralphysiciansgroup.com on 10/7.

Logo



Corine Borbon
Licensing & Credentialing Coordinator

10624 S. Eastern Avenue, Suite A263, Henderson, NV 89052
c: 760-684-0407 | f: 866-439-0227|
w:ruralphysiciansgroup.com

Warning: This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or employee/agent responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you receive this communication in error, please notify me immediately.

From: Mark I. Sedar <msedar@pharmacy.nv.gov>
Sent: Monday, October 11, 2021 10:26 AM
To: Credentialing-RPG <credentialing-RPG@ruralphysiciansgroup.com>
Cc: Dr. Sandra Guidry <drguidry@ruralphysiciansgroup.com>
Subject: RE: NV Board of Pharmacy Form - Heath DeHart, PA

Hi Corine,

Did you previously send the application to me?

Mark Sedar
COO
Nevada State Board of Pharmacy
(775) 850-1440
msedar@pharmacy.nv.gov



This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not

the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

From: Credentialing-RPG <credentialing-RPG@ruralphysiciansgroup.com>
Sent: Monday, October 11, 2021 10:08 AM
To: Mark I. Sedar <msedar@pharmacy.nv.gov>; Credentialing-RPG <credentialing-RPG@ruralphysiciansgroup.com>
Cc: Dr. Sandra Guidry <drguidry@ruralphysiciansgroup.com>
Subject: RE: NV Board of Pharmacy Form - Heath DeHart, PA

CAUTION: This email originated from outside your organization. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Hello Mark,

I wanted to check in to see if we are set for Lindsay Allen and Heath DeHart? We are doing the same thing we did for Rob Aten and having the supervisors sign and remote sign in.

Logo

Corine Borbon
Licensing & Credentialing Coordinator

10624 S. Eastern Avenue, Suite A263, Henderson, NV 89052
c: 760-684-0407 | f: 866-439-0227|
w:ruralphysiciansgroup.com

Warning: This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or employee/agent responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you receive this communication in error, please notify me immediately.

From: Corine Borbon <cborbon@ruralphysiciansgroup.com>
Sent: Thursday, October 7, 2021 12:13 PM
To: Mark I. Sedar <msedar@pharmacy.nv.gov>; Credentialing-RPG <credentialing-RPG@ruralphysiciansgroup.com>
Cc: Dr. Sandra Guidry <drguidry@ruralphysiciansgroup.com>
Subject: NV Board of Pharmacy Form - Heath DeHart, PA

Hello Mark,

Here is the last form. Thank you again for assisting with these.

Logo

Corine Borbon
Licensing & Credentialing Coordinator

10624 S. Eastern Avenue, Suite A263, Henderson, NV 89052
c: 760-684-0407 | f: 866-439-0227|
w:ruralphysiciansgroup.com

Warning: This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or employee/agent responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you receive this communication in error, please notify me immediately.

From: Mark I. Sedar <msedar@pharmacy.nv.gov>
Sent: Thursday, October 7, 2021 11:32 AM
To: Credentialing-RPG <credentialing-RPG@ruralphysiciansgroup.com>
Cc: Rob Aten <aten.robert@gmail.com>; Dr. Sandra Guidry <drguidry@ruralphysiciansgroup.com>
Subject: RE: Pharmacy form for Aten has been signed by Timothy Hockenberry, MD

Hi Robert, the emergency waiver has been approved.

Regards,

Mark Sedar
COO
Nevada State Board of Pharmacy
(775) 850-1440
msedar@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a

particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

From: Credentialing-RPG <credentialing-RPG@ruralphysiciansgroup.com>
Sent: Wednesday, October 6, 2021 4:06 PM
To: Mark I. Sedar <msedar@pharmacy.nv.gov>
Cc: Rob Aten <aten.robert@gmail.com>; Dr. Sandra Guidry <drguidry@ruralphysiciansgroup.com>
Subject: FW: Pharmacy form for Aten has been signed by Timothy Hockenberry, MD

CAUTION: This email originated from outside your organization. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Hello Mr. Sedar,

Please see the attached form for Robert Aten. Thank you.

Logo

Corine Borbon
Licensing & Credentialing Coordinator

10624 S. Eastern Avenue, Suite A263, Henderson, NV 89052
c: 760-684-0407 | f: 866-439-0227|
w:ruralphysiciansgroup.com

Warning: This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or employee/agent responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you receive this communication in error, please notify me immediately.

From: noreply@mail.hellosign.com <noreply@mail.hellosign.com>
Sent: Wednesday, October 6, 2021 4:00 PM
To: Credentialing-RPG <credentialing-RPG@ruralphysiciansgroup.com>
Subject: Pharmacy form for Aten has been signed by Timothy Hockenberry, MD

Logo



Success! Your document has been signed

DOCUMENT

Pharmacy form for Aten

SIGNER

Timothy Hockenberry, MD (thockenb16@gmail.com)

VIEW SIGNED DOCUMENT

You can view the document as an attachment below (if it's under 25 MB) or by clicking this link. This document and others may also be accessed by logging in to your HelloSign account.

Warning: To prevent others from accessing your document, please do not forward this email.

Disclaimer

The information contained in this communication from the sender is confidential. It is intended solely for use by the recipient and others authorized to receive it. If you are not the recipient, you are hereby notified that any disclosure, copying, distribution or taking action in relation of the contents of this information is strictly prohibited and may be unlawful.

This email has been scanned for viruses and malware, and may have been automatically archived by **Mimecast Ltd**, an innovator in Software as a Service (SaaS) for business. Providing a **safer** and **more useful** place for your human generated data. Specializing in; Security, archiving and compliance. To find out more Click Here.

22-351-CS-N
Exhibit 4
Heath DeHart



PROCLAMATION TERMINATING DECLARATION OF EMERGENCY RELATED TO COVID-19

WHEREAS, on March 12, 2020, I, Steve Sisolak, Governor of the State of Nevada, issued a Declaration of Emergency to facilitate the State's response to the COVID-19 pandemic; and

WHEREAS, on March 13, 2020, then-President of the United States, Donald J. Trump, declared a nationwide emergency pursuant to Sec. 501(6) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the "Stafford Act"); and

WHEREAS, the World Health Organization advises that the novel coronavirus that causes COVID-19 virus is highly contagious, and spreads through respiratory transmission, and direct and indirect contact with infected persons and surfaces; and

WHEREAS, the World Health Organization advises that transmission occurs through both droplet and airborne transmission, where droplet transmission occurs when a person is in close proximity to someone who is infected with COVID-19; and

WHEREAS, in late December 2020, Nevada began distributing COVID-19 vaccines, and there is now an abundant supply of vaccines; and

WHEREAS, Nevada is receiving regular supplies of monoclonal antibodies and other therapeutics to treat those who contract COVID-19; and

WHEREAS, the CDC has identified the "Omicron" variant of COVID-19 and has deemed it a "variant of concern" due to its higher transmissibility; and

WHEREAS, beginning in November 2021, Nevada experienced a surge of COVID-19 cases, and nearly all of those cases are suspected to be the Omicron variant; and

WHEREAS, the number of COVID-19 cases have fallen dramatically since Febma1y 2022; and

WHEREAS, the number of hospitalizations related to COVID-19 has substantially declined; and

WHEREAS, through the combined efforts of the State, counties, and local governments, tribal governments, healthcare providers, first responders, business owners, essential workers, and all Nevadans, we are prepared to prevent, treat, and manage COVID-19; an

WHEREAS, Article 5, Section 1 of the Nevada Constitution provides: "The supreme executive power of this State, shall be vested in a Chief Magistrate who shall be Governor of the State of Nevada;"

NOW, THEREFORE, *by the authority vested in me as Governor by the Constitution and the laws of the State of Nevada and the United States, and pursuant to the March 12, 2020 Emergency Declaration,*

IT IS HEREBY ORDERED THAT:

The Declaration of Emergency for COVID-19 issued on March 12, 2020 is hereby terminated, effective at 12:01 a.m. on May 20, 2022.

IN WITNESS WHEREOF, I have hereunto set my hand and caused the Great Seal of the State of Nevada to be affixed at the State Capitol in Carson City, this 18th day of May,, in the year two thousand twenty-two.

Governor of the State of Nevada

Barbara K. Cegavske

Secretary of State

Deputy Secretary of State

22-351-CS-N
Exhibit 5
Heath DeHart

Nevada PRESCRIPTION MONITORING PROGRAM

775-687-5694

Report Prepared: 08/30/2022

Prescriber Activity Report

Date Range: 08/30/2021 - 08/30/2022

Investigation Type:
Case Number:
Primary Drug Category:
Drug Product Name:
Case Notes:
Agency:
Contact: Shannan Johns
Role: Admin
Phone: 7758501440
Email: sjohns@pharmacy.nv.gov

HEATH DEHART
200 S A ST
HAWTHORNE, NV 89415

Report Criteria

DEA Number: MD3516436, Prescriber First Name: HEATH, Prescriber Last Name: DEHART

Summary	
Prescriptions	6
Patients	6
Pharmacies	2

Prescriber Activity

Last	First	DOB	Fill Date	Written Date	Drug Name	ICD-10	Qty	Supply	Store ID	Rx #	Pymt Type
[redacted]	[redacted]	[redacted]1994	02/27/2022	02/27/2022	TRAMADOL HCL 50 MG TABLET		6.0	2	MT G4095	0	Other
[redacted]	[redacted]	[redacted]/1987	02/28/2022	02/28/2022	TRAMADOL HCL 50 MG TABLET		4.0	1	MT G4095	0	Other

Last	First	DOB	Fill Date	Written Date	Drug Name	ICD-10	Qty	Supply	Store ID	Rx #	Pymt Type
[redacted]	[redacted]	[redacted]985	06/04/2022	06/03/2022	ACETAMINOPHEN-COD #2 TABLET		6.0	3	SAFE5199	4610039	Comm Ins
[redacted]	[redacted]	[redacted]987	01/15/2022	01/15/2022	TRAMADOL HCL 50 MG TABLET		2.0	1	MT G4095	0	Other
[redacted]	[redacted]	[redacted]971	04/08/2022	04/01/2022	CHLORDIAZEPOXIDE 10 MG CAPSULE	F10939	7.0	3	SAFE5199	4609659	Comm Ins
[redacted]	[redacted]	[redacted]978	01/11/2022	01/10/2022	HYDROCODONE-ACETAMIN 7.5-325		10.0	3	SAFE5199	2554753	Comm Ins

Dispensers

Store ID	Name	Address	City	State	Zip
MT G4095	MT GRANT GENERAL HOSPITAL	200 SOUTH A STREET	HAWTHORNE	NV	89415
SAFE5199	SAFEWAY INC	HIGHWAY 95 & ARMORY	HAWTHORNE	NV	89415

Therapeutic Class Summary

Therapeutic Class 4	Script Count	Patient Count	Pharmacy Count
OPIATE AGONISTS	5	5	2
BENZODIAZEPINES (ANXIOLYTIC,SEDATIV/HYP)	1	1	1

Disclaimer:

By proceeding beyond this page and accessing this Prescription Monitoring Program (PMP) system, I certify that I am currently registered and authorized to prescribe or dispense controlled substances, or the duly authorized delegate thereof. I understand that my use of this PMP system is permitted only in connection with providing medical or pharmaceutical care to a patient, which includes evaluating a patient for medical treatment, and only to the extent authorized by law. I understand that my access to or disclosure of any PMP data for any purpose not authorized by law may subject me to disciplinary action, civil penalties, or criminal prosecution. I further understand that I must treat the information in the PMP system as confidential, just as I would any other protected health information. I will protect any PMP information in my possession in accordance with Federal and state laws governing protected health information. I understand that I am responsible for all use of my username and password. I will never share my password with anyone, including my co-workers and staff. If my authentication or password is lost or compromised, I agree to notify the PMP immediately. I understand the PMP will monitor for unusual or potentially unauthorized use of the system.

[redacted]

22-351-CS-N
Exhibit 6
Heath DeHart

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Advanced Nurse Practitioner and Physician Assistant– Prescribing Registration Waiver Request
Governor Sisolak's COVID-19 Declaration of Emergency Directive 011

On April 1, 2020, Governor Sisolak issued Emergency Directive 011 ("Directive") to temporarily waive licensing requirements. The waiver applies to qualified APRNs or PAs who hold licenses that are active, expired, or inactive, in good standing in Nevada or another state. Ineligible APRNs and PAs include those who have licenses that are currently revoked or have been surrendered as a result of disciplinary proceedings. All APRNs and PAs who wish to prescribe under this Directive must complete and return this form to the Nevada State Board of Pharmacy. Once this form has been approved, you are eligible to prescribe under the Directive. Please note, this is a waiver of licensure. You will not be issued a license in Nevada, but may prescribe in Nevada upon approval of this form and only for the duration of the Directive. If you wish to apply for licensure, you must complete the appropriate form and pay the required fee at www.bop.nv.gov

You may fax this completed form to 775-850-1444, mail to 985 Damonte Ranch Parkway, Ste. 206, Reno, Nevada 89521 or email to pharmacy@pharmacy.nv.gov.

Personal Information

First: Heath Middle: Gabriel Last: DeHart

Date of Birth: [redacted] SSN or ITIN: [redacted] License Type (circle one): APRN PA

Home Address: [redacted] S 900 E

City: St. George State: UT Zip: 84790

Email Address: [redacted] Contact Number: [redacted]

Nevada Employer Information

Practice Name:

Practice Address:

City: State: Zip:

Name of Facility Director/Supervising Physician (if PA must be the Supervising Physician): David Garvey, MD

List your license(s), including DEA number(s), in all jurisdictions and provide proof of licensure (use another sheet if additional space is needed)

State	License number	License Status					License in Good Standing?	
		Active	Inactive	Expired	Revoked	Surrendered	Yes	No
UT	5500664-1206	X					X	
AZ	6398	X					X	
FL	PA 9111291	X					X	
IA	090136		X				X	
DEA - MD3516436		X					X	

Waiver Information	Yes	No
Have you been granted a waiver pursuant to Governor Sisolak's COVID-19 Declaration of Emergency Directive 011 from the Nevada State Board of Nursing, Board of Medical Examiners, or Board of Osteopathic Medicine?	✓	

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any of the number questions (1-4) above, include the following information and provide documentation:

Board Administrative Action:	State:	Date:	Case #

Criminal Action:	State	Date:	Case#:	County:	Court:

Types of Drugs you may Prescribe under this Waiver

You may prescribe **Dangerous Drugs** under this waiver if you have provided proof as requested above that:

1. All of your practice licenses are active, expired, or inactive, and in good standing in Nevada or another state; and
2. You have you been granted a waiver pursuant to Governor Sisolak's COVID-19 Declaration of Emergency Directive 011 from the Nevada State Board of Nursing, Board of Medical Examiners, or Board of Osteopathic Medicine.

You may also prescribe and administer **Controlled Substances** under this waiver if you have provided proof as requested above that:

1. You have an active **DEA license in Good Standing** in another state; and none of your DEA licenses were revoked or suspended.

I hereby certify, under penalty of perjury, that the information on this application is true, accurate and correct. I further agree to abide by all statutes, rules or regulations governing the prescribing in Nevada and understand that a violation of any such statute, rules or regulations may be grounds for suspension or revocation of this permit of authorization.

Heath DeHart — 10 / 06 / 2021

Signature of Applicant (Electronic Signature Permitted) — Date

Heath DeHart, PA-C — 10 / 07 / 2021

Signature of Facility Director/Supervising Physician
(If PA must be the Supervising Physician)
(Electronic Signature Permitted) — Date

Board Use Only	Date Received: _____ ☐Approved on _____ ☐Denied on _____
	Approved for: ☐ Dangerous Drugs Only ☐ Dangerous Drugs and Controlled Substances
	Approval Signature: _____

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
MD3516436	06-30-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	MLP-PHYSICIAN ASSISTANT	06-24-2021

DEHART, HEATH PA
BANNER DESERT MEDICAL CENTER
1400 S DOBSON RD
MESA, AZ 852024707

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

REGISTERED ACTIVITY WITHIN SCHEDULE IS RESTRICTED BY YOUR STATE.

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
MD3516436	06-30-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	MLP-PHYSICIAN ASSISTANT	06-24-2021

DEHART, HEATH PA
BANNER DESERT MEDICAL CENTER
1400 S DOBSON RD
MESA, AZ 852024707

REGISTERED ACTIVITY WITHIN SCHEDULE IS RESTRICTED BY YOUR STATE.

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

22-351-CS-N
Exhibit 7
Heath DeHart

NRS 622A.390 Posthearing motions; rehearing and reconsideration; vacation and modification of final decision.

1. After the close of the hearing, a party may file only the following motions:

(a) A motion requesting a rehearing.

(b) A motion requesting reconsideration of the findings and recommendations of the hearing panel or officer or the final decision of the regulatory body.

(c) A motion requesting that the final decision of the regulatory body be vacated or modified.

(d) With leave of the regulatory body or hearing panel or officer, any other motion requesting appropriate action or relief after the close of the hearing.

2. A motion requesting a rehearing or reconsideration must be filed with:

(a) The hearing panel or officer not later than 15 days after the date of service of the findings and recommendations of the hearing panel or officer.

(b) The regulatory body not later than 15 days after the date of service of the final decision of the regulatory body.

3. A party who opposes the motion may file a response to the motion not later than 7 days after the date of service of the motion.

4. The regulatory body may authorize the president or chair of the regulatory body to rule on the motion. The hearing panel may authorize the chair or presiding officer of the hearing panel to rule on the motion.

5. A motion requesting a rehearing or reconsideration may be based only on one of the following grounds:

(a) Newly discovered or available evidence.

(b) Error in the hearing or in the findings and recommendations or the decision that would be grounds for reversal of the findings and recommendations or the decision.

(c) The need in the public interest for further consideration of the issues or evidence, or both.

6. The regulatory body or hearing panel or officer shall enter an order ruling on the motion requesting a rehearing or reconsideration not later than 25 days after the date on which the motion is filed. A copy of the order must be served on each party. The regulatory body or hearing panel or officer may:

(a) Deny the motion;

(b) Order a rehearing or partial rehearing;

(c) Order reconsideration of the findings and recommendations or the decision; or

(d) Direct other proceedings as the regulatory body or hearing panel or officer deems appropriate.

7. If the regulatory body or hearing panel or officer orders a rehearing, the rehearing must be confined to the issues upon which the rehearing was ordered.

(Added to NRS by 2005, 750)

22-351-CS-N
Exhibit 8
Heath DeHart

NAC 639.170 Waiver of regulation upon declaration of emergency: Authority; required notices. (NRS 639.070**)**

1. The President, Executive Secretary or General Counsel of the Board may waive any of the requirements set forth in any regulation adopted by the Board governing the practice of pharmacy if a federal, state or local official authorized to issue a declaration of emergency concerning the health and welfare of the general public submits a notice of such declaration of emergency to the Board.

2. If the President, Executive Secretary or General Counsel of the Board issues a waiver pursuant to subsection 1, he or she shall:

(a) Provide written notification of the waiver, identifying the requirements of the applicable regulations that have been waived, any conditions of the waiver and the period of the waiver, to each pharmacy, pharmacist or other person to whom the Board deems necessary to effectuate the waiver; and

(b) Provide written notification of the termination of the waiver, by the most accessible and efficient means, to the same persons that were provided a written notification of the waiver pursuant to paragraph (a).

(Added to NAC by Bd. of Pharmacy by R189-01, eff. 3-4-2002)

NAC 453.285 Placement of registration on inactive status: Grounds; effect; duration; notice; reinstatement; appeal. (NRS 453.221**,** 453.226**,** 639.070**)**

1. The Executive Secretary of the Board shall, without a hearing, place the registration of a practitioner on inactive status if:

(a) The Board is notified by an occupational licensing board that a license of the practitioner issued by the occupational licensing board has been placed on inactive status; and

(b) The license that was placed on inactive status is the license in connection with which the practitioner was issued a certificate of registration.

2. A practitioner may not dispense any controlled substance within this State during the period that his or her registration is on inactive status.

3. A registration that is placed on inactive status pursuant to subsection 1 will remain inactive until such time as the registrant presents proof to the Executive Secretary of the Board that the occupational licensing board that licenses the practitioner has reinstated the practitioner's license to active status.

4. If a registration is placed on inactive status pursuant to subsection 1, the Board will provide written notice to the registrant as soon as practicable after the registration is placed on inactive status. The notice shall inform the registrant that:

(a) The registrant may petition the Executive Secretary of the Board at any time for reinstatement of the registration to active status;

(b) The registrant's Internet access to the database of the program established pursuant to NRS 453.162 is suspended while the registration remains on inactive status; and

(c) The registrant may request a hearing before the Board to contest the placement of the registration on inactive status.

5. A registrant whose registration is placed on inactive status pursuant to subsection 1 may petition the Executive Secretary of the Board at any time for reinstatement of the registration to active status.

6. If the Executive Secretary of the Board denies a petition for reinstatement of the registration to active status, the Board will provide written notice to the registrant as soon as practicable after the denial of the petition. The notice shall inform the registrant that he or she may request a hearing before the Board to appeal the denial of the petition.

7. To request a hearing before the Board to contest the placement of a registration on inactive status or appeal the denial of a petition for reinstatement of the registration to active status, the registrant must submit a written request for a hearing to the Board not later than 30 days after the date of issuance of the notice pursuant to subsection 4 or 6.

8. If a registrant requests a hearing before the Board pursuant to subsection 7, the Board will conduct a hearing at the next regularly scheduled meeting of the Board, but in any event, the hearing must be instituted and determined within 45 days after the date of the request for a hearing, unless a continuance is requested by the registrant.

(Added to NAC by Bd. of Pharmacy by R071-19, eff. 2-7-2020)

6B

FILED
OCT - 9 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

ECHO HEALTH LLC, DBA NOVA SPECIALTY PHARMACY,
Unlicensed

v.

OBIECHINA EZEKWESILI, PHARM.D.,
Unlicensed

Respondents.

Case No. 24-354-PH-O

STATEMENT TO THE RESPONDENTS AND NOTICE OF HEARING

TO THE RESPONDENT ABOVE-NAMED, PLEASE TAKE NOTICE THAT:

The Nevada State Board of Pharmacy ("Board"), pursuant to NRS 639.2895(3), has imposed upon Respondents Echo Health LLC, dba Nova Specialty Pharmacy and Obiechina Ezekwesili, Pharm.D., (hereinafter "Respondents") a fine of Six Hundred and Fifty-Five Thousand Dollars and No/100s Cents ($655,000.00). Respondents have contested the above-described administrative action. Pursuant to NRS 639.070, NRS 639.2895, and NRS 233B.121-.126, inclusive, the Board has the authority and jurisdiction to adjudicate this contested case. For purposes of the forthcoming hearing in this matter, it is alleged that:

FACTUAL ALLEGATIONS

1. Respondents never possessed a Nevada pharmacy license.

2. Respondents never possessed or employed anyone who possessed a Nevada pharmacist registration.

3. Despite not being properly licensed, Respondents filled and mailed at least 103 prescriptions for dangerous drugs to at least 64 Nevada based patients.

4. Respondents shipped a number of drugs into Nevada, including B12 Injections 2000mcg/mL; Lipothropic(mic) + B12 Injections 2mg Injections; Minoxidil 10%, Finasteride 0.1%, Biotin 0.2%, and Caffeine Citrate 0.05% Hydroalcoholic Solution; Semaglutide 2.5mg/mL Liquid; Semaglutide/B6 1mg/mL Liquid; Semaglutide/B6 2mg/mL Liquid; Semaglutide/B6 5mg/mL Liquid; and Tirzepatide 15mg/mL Injection.

5. According to a Texas Board of Pharmacy Inspection Report, Respondents failed to keep a perpetual inventory of controlled substances.

6. According to a Texas Board of Pharmacy Inspection Report, Respondents failed to properly conduct drug regimen reviews.

7. According to a Texas Board of Pharmacy Inspection Report, Respondents failed to properly monitor pressure differentials.

8. According to a Texas Board of Pharmacy Inspection Report, Respondents failed to properly remove debris from underneath fingernails using a nail cleaner under running warm water.

9. According to a Texas Board of Pharmacy Inspection Report, Respondents failed to engage in proper hand hygiene.

10. According to a Texas Board of Pharmacy Inspection Report, Respondents failed to perform antiseptic hand cleansing using waterless alcohol-based surgical scrubs once inside the buffer area and prior to donning sterile gloves.

11. According to a Texas Board of Pharmacy Inspection Report, Respondents failed to clean and disinfect work surfaces and floors in the ante-area and buffer area with dedicated cleaning supplies.

12. According to a Texas Board of Pharmacy Inspection Report, Respondents failed to maintain proper documentation of cleaning procedures within the pharmacy.

13. According to a Texas Board of Pharmacy Inspection Report, Respondents failed to maintain records related to compounded sterile preparations for a minimum of two years.

14. According to a Texas Board of Pharmacy Inspection Report, Respondents failed to maintain records that include the date and time of preparation of compounded sterile preparations for the required time period.

15. According to a Texas Board of Pharmacy Inspection Report, Respondents failed to maintain compounding records that include the quantities of materials used in compounded sterile preparations for the required time period.

16. According to a Texas Board of Pharmacy Inspection Report, Respondents failed to maintain compounding records that include the signature or initials of who conducted the final check of a compounded sterile preparation.

17. According to a Texas Board of Pharmacy Inspection Report, Respondents failed to maintain compounding records that include the container used and the number of units prepared for a compounded sterile preparation.

18. According to a Texas Board of Pharmacy Inspection Report, Respondents failed to maintain compounding records that include the criteria used to determine the beyond-use date of a compounded sterile preparation.

19. According to a Texas Board of Pharmacy Inspection Report, Respondents failed to maintain compounding records that include documentation of performance of quality control procedures.

20. Respondents shipped dangerous drugs all over the country, to over 40 states despite only possessing a pharmacy license in Texas.

21. According to a Texas Board of Pharmacy Inspection Report, Respondents failed to ensure that a pharmacist reviewed all compounding records for accuracy and performed final checks of compounded sterile preparations.

22. According to a Texas Board of Pharmacy Inspection Report, Respondents failed to develop and implement written policies and procedures for in-process checks for compounded sterile preparations.

APPLICABLE LAW

23. "[I]t is unlawful for any person to manufacture, engage in wholesale distribution, compound, sell or dispense, or permit to be manufactured, distributed at wholesale, compounded, sold or dispensed, any drug, poison, medicine or chemical, or to dispense or compound, or permit to be dispensed or compounded, any prescription of a practitioner, unless the person [h]olds the appropriate certificate, license or permit required by this chapter or chapter 453 or 454 of NRS, as applicable, that authorizes the person to take such action; and [c]omplies with the regulations adopted by the Board." NRS 639.100(1).

24. "Every pharmacy located outside Nevada that dispenses prescriptions to patients located in Nevada must be licensed by the Board." NRS 639.2328(1).

25. "To be licensed or to renew a license, such a pharmacy must... provide to the Board... the name of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board." NRS 639.2328(2)(d)(4).

26. "Every retail pharmacy, hospital or any practitioner who engages in the practice of dispensing or furnishing drugs to patients and every manufacturer or wholesaler that dispenses dialysate drugs to patients pursuant to NRS 639.573 shall maintain a complete and accurate record of all dangerous drugs purchased and those sold on prescription, dispensed, furnished or disposed of otherwise. The records must be retained for a period of 2 years and must be open to inspection by members, inspectors or investigators of the Board or inspectors of the Food and Drug Administration." NRS 454.286.

27. A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products shall ensure that each pharmacist and pharmaceutical technician engaged in the practice of compounding drug products [i]s competent and proficient in compounding the drug products that the pharmacist or pharmaceutical technician will be

authorized and expected to compound; [c]omplies with the provisions of NAC 639.661 to 639.690, inclusive, concerning the drug products which the pharmacist or pharmaceutical technician compounds and the compounded drug products which the pharmacist or pharmaceutical technician dispenses at the pharmacy; and [r]eceives, on an ongoing basis, sufficient training to maintain that competency and proficiency." NAC 639.67013(1)

28. "A pharmacy engaged in the practice of compounding drug products shall establish and maintain written policies and procedures for compounding drug products to ensure that each final compounded drug product has the identity, strength, quality and purity which the compounded drug product is purported or represented to have." NAC 639.67015(1).

29. The Board has adopted *United States Pharmacopeia - National Formulary*, 2023 edition and the requirements therein by reference. NAC 639.670(1)(c) and (2).

30. The Board may discipline the holder of a license, certificate, or registration if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

31. The Board may discipline the holder of a license, certificate, or registration if the holder or applicant has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

32. The Board may discipline the holder of a license, certificate, or registration if the holder or applicant has, as a managing pharmacist, violated any provision of law or regulation concerning recordkeeping or inventory in a store over which he or she presides. NRS 639.210(15).

33. Unprofessional conduct and conduct contrary to the public interest includes, "[p]erforming any of his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner." NAC 639.945(1)(i).

34. Unprofessional conduct and conduct contrary to the public interest includes, "[p]erforming any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration. NAC 639.945(1)(k).

35. "The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ." NAC 639.945(3).

36. A pharmacy shall maintain a perpetual inventory of any controlled substance listed in schedule II. NAC 639.485(2).

37. "Upon receipt of a prescription and after review of the patient's record, a pharmacist shall communicate matters which will enhance therapy through drugs with the patient or a person caring for the patient. The communication must include appropriate elements of counseling for the patient, as established in regulations adopted by the Board." NRS 639.266(1).

38. "The pharmacist, intern pharmacist or dispensing practitioner shall review a patient's record before dispensing a prescription to determine its therapeutic appropriateness." NAC 639.707(4).

39. The Board may impose an administrative fine of not more than $5,000.00 per offense, upon any person who, without a license, registration, or permit, engages in any activity that requires a license, registration, or permit issued by the Board. NRS 639.100(1); NRS 639.2895(3).

COUNT ONE – ONE HUNDRED AND THREE
(Unlicensed Activity – Respondent Pharmacy and Pharmacist)

40. Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D, unlawfully filled and mailed 103 prescriptions for 64 unique patients for dangerous drugs into the state of Nevada without having first obtained a valid Nevada Pharmacy license. NRS 639.100(1); NRS 639.210(4); and NAC 639.945(1)(i).

41. Pursuant to NRS 639.2895, the Board may impose on Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D, an administrative fine upon them of not more than $5,000.00 per offense, but not to exceed $655,000.00 in totality.

COUNT ONE HUNDRED AND FOUR – TWO HUNDRED AND SIX
(Unlicensed Activity – Respondent Pharmacy and Pharmacist)

42. Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D, unlawfully filled and mailed 103 prescriptions for 64 unique patients for dangerous drugs into the state of Nevada without employing at least one Nevada registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328(2)(d)(4); NRS 639.210(4); NAC 639.945(1)(i).

43. Pursuant to NRS 639.2895, the Board may impose on Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D, an administrative fine upon them of not more than $5,000.00 per offense, but not to exceed $655,000.00 in totality.

COUNT TWO HUNDRED AND SEVEN – TWO HUNDRED AND SEVENTY-ONE
(Unprofessional Conduct – Failure to Review Patient Profile Prior to the Issuance of a New Prescription – Respondent Pharmacy and Pharmacist)

44. Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D, failed to review patient profile prior to the issuance of new prescriptions as required by Nevada law. NRS 639.266(1); NAC 639.707(4); NRS 639.210(4); and NAC 639.945(1)(i).

45. Pursuant to NRS 639.2895, the Board may impose on Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D, an administrative fine upon them of not more than $5,000.00 per offense, but not to exceed $655,000.00 in totality.

COUNT TWO HUNDRED AND SEVENTY-TWO
(Unprofessional Conduct – Failure to Properly Monitor Pressure Differentials – Respondent Pharmacy and Pharmacist)

46. Respondents Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D failed to properly monitor pressure differentials, as required by the *United States Pharmacopeia - National Formulary*, 2008 edition adopted by the Board by reference. NAC 639.670(1)(c) and (2); NRS 639.210(4); and NAC 639.945(1)(i).

47. Pursuant to NRS 639.2895, the Board may impose on Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D, an administrative fine upon them of not more than $5,000.00, but not to exceed $655,000.00 in totality.

COUNT TWO HUNDRED AND SEVENTY-THREE
(Unprofessional Conduct – Failure to Properly Remove Debris from Underneath Fingernails Using a Nail Cleaner Under Running Warm Water – Respondent Pharmacy and Pharmacist)

48. Respondents Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D failed to ensure staff properly removed debris from underneath fingernails using a nail cleaner under running warm water as required by the *United States Pharmacopeia - National Formulary*, 2008 edition adopted by the Board by reference. NAC 639.670(1)(c) and (2); NRS 639.210(4); and NAC 639.945(1)(i).

49. Pursuant to NRS 639.2895, the Board may impose on Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili,

Pharm.D, an administrative fine upon them of not more than $5,000.00, but not to exceed $655,000.00 in totality.

COUNT TWO HUNDRED AND SEVENTY-FOUR
(Unprofessional Conduct – Failure to Engage in Proper Hand Hygiene – Respondent Pharmacy and Pharmacist)

50. Respondents Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D failed to ensure compounding staff engaged in proper hand hygiene as required by the *United States Pharmacopeia - National Formulary*, 2008 edition adopted by the Board by reference. NAC 639.670(1)(c) and (2); NRS 639.210(4); and NAC 639.945(1)(i).

51. Pursuant to NRS 639.2895, the Board may impose on Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D, an administrative fine upon them of not more than $5,000.00, but not to exceed $655,000.00 in totality.

COUNT TWO HUNDRED AND SEVENTY-FIVE
(Unprofessional Conduct – Failure to Perform Antiseptic Hand Cleansing Using Waterless Alcohol-Based Surgical Scrubs – Respondent Pharmacy and Pharmacist)

52. Respondents failed to perform antiseptic hand cleansing using waterless alcohol-based surgical scrubs once inside the buffer area and prior to donning sterile gloves as required by the *United States Pharmacopeia - National Formulary*, 2008 edition adopted by the Board by reference. NAC 639.670(1)(c) and (2); NRS 639.210(4); and NAC 639.945(1)(i).

53. Pursuant to NRS 639.2895, the Board may impose on Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D, an administrative fine upon them of not more than $5,000.00, but not to exceed $655,000.00 in totality.

COUNT TWO HUNDRED AND SEVENTY-SIX
(Unprofessional Conduct – Failure to Clean and Disinfect Work Surfaces and Floors in the Ante-Area and Buffer Area with Dedicated Cleaning Supplies – Respondent Pharmacy and Pharmacist)

54. Respondents failed to clean and disinfect work surfaces and floors in the ante-area and buffer area with dedicated cleaning supplies as required by the *United States Pharmacopeia - National Formulary*, 2008 edition adopted by the Board by reference. NAC 639.670(1)(c) and (2); NRS 639.210(4); and NAC 639.945(1)(i).

55. Pursuant to NRS 639.2895, the Board may impose on Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D, an administrative fine upon them of not more than $5,000.00, but not to exceed $655,000.00 in totality.

COUNT TWO HUNDRED AND SEVENTY-SEVEN
(Unprofessional Conduct – Failure to Maintain Proper Documentation of Cleaning Procedures – Respondent Pharmacy and Pharmacist)

56. Respondents failed to maintain proper documentation of cleaning procedures within the pharmacy as required by the *United States Pharmacopeia - National Formulary*, 2008 edition adopted by the Board by reference. NAC 639.670(1)(c) and (2); NRS 639.210(4); NRS 639.210(15); and NAC 639.945(1)(i).

57. Pursuant to NRS 639.2895, the Board may impose on Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D, an administrative fine upon them of not more than $5,000.00, but not to exceed $655,000.00 in totality.

COUNT TWO HUNDRED AND SEVENTY-EIGHT
(Unprofessional Conduct – Failure to Maintain Records Related to Compounded Sterile Preparations for Required Time Period – Respondent Pharmacy and Pharmacist)

58. Respondents failed to maintain records that include the date and time of preparation of compounded sterile preparations for the required time period as required by the *United States Pharmacopeia - National Formulary*, 2008 edition adopted by the Board by

reference and by Nevada law. NAC 639.670(1)(c) and (2); NRS 454.286; NRS 639.210(4); NRS 639.210(15); and NAC 639.945(1)(i).

59. Pursuant to NRS 639.2895, the Board may impose on Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D, an administrative fine upon them of not more than $5,000.00, but not to exceed $655,000.00 in totality.

COUNT TWO HUNDRED AND SEVENTY-NINE
(Unprofessional Conduct – Failure to Maintain Records Regarding the Date and Time of Preparation of Sterile Compounded Preparations – Respondent Pharmacy and Pharmacist)

60. Respondents failed to maintain compounding records that include the quantities of materials used in compounded sterile preparations for the required time period as required by the *United States Pharmacopeia - National Formulary*, 2008 edition adopted by the Board by reference and by Nevada law. NAC 639.670(1)(c) and (2); NRS 454.286; NRS 639.210(4); NRS 639.210(15); and NAC 639.945(1)(i).

61. Pursuant to NRS 639.2895, the Board may impose on Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D, an administrative fine upon them of not more than $5,000.00, but not to exceed $655,000.00 in totality.

COUNT TWO HUNDRED AND EIGHTY
(Unprofessional Conduct – Failure to Maintain Records Regarding the Quantities of Materials Used in Compounded Sterile Preparations – Respondent Pharmacy and Pharmacist)

62. Respondents failed to maintain compounding records that include the quantities of materials used in compounded sterile preparations for the required time period as required by the *United States Pharmacopeia - National Formulary*, 2008 edition adopted by the Board by reference. NAC 639.670(1)(c) and (2); NRS 639.210(4); NRS 639.210(15); and NAC 639.945(1)(i).

63. Pursuant to NRS 639.2895, the Board may impose on Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D, an administrative fine upon them of not more than $5,000.00, but not to exceed $655,000.00 in totality.

COUNT TWO HUNDRED AND EIGHTY-ONE
(Unprofessional Conduct – Failure to Maintain Records that Include the Signature of Initials of who Conducted the Final Check of a Compounded Sterile Preparation – Respondent Pharmacy and Pharmacist)

64. Respondents failed to maintain compounding records that include the signature or initials of who conducted the final check of a compounded sterile preparation as required by the *United States Pharmacopeia - National Formulary*, 2008 edition adopted by the Board by reference. NAC 639.670(1)(c) and (2); NRS 639.210(4); NRS 639.210(15); and NAC 639.945(1)(i).

65. Pursuant to NRS 639.2895, the Board may impose on Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D, an administrative fine upon them of not more than $5,000.00, but not to exceed $655,000.00 in totality.

COUNT TWO HUNDRED AND EIGHTY-TWO
(Unprofessional Conduct – Failure to Maintain Records that Include the Container Used and the Number of Units Prepared for a Compounded Product – Respondent Pharmacy and Pharmacist)

66. Respondents failed to maintain compounding records that include the container used and the number of units prepared for a compounded sterile preparation as required by the *United States Pharmacopeia - National Formulary*, 2008 edition adopted by the Board by reference. NAC 639.670(1)(c) and (2); NRS 639.210(4); NRS 639.210(15); and NAC 639.945(1)(i).

67. Pursuant to NRS 639.2895, the Board may impose on Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili,

Pharm.D, an administrative fine upon them of not more than $5,000.00, but not to exceed $655,000.00 in totality.

COUNT TWO HUNDRED AND EIGHTY-THREE
(Unprofessional Conduct – Failure to Maintain Records that Include the Criteria Used to Determine the Beyond-Use Date of a Sterile Compounded Preparation – Respondent Pharmacy and Pharmacist)

68. Respondents failed to maintain compounding records that include the criteria used to determine the beyond-use date of a compounded sterile preparation as required by the *United States Pharmacopeia - National Formulary*, 2008 edition adopted by the Board by reference. NAC 639.670(1)(c) and (2); NRS 639.210(4); NRS 639.210(15); and NAC 639.945(1)(i).

69. Pursuant to NRS 639.2895, the Board may impose on Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D, an administrative fine upon them of not more than $5,000.00, but not to exceed $655,000.00 in totality.

COUNT TWO HUNDRED AND EIGHTY-FOUR
(Unprofessional Conduct – Failure to Maintain Records that Include Documentation of Performance of Quality Control Procedures – Respondent Pharmacy and Pharmacist)

70. Respondents failed to maintain compounding records that include documentation of performance of quality control procedures as required by the *United States Pharmacopeia - National Formulary*, 2008 edition adopted by the Board by reference. NAC 639.670(1)(c) and (2); NRS 639.210(4); NRS 639.210(15); and NAC 639.945(1)(i).

71. Pursuant to NRS 639.2895, the Board may impose on Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D, an administrative fine upon them of not more than $5,000.00, but not to exceed $655,000.00 in totality.

COUNT TWO HUNDRED AND EIGHTY-FIVE
(Unprofessional Conduct – Performing any Act, Task or Operation for Which Licensure, Certification or Registration is Required Without the Required License, Certificate or Registration – Respondent Pharmacy and Pharmacist)

72. Respondents shipped dangerous drugs all over the country, to over 40 states despite only possessing a pharmacy license in Texas. Receiving, filling, and shipping prescriptions despite not possessing the required licenses to do so across multiple states constitutes unprofessional conduct as Respondents performed acts, tasks, or operations for which licensure or registration was required, without having obtained the required license or registration. NRS 639.210(4); NAC 639.945(1)(k).

73. Pursuant to NRS 639.2895, the Board may impose on Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D, an administrative fine upon them of not more than $5,000.00, but not to exceed $655,000.00 in totality.

COUNT TWO HUNDRED AND EIGHTY-SIX
(Unprofessional Conduct – Failure to Have Pharmacist Review Compounding Records for Accuracy and Perform Final Checks of Compounded Products – Respondent Pharmacy and Pharmacist)

74. Respondents failed to ensure that a pharmacist reviewed all compounding records for accuracy and performed final checks of compounded sterile preparations as required by the *United States Pharmacopeia - National Formulary*, 2008 edition adopted by the Board by reference. NAC 639.670(1)(c) and (2); NRS 639.210(4); and NAC 639.945(1)(i).

75. Pursuant to NRS 639.2895, the Board may impose on Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D, an administrative fine upon them of not more than $5,000.00, but not to exceed $655,000.00 in totality.

COUNT TWO HUNDRED AND EIGHTY-SEVEN
(Unprofessional Conduct – Failure to Develop and Implement Written Policies and Procedures for In-Process Checks of Compounded Sterile Preparations – Respondent Pharmacy and Pharmacist)

76. Respondents failed to develop and implement written policies and procedures for in-process checks for compounded sterile preparations as required by the *United States Pharmacopeia - National Formulary*, 2008 edition adopted by the Board by reference. NAC 639.670(1)(c) and (2); NRS 639.210(4); NAC 639.67015(1); and NAC 639.945(1)(i).

77. Pursuant to NRS 639.2895, the Board may impose on Respondent Echo Health dba Nova Specialty Pharmacy and Owner and Pharmacist-in-charge Obiechina Ezekwesili, Pharm.D, an administrative fine upon them of not more than $5,000.00, but not to exceed $655,000.00 in totality.

NOTICE TO RESPONDENTS

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 639.2895(2); NRS 233B.127(3). You have the right to a hearing before the Board to answer the allegations and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.127(3); NRS 622A.300(1) and (3). If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

The Board has scheduled your hearing on this matter for December 4, 2024, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada 89123.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. You may request and

the Board may at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session. NRS 241.030 and NRS 241.033.

DATED this 9th day of October, 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 10th day of October 2024, I personally served a true and correct copy of the foregoing **Statement to the Respondent and Notice of Hearing** by placing a copy in the United States Mail, postage prepaid, addressed to the following:

2651 E Broad St, Suite 101
Mansfield, TX 76063

And by sending an electronic copy via email addressed to:
pharmacy@novaspecialtypharmacy.com

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

Nevada State Board of Pharmacy

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521
(775) 850-1440 • FAX (775) 850-1444
Email: Pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

September 11, 2024

VIA CERTIFIED U.S. MAIL & ELECTRONIC MAIL

Obiechina Ezekwesili, Pharm.D. (Unlicensed)
Echo Health LLC, dba Nova Specialty Pharmacy
2651 E. Broad Street, Suite 101
Mansfield, TX 76063
Email: pharmacy@novaspecialtypharmacy.com

CEASE-AND-DESIST and CITATION-AND-FINE: Case No. 24-354-PH-O – Unlicensed Operation of a Pharmacy and Practice of Pharmacy in Nevada

To Whom it May Concern:

The Nevada State Board of Pharmacy (hereinafter "Board") has determined that you own and serve as the managing pharmacist of Echo Health LLC, dba Nova Specialty Pharmacy (hereinafter "Nova"). The Board has also found that Nova is operating an unlicensed pharmacy in the state of Nevada. Nova sold or dispensed prescriptions to Nevada-based patients at least 103 times. Additionally, according to an inspection report obtained from the Texas State Board of Pharmacy, Nova failed to maintain quality standards for the compounded drugs that it dispensed to its Nevada-based patients. Failure to adhere to proper quality standards when compounding drugs may result in patient harm.

Under Nevada law, no person (including a pharmacy or pharmacist) may manufacture, engage in wholesale distribution, compound, sell or dispense, or permit to be manufactured, distributed at wholesale, compounded, sold or dispensed, any drug, poison, medicine or chemical, or to dispense or compound, or permit to be dispensed or compounded, any prescription of a practitioner, unless the person holds the appropriate license and complies with the regulations adopted by the Board. NRS 639.100(1). Any person who violates NRS 639.100(1) may be charged with a felony. *See* NRS 639.100(2). Additionally, any person engaged in the unlicensed practice of pharmacy in Nevada may be subject to administrative fines and/or claims for injunctive relief. NRS 639.2895. By shipping prescriptions into the state of Nevada at least 103 times, Nova has sold or dispensed a drug without the appropriate license (a pharmacy license) at least 103 times. Further, as Nova's owner and managing pharmacist, you caused or permitted Nova to sell or dispense drugs on each of these occasions, thereby engaging in the unlicensed practice of pharmacy.

In addition to being properly licensed, a pharmacy and/or pharmacist must comply with all applicable regulations adopted by the Board. Based on the Texas report noted above, Nova failed to comply with compounding regulations adopted by the Board at least 28 times. *See* NRS

9171 9690 0935 0313 5396 45

3414

639.210(4); NRS 639.210(15); NAC 639.482; NAC 639.485; NAC 639.670; NAC 639.6705; NAC 639.67037; NAC 639.67069; NAC 639.67077; NAC 639.67079; NAC 639.6701; NAC 639.67013; NAC 639.67019; NAC 639.6702; NAC 639.67055; NAC 639.707; NAC 639.708; NAC 639.751; NAC 639.945(1)(a); NAC 639.945(1)(f); NAC 639.945(1)(j); and NAC 639.945(1)(k). Please note that some of the regulations listed previously have been purportedly violated in multiple ways and/or more than once. Finally, the Board also has evidence that Nova failed to employ a Nevada licensed pharmacist during the period of time they shipped drugs into Nevada, in violation of Nevada law. NRS 639.2328.

As noted previously, the Board may seek injunctive relief and/or impose administrative fines against any person engaged in the unlicensed practice of pharmacy in Nevada. In this case, you and/or your employer, Echo Health LLC, dba Nova Specialty Pharmacy, are jointly and severally liable for a fine of up to $5,000 for each of the 131 violations identified above. NRS 639.100(3). NRS 639.2895.

Accordingly, the Board hereby orders you to immediately **CEASE and DESIST** your operation of an unlicensed pharmacy in the state of Nevada. Do not ship any more drugs or fill any more prescriptions for Nevada-based patients. Additionally, this letter shall serve as a **CITATION** pursuant to NRS 639.2895(2) for operating a pharmacy and engaging in the practice of pharmacy in this state without having obtained the required pharmacy license and/or pharmacist registration issued by the Board. Based on the above evidentiary summary, the Board has assessed **administrative fines** against you and/or your employer in the total amount of **Six Hundred and Fifty-Five Thousand Dollars and 00/100 Cents ($655,000.00).**

If you do not intend to contest the above fines, please pay the amount listed above within 30 days of receipt of this citation, or otherwise contact Board staff to request an extension for good cause shown. Payment must be made by *certified check, cashier's check,* or *money order* payable to **"State of Nevada, Office of the Treasurer,"** and it must be received at the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

You may appeal this citation by submitting a notice of appeal requesting a public hearing before the Board. You must submit any such notice of appeal not later than 30 days after receipt of this citation. NRS 639.2895(2). Please mail or personally deliver any notice of appeal to the Reno address listed on the letterhead.

Pursuant to the Nevada Public Records Act, this citation constitutes a public record that must be released to anyone who makes a proper request for it. Additionally, once it becomes a final determination in accordance with the Nevada Administrative Procedure Act, this matter will be reported to the National Practitioner Data Bank. If you have any questions, please contact the Board's General Counsel, Gustaf Vanderdonck, at 775-850-1440, ext. 132, or *via* email at gvanderdonck@pharmacy.nv.gov.

Sincerely,

Nevada State Board of Pharmacy

7

7A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada	☐ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☐ Out-of-Nevada	☑ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FC11780267 current
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH 04428		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Complete Care Pharmacy

Physical Address: 1090 E. Desert Inn Road, Suite 204

City: Las Vegas State: NV Zip: 89109

Mailing Address (if different from physical address): 1620 W. Northwest Hwy, Suite 100

City: Grapevine State: TX Zip: 76051

Telephone: 702-983-2243 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 725-210-0337 Contact Email: completecare@rhsconsultants.com

Website: N/A

Nevada Business License # (if applicable) NV20212016561

Supervising/Managing Pharmacist Name (NRS 639.220): Eric Alonzo

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 22882

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Eric Alonzo	NV Pharmacist Registration #: 22882
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): None

Corporation/Organization Name: AdvanceCare Holdings

Mailing Address: 1521 Alton Rd., Ste. 463

City: Miami Beach State: FL Zip: 33139

Telephone: 909-238-6373 Email: korin@mistr.com

Contact Person Name: Tristan Schukraft

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner (title) for Complete Care Pharmacy + Medical Supplies, Incorp (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

TRISTAN SCHOKRAFT

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

10/18/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, TRISTAN SCHUKRAFT hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the owner (title) for Complete Care Pharmacy + Medical Supplies Incorp. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 30th day of August, 2024

Notary Public

Aff. 297

RECIBO
1U22-02404857
Sello
9397
07/15/2024
$5.00
Sello de Asistencia Legal
80043-2024-0715-54908014

JULIAN EUGENIO SUCRE CONCEPCION
ABOGADO-NOTARIO

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Eric Alonzo Pharmacist Registration #: 22882

Pharmacy Name: Complete Care Pharmacy

Initial each statement below to indicate you have read and agree with the following:

EA — I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

EA — I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

EA — I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

EA — I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

EA — I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✔

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

E. Alonzo

Original signature of Managing Pharmacist (copies or stamps not accepted)

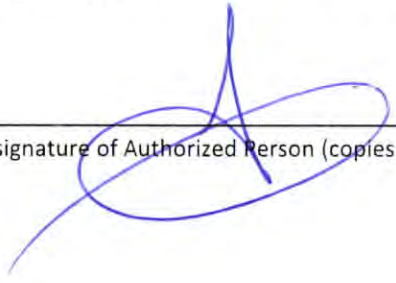
10.18.24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

TRISTAN SCHOKRAFT

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

10-18-24

Date

Board Use Only	Date Received: 10/21/24	Amount: $500-cc

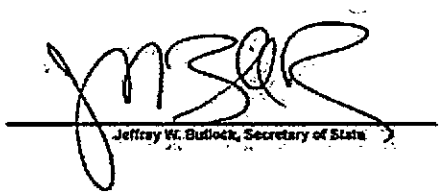
Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ADVANCECARE HOLDINGS LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIFTH DAY OF SEPTEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN ASSESSED TO DATE.





4333990 8300

SR# 20243601103

Authentication: 204313252

Date: 09-05-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

Pharmacy Application – Section 12 Answers
NEVADA STATE BOARD OF PHARMACY
Change of Ownership – Applicant for new Owner: AdvanceCare Holdings LLC

- **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)**
  - The Officer and Director of AdvanceCare Holdings LLC is:
    - Tristan Schukraft – Manager and Sole Director

- **List the top four stockholders and their percent ownership. NRS 639.231(3)**
  - The only member (stockholder) of AdvanceCare Holdings LLC is as follows:
    - Tristan Schukraft – 100%

- **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)**
  - The only member (stockholder) of AdvanceCare Holdings LLC is as follows:
    - Tristan Schukraft – 100%

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Complete Care Pharmacy

Pharmacy/Wholesaler License # (if applicable): PH04428

Physical Address: 1090 E Desert Inn Rd Ste 204

City: Las Vegas State: NV Zip: 89109

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 702-983-2243 Website: https://www.communityoutreachmedicalcenter.org/completecare-pharmac

Licensing Company Email: completecare@nvcomc.org

Section 2: Personal Information

First: Eric Middle: J Last: Alonzo

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Dancing Lasso Ct

City: Las Vegas State: NV Zip: 89178

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Washington State University		08/15-05/19	
Address	**City**	**State**	**Zip**
412 E Spokane Falls Blvd	Spokane	WA	99202
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Washington State University		08/09-12/13	
Address	**City**	**State**	**Zip**
255 E Main St, Pullman, WA 99163	Pullman	WA	99163
Diploma/Degree obtained, if any			
Bachelors of Science			

School Name		From - To (MM/YY – MM/YY)	
Kentwood High School		09/05-06-09	
Address	**City**	**State**	**Zip**
25800 164th Ave SE	Covington	WA	98042
Diploma/Degree obtained, if any			
High school diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/21-10/24	[redacted]Dancing Lass Ct	Las Vegas	NV	89178
10/14-07/21	[redacted]SE 228th Pl	Kent	WA	98031

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Omnicell			08/22-10/24	
Business Address		City	State	Zip
1090 E Desert Inn Rd Ste 204		Las Vegas	NV	89109
Phone	Title		Number of Employed Hours	
702-983-2243	Pharmacist PIC		4400	
Description of Duties				
Oversee all pharmacy operations.				

Business Name			From - To (MM/YY – MM/YY)	
Healthpoint			03/20-07/22	
Business Address		City	State	Zip
955 Powell Ave SW		Renton	WA	98057
Phone	Title		Number of Employed Hours	
425-277-1311	Pharmacist		4576	
Description of Duties				
Provide pharmacy services to patients.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Eric Alonzo, **certify that as the designated representative for**

Complete Care Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ea I am at least 21 years of age;
3. ea I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ea I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ea I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ea I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ea I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Eric, Alonzo

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/18/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Eric, Alonzo

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/18/24

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Eric Alonzo, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10.18.24

Date

Subscribed and Sworn to before me this 18th day of October 2024

Notary Public Signature

CHERYL ROBINSON
Notary Public, State of Nevada
No. 22-5481-01
My Appt. Exp. September 12, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Complete Care Pharmacy & Medical Supplies Incorp.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH04428

Physical Address: 1090 E Desert Inn Rd Ste 204

City: Las Vegas State: NV Zip: 89109

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 702-983-2243 Website: https://www.communityoutreachmedicalcenter.org/completecare-pharmac

Licensing Company Email: kogden@nvcomc.org

Section 2: Personal Information

First: Tristan Middle: David Last: Schukraft

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Addre[redacted]lton Rd, Suite 463

City: Miami Beach State: FL Zip: 33139

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY - MM/YY)	
Agoura High School		08/1993-05/1997	
Address	City	State	Zip
28545 Driver Ave.	Agoura Hills	CA	91301
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY - MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY - MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY - MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY - MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY - MM/YY)	Address	City	State	Zip
04/2022-current	[redacted] Calle Italia	San Juan	PR	00911
12/21-12/2022	[redacted]	San Juan	PR	00907
05/2018-12/2021	[redacted] Collins Ave. #344	Miami Beach	FL	33139
10/2014-05/2018	[redacted] Santa Monica, #312	West Hollywood	CA	90069

Section 7. Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY - MM/YY)
MISTR LLC			07/2018-current
Business Address	**City**	**State**	**Zip**
151 Calle de San Francisco, Ste. 200	San Juan	PR	00901
Phone	**Title**		
747-999-6249	CEO / Founder		
Description of Duties			
Managed and implemented all strategies and plans of this Telemedicine business.			

Business Name			From - To (MM/YY - MM/YY)
Tryst Puerto Rico			10/2022-current
Business Address	**City**	**State**	**Zip**
1 Calle Vendig St.	San Juan	PR	00901
Phone	**Title**		
787-965-5239	Owner		
Description of Duties			
Owner of Hotel & bar/restaurant.			

Business Name			From - To (MM/YY - MM/YY)
The Abbey Food & Bar			04/2023-current
Business Address	**City**	**State**	**Zip**
692 North Robertson Blvd.	West Hollywood	CA	90069
Phone	**Title**		
(310) 289-8410	Owner		
Description of Duties			
Owner of Restaurant & Bar/Night club			

Business Name			From - To (MM/YY - MM/YY)
Frontiers Media			05/2014 - 05/2016
Business Address	**City**	**State**	**Zip**
4600 Greenville Ave. Ste. 250	Dallas	TX	75206
Phone	**Title**		
	CEO / Founder		
Description of Duties			
Developed, manage and implement all strategies and plans of this Telemedicine business.			

Business Name			From - To (MM/YY - MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tristan Schukraft
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

09/05/24
Date

Aff. 298

Please have this section completed in the presence of a Notary Public.

State of Puerto Rico, ss. County of San Juan

I, Tristan Schukraft, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

09/05/24
Date

Subscribed and Sworn to before me this 5th day of September.

Notary Public Signature

JULIÁN EUGENIO SUCRE CONCEPCION ABOGADO NOTARIO (Seal)



7B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada	☐ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☐ Out-of-Nevada	☑ Ownership Change*	☐ Hospital (# beds _____)	☑ Dangerous drugs
	☐ Location Change *	☐ Internet	☑ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FL3326825
	☑ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 04520		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☐ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☑ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Laughlin Pharmacy

Physical Address: 3080 S Needles Hwy Ste 1800 & 1900

City: Laughlin State: NV Zip: 89029

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-709-5300 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 702-709-5303 Contact Email: ymwell2022@gmail.com

Website: —

Nevada Business License # (if applicable) E41912722024-6

Supervising/Managing Pharmacist Name (NRS 639.220): Youjin Seo

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): NV18704

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Youjin Seo	NV Pharmacist Registration #: 19704
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: HIVE LLC

Mailing Address: 2877 Green falls Ave

City: Henderson State: NV Zip: 89052

Telephone: 702 954 9534 Email: greensky1335@icloud.com

Contact Person Name: Yajin Seo

Please check type of partnership (NAC 639.214) ☐ General ☑ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☑ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacy manager (title) for Laughlin Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Youjin Seo

Print Name of Authorized Person

Youjin Seo

Original signature of Authorized Person (copies or stamps not accepted)

7-22-24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Youjin Seo hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacy manager (title) for Laughlin Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 23rd day of July, 2024

Notary Public

CARLO GOSIOCO
Notary Public, State of Nevada
Appointment No. 23-1185-01
My Appt. Expires Aug 14, 2027

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Youjin Seo Pharmacist Registration #: NV 18704

Pharmacy Name: Laughlin Pharmacy

Initial each statement below to indicate you have read and agree with the following:

YS I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

YS I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

YS I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

YS I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

YS I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✓

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Youjin Seo 7-22-24

Original signature of Managing Pharmacist (copies or stamps not accepted) Date

The descriptive narrative of the traffic accident written by Youjin Seo Traffic case #105310739

My sister in law asked me if I could pick her up in Park City, UT. I never drove by myself to Park City before and wasn't familiar with the road so I asked my friend to drive with me. When I got to my friend's place (Willow Cove apartment), the parking stall was pretty tight. I tried to adjust several times to park and I felt that my car bumper hit a tire of the pickup truck which was parked in the next stall.

After I checked the condition of the tire and my car bumper, I went up to my friend's house while running my car to ask her opinion on what to do. She said she knows where the truck owner lives and she will explain to him in person since the damages are barely noticeable. I didn't have much experience and never been involved in any type of car accident before. I was vulnerable to take my friend's advice. When we got out of her apartment, she mentioned that I'm not allowed to park my car in the residential parking area so I moved my car to the public parking area which was the closest available one from the pickup truck. While leaving my car there,I requested my friend to drive her car instead.

After we got back from Park City, the note from the truck owner was left on my car windshield. The note was saying that I need to contact him right away. When I called him back, he said that he wanted to give me a lesson about not leaving contact information after the accident and he said that he already called the police.

After I explained what was going on, he said that he wanted to help me cancel the police report. So we called back to the police station but the officer said that it's impossible to cancel the report once the report was accepted by the police station. I got a fine and my license had been on probation for 6 months. Based on my clean driving history, my case was dismissed.

PRINT NAME: Youjin Seo

SIGN: Youjin Seo

DATE: 7-22-2024

WEST JORDAN CITY JUSTICE COURT
SALT LAKE COUNTY, STATE OF UTAH

WEST JORDAN CITY vs. YOUJIN SEO

CASE NUMBER 105310739 Traffic Court Case

CHARGES

Charge 1 - 41-6A-401 - FAIL TO GIVE NAME & ASSISTANCE AT ACCIDENT - Class B Misdemeanor
Offense Date: October 13, 2010
Location: 9300 S REDWOOD RD
Plea: December 21, 2010 No Contest
Disposition: July 21, 2011 Dismissed (w/o prej)

CURRENT ASSIGNED JUDGE

RONALD E KUNZ

PARTIES

Plaintiff - WEST JORDAN CITY

Defendant - YOUJIN SEO

DEFENDANT INFORMATION

Defendant Name: YOUJIN SEO
Offense Tracking Number: 19678416
[redacted]
Law Enforcement Agency: SOUTH JORDAN POLICE
Prosecuting Agency: WEST JORDAN CITY
Citation Number: J4441304
Violation Date: 10-13-2010

ACCOUNT SUMMARY

Total Revenue Amount Due:	622.64
Amount Paid:	622.64
Amount Credit:	0.00
Balance:	0.00

Time Pay: 50.00 monthly on the 25th.
Most Recent Payment: January 24, 2011
Final Payment: January 25, 2012

REVENUE DETAIL - TYPE: PLEA ABEY. MISDMNR

Original Amount Due:	620.00
Amended Amount Due:	620.00
Amount Paid:	620.00

ASE NUMBER: 105310739 Traffic Court Case

Balance:	0.00

REVENUE DETAIL - TYPE: Interest

Amount Paid:	1.39
Amount Credit:	0.00
Balance:	0.00

Account Adjustments Sum To Date	Amount	Reason
2011-01-24	1.39	Criminal post judgment interest

REVENUE DETAIL - TYPE: COPY FEE

Original Amount Due:	1.25
Amended Amount Due:	1.25
Amount Paid:	1.25
Amount Credit:	0.00
Balance:	0.00

:ASE NOTE

10h015186

'ROCEEDINGS

.0-19-2010 Filed: Citation

.0-19-2010 Judge RONALD E KUNZ assigned.

.0-19-2010 ARRAIGNMENT scheduled on November 22, 2010 at 03:00 PM in Courtroom 1 with Judge RONALD E KUNZ

.0-19-2010 NOTICE for Case 105310739 ID 5522176
Judge: RONALD E KUNZ
ARRAIGNMENT is scheduled.
Date: 11/22/2010
Time: 03:00 p.m.
Location: Courtroom 1
West Jordan Justice Court
8040 S. Redwood Rd.
West Jordan, UT 84088
Before Judge: RONALD E KUNZ
Delivered/Mailed/Faxed a true copy of this notice to above said defendant.

.0-19-2010 Note: def called to get court date/time - clerk verified address and phone number -

.0-20-2010 Note: Arr made for Korean interp-Heidi Anderson for 11/22/10 at 3 pm

.1-22-2010 NOTICE for Case 105310739 ID 5604918
Judge: RONALD E KUNZ
PRETRIAL CONFERENCE is scheduled.
Date: 12/21/2010

Location: Courtroom 1
West Jordan Justice Court
8040 S. Redwood Rd.
West Jordan, UT 84088
before Judge RONALD E KUNZ
CC: CA's Office
Delivered/Mailed/Faxed a true copy of this notice to above said defendant.

.1-22-2010 Ruling Entry - Minutes for Arraignment
Judge: RONALD E KUNZ
PRESENT
Clerk: karyw
Defendant Present
Defendant pro se
Interpreter: Heidi Anderson (Korean)
Language: Korean
ARRAIGNMENT
Advised of rights and penalties.
The defendant is advised of right to counsel.
Defendant is arraigned.
NG plea entered-Def requested an LDA-def told to come meet with the pros and that, if they will be recommending jail, then the court will then revisit the issue-PTC set-def told date/time in open court
PRETRIAL CONFERENCE is scheduled.
Date: 12/21/2010
Time: 01:30 p.m.
Location: Courtroom 1
West Jordan Justice Court
8040 S. Redwood Rd.
West Jordan, UT 84088
before Judge RONALD E KUNZ

.1-22-2010 PRETRIAL CONFERENCE scheduled on December 21, 2010 at 01:30 PM in Courtroom 1 with Judge RONALD E KUNZ

.1-22-2010 Note: Arr made for Korean interp-Heidi Anderson for 12/21/10 at 1:30 pm

.2-01-2010 Filed: Information Replaces Citation from ca's office

.2-21-2010 Ruling Entry - Minutes for PRETRIAL
Judge: RONALD E KUNZ
PRESENT
Clerk: karyw
Prosecutor: NAMBA, B J
Defendant Present
Defendant pro se
Interpreter: Heidi Anderson (Korean)

ASE NUMBER: 105310739 Traffic Court Case

HEARING
Resolution
Def to plead NC
City moves to hold that plea in abeyance
Cities motion granted
Defendant said that she knows and understands her rights-waiver signed
NC plea entered

PLEA IN ABEYANCE
Defendant's plea is held in abeyance.
Conditions of Agreement:
Submit to full set of fingerprints through West Jordan Police Dept
No repeat offenses for 6 months
Upon successful completion of all PIA terms, the violation will be dismissed
Plea in abeyance fees to be paid in full by the end of the PIA period
Commit no moving violations during the term of the PIA

PLEA IN ABEYANCE ADDITIONAL CONDITIONS
Def to attend 1 session West Jordan Traffic School within 30 days-CLERK TO ASSIGN DATE
Def to pay $620 plea in abeyance fees
Tracking review date for Plea in Abeyance: 06/21/2011
The defendant is ordered to pay the fee of 620.00 for PLEA ABEY. MISDMNR.

SENTENCE FINE PAYMENT NOTE
Def to pay $50/mo beg 1/20/11 HOWEVER ALL FEES/COSTS MUST STILL BE PAID IN FULL WITHIN THE PLEA IN ABEYANCE PERIOD (6/21/11)

SCHEDULED TIMEPAY
The following cases are on timepay 105310739.
The defendant is to pay $50.00 monthly on the 25th.
The number of payments scheduled is 12 plus a final payment of $28.59.
The first payment is due on 01/25/2011 the final payment of $28.59 is due on 01/25/2012 . The final payment may vary based on interest.
Pay fine to The Court.

.2-21-2010 Charge 1 Disposition is Plea in abeyanc
.2-21-2010 Fee Account created Total Due: 620.00
.2-21-2010 Note: Added to payment schedule 732198
.2-21-2010 Note: def came out of court - def will attend Traffic School on 12/27/10 at 6:45 pm

ASE NUMBER: 105310739 Traffic Court Case

)1-14-2011	Filed: notification of charges/waiver of rights signed by defendant
)1-24-2011	Fee Account created Total Due: 1.39
)1-24-2011	Note: Added to payment schedule 732198
)1-24-2011	PLEA ABEY. MISDMNR Payment Received: 620.00
)1-24-2011	Interest Payment Received: 1.39
)7-21-2011	Note: Checked DL & CORIS no new viol found
)7-21-2011	Charge 1 Disposition is Dismissed
)7-21-2011	Stay Ends December 21, 2010
)7-21-2011	Stay Ends December 21, 2010
)7-21-2011	Stay Ends December 21, 2010
)7-21-2011	Stay Ends December 21, 2010
)7-21-2011	Stay Ends December 21, 2010
)7-21-2011	Case Closed Disposition Judge is RONALD E KUNZ
.1-28-2011	Note: Def came in to get a copy of docket.
)2-27-2012	Note: def came in for copy of docket
.1-18-2013	Note: def called will be sending in $6.00 for certified copy of docket and charging document-said she might send a friend in to pick up
.1-18-2013	Note: def friend came in to get copy of docket (Puja Sharma)
.1-18-2013	Fee Account created Total Due: 1.25
.1-18-2013	COPY FEE Payment Received: 1.25
.1-18-2013	Note: Puja Sharma- Basmet came in for cert copy of docket

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Youjin Seo

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

7-22-2024

Date

Board Use Only	Date Received: 7/24/24	Amount: $500 + 4, 05214202609

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **HIVE LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 07/18/2024, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 07/22/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202407224818085
You may verify this certificate online at https://www.nvsilverflume.gov/home

LIST OF THE NAME OF ALL GENERAL PARTNERS

HIVE LLC - SINGLE MEMBER LLC

YOUJIN SEO - 100% OWNERSHIP

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler LAUGHLIN PHARMACY

Pharmacy/Wholesaler License # (if applicable) PH04520

Physical Address 3080 S NEEDLES HWY STE 1800 & 1900

City LAUGHLIN State NV Zip 89029

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-709-5300 Website _____

Licensing Company Email YMWELL2022@GMAIL.COM

Section 2: Personal Information

First YOUJIN Middle _____ Last SEO

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] GREEN FALLS AVE

City HENDERSON State NV Zip 89052

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.500S) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
SAM'S CLUB PHARMACY			4/15-3/23	
Business Address		**City**	**State**	**Zip**
7175 SPRING MOUNTAIN ROAD		LAS VEGAS	NV	89117
Phone	**Title**		**Number of Employed Hours**	
702-247-1129	PHARMACY MANAGER		14,076	
Description of Duties				
PHARMACY MANAGER MANAGING PHARMACY STAFF AND DAILY OPERATION OF PHARMACY IN COMPLIANCE OF NV LAW AND BOP				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
ROSEMAN UNIVERSITY		06/10-08/13	
Address	**City**	**State**	**Zip**
10920 S RIVER FRONT PKWY	SOUTH JORDAN	UT	84095
Diploma/Degree obtained, if any			
DOCTORATE OF PHARMACY			
School Name		**From - To (MM/YY – MM/YY)**	
UTAH VALLEY UNIVERSITY		01/07-05/10	
Address	**City**	**State**	**Zip**
800 W UNIVERSITY PKWY	OREM	UT	84058
Diploma/Degree obtained, if any			
BIOLOGY			
School Name		**From - To (MM/YY – MM/YY)**	
MYUNGDUK GIRLS' HIGH SCHOOL		01/02-01/05	
Address	**City**	**State**	**Zip**
34-10 GANSEO-RO 47 GIL, GANSEO-GU	SEOUL, S.KOREA		
Diploma/Degree obtained, if any			
HIGHSCHOOL			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/18-current	[redacted] Green falls ave	henderson	nv	89052
8/16-12/18	[redacted] Settlers Inn Ct	las vegas	nv	89178
4/15-8/16	[redacted] Amber Pine St Apt 206	las vegas	nv	89144
12/13-4/15	[redacted] Alan Ladd Dr	Kingman	AZ	86409

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Youjin Seo, **certify that as the designated representative for** Laughlin Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. YS I am at least 21 years of age;
3. YS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. YS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. YS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. YS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. YS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Youjin Seo

Print Name (First, Last)

Youjin Seo

Original Signature (electronic, copies or stamps not accepted)

7-22-2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

You jin Seo

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7-22-2024

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, You jin Seo, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7-23-2024

Date

Subscribed and Sworn to before me this 23rd day of July, 2024.

Notary Public Signature

CARLO GOSIOCO
Notary Public, State of Nevada
Appointment No. 23-1185-01
My Appt. Expires Aug 14, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Laughlin Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) ph04520

Physical Address 3080 S Needles Hwy Ste 1800, 1900

City Laughlin State NV Zip 89029

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-709-5300 Website n/a

Licensing Company Email ymwell2022@gmail.com

Section 2: Personal Information

First Youjin Middle _____ Last Seo

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Addres[redacted]Green Falls Ave

City Henderson State nv Zip 89052

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
ROSEMAN UNIVERSITY		6/10-08/13	
Address	**City**	**State**	**Zip**
10920 S RIVER FRONT PKWY	SOUTH JORDAN	UT	84095
Diploma/Degree obtained, if any			
DOCTORATE OF PHARMACY			

School Name		From - To (MM/YY – MM/YY)	
UTAH VALLEY UNIVERSITY		01/07-05/10	
Address	**City**	**State**	**Zip**
800 W UNIVERSITY PKWY	OREM	UT	84058
Diploma/Degree obtained, if any			
BIOLOGY			

School Name		From - To (MM/YY – MM/YY)	
MYUNGDUK GIRLS' HIGH SCHOOL		01/02-01/05	
Address	**City**	**State**	**Zip**
34-10 GANSEO-RO 47 GIL, GANSEO-GU	SEOUL,S.KOREA		
Diploma/Degree obtained, if any			
HIGH SCHOOL			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/18- CURRENT	[redacted]GREEN FALLS AVE	HENDERSON	NV	89052
8/16-12/18	[redacted]SETTLERS INN CT	LAS VEGAS	NV	89178
4/15-8/16	[redacted]AMBER PINE ST APT 206	LAS VEGAS	NV	89144
12/13-04/15	[redacted]ALAN LADD DR	KINGMAN	AZ	86409
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
WESTERN ARIZONA REGIONAL MEDICAL CENTER			03/23-11/23	
Business Address		**City**	**State**	**Zip**
2735 SILVER CREEK RD		BULLHEAD CITY	AZ	88442
Phone	**Title**			
928-763-2273	STAFF PHARMACIST			
Description of Duties				
Verifying and processing inpatient orders Managing inventory of prescriptions, OTC, related medical supplies				

Business Name			From - To (MM/YY – MM/YY)	
Sam's Club Pharmacy			04/15-03/23	
Business Address		**City**	**State**	**Zip**
7175 Spring Mountain Rd		Las Vegas	NV	89117
Phone	**Title**			
702-247-1129	Pharmacy Manager			
Description of Duties				
Managing pharmacy staff and daily operation of retail pharmacy				

Business Name			From - To (MM/YY – MM/YY)	
Smith's food and drugs			08/13-04/15	
Business Address		**City**	**State**	**Zip**
3490 Stockton hill Rd		Kingman	AZ	86401
Phone	**Title**			
928-757-3338	Pharmacy Manager			
Description of Duties				
Managing pharmacy staff and daily operation of retail pharmacy				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Youjin Seo

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7-22-2024

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Youjin Seo, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7-23-2024

Date

Subscribed and Sworn to before me this 23rd day of July, 2024.

Notary Public Signature

CARLO GOSIOCO
Notary Public, State of Nevada
Appointment No. 23-1185-01
My Appt. Expires Aug 14, 2027

(Seal)

8

8A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☒ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FO3651519
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☒ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☒ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☒ Other: SPECIALTY

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: OWL SPECIALTY PHARMACY

Physical Address: 1010 E ARROW HWY

City: COVINA State: CA Zip: 91724

Mailing Address (if different from physical address): SAME AS PHYSICAL ADDRESS

City: _____ State: _____ Zip: _____

Telephone: 626-209-8169 Toll Free # (NAC 639.708, NRS 639.23286): 855-797-0857

Fax: 626-209-8171 Contact Email: GHUNT@POLARISRX.COM

Website: WWW.OWLSPECIALTYPHARMACY.COM

Nevada Business License # (if applicable) PHY 58956

Supervising/Managing Pharmacist Name (NRS 639.220): ANI DERBOGHOSSIAN

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 20823

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: ANI DERBOGHOSSIAN	NV Pharmacist Registration #: 20823
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: CALIFORNIA

Parent Company (if any): POLARIS PHARMACY SERVICES, LLC

Corporation/Organization Name: POLARIS SPECIALTY PHARMACY, LLC

Mailing Address: 2900 NW 60TH STREET

City: FORT LAUDERDALE State: FL Zip: 33309

Telephone: 800-589-9747 Email: GHUNT@POLARISRX.COM

Contact Person Name: GINA HUNT

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO (title) for OWL SPECIALTY PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

DAVID ROMBRO

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

9/11/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, DAVID ROMBRO hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CEO (title) for OWL SPECIALTY PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 11 day of Sep, 2024

Notary Public

IVOR STEWART
Notary Public - State of Florida
Commission # HH 339460
My Comm. Expires Apr 2, 2027
Bonded through National Notary Assn.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

DAVID ROMBRO

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

CEO

Original signature of Authorized Person (copies or stamps not accepted)

9/4/24

Date

Board Use Only	Date Received: 9/12/24	Amount: $500 ck 4232

Challenges Polaris Faced in Minnesota

Polaris entered the Minnesota market in November 2018. The company operates only one pharmacy in Minnesota, which is located at 5220 Park Glen Road, St. Louis Park. Polaris' early experience in Minnesota was not without its challenges, but the company has made a good faith effort to address its challenges and is constantly looking to improve.

When Polaris entered the Minnesota market, it was surprised to find a labor market (particularly for pharmacy technicians) that was much tighter than other markets in which Polaris operates and experienced more staff turnover in Minnesota than it is accustomed to in other markets. The Covid-19 pandemic obviously put an incredible amount of stress on every stakeholder in the pharmacy industry, and Polaris was no exception. The pandemic made it even more difficult for Polaris to recruit, hire, and retain talented staff.

Polaris continues to believe it did not engage in central services by having Minnesota-licensed technicians located in Florida perform remote order entry tasks in connection with prescription orders filled in Minnesota. In letters to the Board dated July 19, 2019, Polaris explained why it began using Minnesota-licensed technicians based in Florida to assist Polaris Minnesota with order entry tasks.

In sum, during its initial months of operation, Polaris faced an unanticipated and unacceptable backlog of prescription orders that needed to be filled in Minnesota. The backlog resulted largely from Polaris' inability to recruit and retain enough capable pharmacy technicians in Minnesota during the early months of operation. To address the backlog and ensure the timely delivery of prescriptions to Minnesota patients, Polaris initially had Minnesota-licensed technicians based in Florida perform order entry services on behalf of Polaris Minnesota. These technicians were experienced technicians who were licensed in Minnesota before they performed order entry work for Polaris Minnesota. Further, while performing remote order entry work from a Polaris Florida location, these technicians were connected virtually to Polaris Minnesota's physical workspace through Polaris' FrameworkLTC software platform, which is commonly used across the long-term care pharmacy industry. At all times, the work of these technicians was overseen by a licensed pharmacist at the Florida pharmacy (where the data was entered into FrameworkLTC), as well as a Minnesota-licensed pharmacist in the Minnesota pharmacy, who ultimately controlled and was responsible for the technicians' work and any prescriptions filled in connection with data they entered into the system. Additionally, until May 2019, Polaris had IND Consulting and its "Team X" do some remote order entry work for Polaris Minnesota. Aside from the order entry function, Polaris Minnesota's prescription processing and filling functions have always taken place entirely in the Minnesota pharmacy. Polaris has at times relied on similar remote order entry processes in other states without triggering central service pharmacy requirements.

Accordingly, when Polaris started using this process to help deal with the Minnesota backlog, it did not anticipate that it might be triggering central services pharmacy requirements. For this reason, Polaris initially did not submit or seek approval from the Board for a central prescription drug processing policy or procedure. In March 2019, after Board staff expressed a

view that Polaris' use of Minnesota-licensed technicians based in Florida to perform remote entry work constituted an unauthorized central service arrangement, Polaris took immediate steps to address the issue. Polaris initially flew Minnesota-licensed technicians from Florida to Minnesota, so they could be physically present in the Polaris Minnesota pharmacy while performing the same order entry functions they had been performing in Florida.

Finally, Polaris sought Board approval of several remote order entry variances, with the goal of being authorized to resume using Minnesota-licensed technicians based in Florida to perform remote order entry for Polaris Minnesota, and particularly to deal with emergencies or backlogs. When Board staff initially raised this issue in March 2019, Polaris did not believe it could immediately shift all order entry functions to its limited staff in Minnesota without compromising patient safety and welfare. At the time, Polaris was still working through the backlog, onboarding new care facilities, and working hard to locate, hire, train, and retain technicians and other staff in Minnesota in a challenging labor market. Under the circumstances, Polaris determined it was necessary to continue using Minnesota licensed, Florida-based technicians for a period of time in order to deal with the backlog and continue filling prescriptions in a timely manner for patients who needed them, while simultaneously building up its Minnesota workforce and making the changes necessary to meet the expectations of Board staff. As soon as Polaris was staffed and equipped to perform all order entry functions in Minnesota, it stopped utilizing technicians who were not physically located in Minnesota altogether. Accordingly, from June 2019 to the present, Polaris has only used Minnesota-licensed technicians physically located in the Polaris Minnesota pharmacy to perform order entry work on prescription orders filled in Minnesota. Polaris took concerns raised by Board staff over remote order entry issues seriously, and it believes it acted reasonably under the circumstances to address those concerns, while also maintaining high levels of patient care.

Polaris remained committed to working cooperatively with the Board to better understand what it must do in order to utilize remote order entry processes in the future. Polaris would always attempt to rely on technicians physically located in its Minnesota pharmacy to perform data entry and other prescription filling functions. The Board acknowledged granting variance requests to many pharmacy chains and health-systems that authorize the use of remote order entry processes. In March 2020, the Board also issued Covid-19 related guidance acknowledging that pharmacists and technicians could perform various prescription drug filling functions while working remotely—including data entry of prescriptions and orders; verifying prescriptions; certifying data entry and the finished prescriptions (i.e., the product check); conducting profile and prospective drug utilization reviews; and stage-checking for compounding—so long as affiliated pharmacies were using adequate computer software and hardware for the tasks being performed. While the Board's Covid-19 guidance evolved after Governor Walz's Peacetime Emergency declaration was rescinded, Polaris continues to believe remote order entry processes like those implemented during the first few months of Polaris' operations in Minnesota were safe, effective, and should have a place in the delivery of modern pharmacy services.

The Board approved the central services variance #265679-010 on July 13, 2022 between Polaris Pharmacy Services of Minnesota, LLC and both the Polaris Pharmacies located in Tampa and Ft. Lauderdale Florida for urgent or emergent needs.

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of Polaris Pharmacy Services of Minnesota, LLC License No. 265679	**STIPULATION AND CONSENT ORDER**

STIPULATION

Polaris Pharmacy Services of Minnesota, LLC ("Licensee") and the Minnesota Board of Pharmacy Committee on Professional Standards ("Committee") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to license and regulate pharmacies and to take disciplinary action as appropriate.

2. Licensee holds a pharmacy license from the Board and is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On August 18, 2021, Licensee met with the Committee to discuss the allegations described in a Notice of Conference. Board members Kendra Metz and Stuart Williams comprised the Committee. The Board's Executive Director, Cody Wiberg; Deputy Director, Jennell Bilek; and staff attorney, Brian Park, were also present. Alex Mountain, Assistant Attorney General, represented the Committee. Brian A. Dillon, of Lathrop GPM LLP, represented licensee and was

accompanied by Licensee's Pharmacist-in-Charge, Neil Uitto; Polaris' Chief Operating Officer, Steven Baker; and Polaris' Executive Vice President of Operations, Todd Zisek.

III.

FACTS

4. On or about November 1, 2018, the Board licensed Licensee as a pharmacy in Minnesota.

5. Licensee is a closed door, long-term care ("LTC") pharmacy that prepares sterile and non-sterile compounded drug products for dispensing.

6. Licensee has two affiliated pharmacy locations in Florida, both licensed by the Board as follows:

a. On or about July 8, 2016, the Board issued Polaris Rx, located in Fort Lauderdale, Florida ("Pharmacy 1"), non-resident pharmacy license #265101.

b. On or about December 5, 2018, the Board issued Polaris Pharmacy Services of Tampa, located in Tampa, Florida ("Pharmacy 2"), non-resident pharmacy license #265721.

7. On or about March 19, 2019, two Board Surveyors visited Licensee for the purpose of completing a routine inspection, met with the pharmacist-in-charge, and identified the following:

a. Seven pharmacy technicians registered by the Board and employed by Pharmacy 1 and Pharmacy 2, were living in Florida but listed their current physical address as Licensee's address in Minnesota.

b. During the inspection, the Board Surveyors cited Licensee for engaging in central services with Pharmacy 1 and Pharmacy 2, by allowing pharmacy technicians working in Florida to remotely perform data entry of prescription drug information for Minnesota patients into

Licensee's Frameworks LTC prescription processing and dispensing software system ("FW-LTC"), followed by verification of the data entry by Licensee's pharmacist staff members working in Minnesota ("Central Service").

c. Prior to beginning Central Service, Licensee failed to submit a copy of its policy and procedure manual and failed to obtain Board approval to participate in a Central Service arrangement with Pharmacy 1 and Pharmacy 2.

d. Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the March 2019 citation.

e. Licensee's nonsterile compounding records failed to include an assigned beyond use date ("BUD") for the final compounded drug product, or included a BUD exceeding those recommended within United States Pharmacopeia, General Chapter 795 for Pharmaceutical Compounding - Nonsterile Preparations ("USP 795"), without documentation of a reference for literature or a stability study applicable to the specific drug product allowing for extension of the BUD. Licensee avers that it responded to these findings by providing education to its staff to ensure compounded components included lot numbers, expiration dates, and BUDs, along with noting the supporting reference sources. Licensee states that it is not aware of any other issues regarding its compliance with BUD requirements since 2019.

8. On or about March 20, 2019, the Board received a complaint alleging that Licensee was utilizing pharmacy technicians from outside of Minnesota to enter prescription data. On or about April 9, 2019, a Board Surveyor reminded Licensee, after expanding its operations to 24-

hours, that pharmacy technicians working outside of its Minnesota location could not be used to help with covering the additional hours that the pharmacy is open, due to the lack of Board approved policies for Central Services with Pharmacy 1 and Pharmacy 2. As noted above, Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the Board's concern regarding the use of out-of-state technicians to enter prescription data.

9. On June 11, 2019, two Board Surveyors visited Licensee for the purpose of an investigation, met with representatives of the Licensee, and identified the following:

a. The pharmacist-in-charge stated that, as far as she was aware, Pharmacy 1 and Pharmacy 2, both located in Florida, were the only two locations providing Central Services for Licensee.

b. Licensee utilized a company named IND Consulting ("IND") for emergency kit ("E-kit") billing and entry of patient information when pharmacy services are initiated in a new LTC facility. IND's website states its staff are able to provide services including, but not limited to, billing services, medical record entry, and data entry solutions, with guaranteed staffing in fully operational data centers that are open 24 hours a day and 365 days a year, located within or outside of the United States across the globe in Mexico, India, the Philippines, and Florida. During the conference with the Committee, Licensee admitted that IND consulting had been used to enter prescription data for prescription drug orders ultimately dispensed by its

Minnesota pharmacy. Licensee cannot definitively state where individuals affiliated with IND were licensed or physically located when entering such data.

c. At the end of the visit, the Board Surveyor's provided an Investigative Report requesting additional information and reminding Licensee again that it cannot engage in Central Services without Board approval.

10. On February 12, 2020, two Board Surveyors visited Licensee for the purposes of an investigation, met with representatives of Licensee, and identified the following:

a. After arriving at 4:36 a.m., one of the Board Surveyors observed two of Licensee's pharmacy technicians were allowed badge access to the pharmacy entrance prior to the arrival of RPh 3 at around 5:55 a.m. One technician was found to be working in the sterile compounding area and another was logged into Licensee's computer. A representative of Licensee later stated that three pharmacy technicians had been given keys and passcodes to access Licensee's pharmacy. During its conference with the Committee, Licensee admitted that this allegation is true, but stated that senior management took corrective action upon learning of the situation, including immediately revoking the access code of all non-pharmacists and physically rekeying all doors within the pharmacy. Licensees avers that periodic security assessments confirm that no unauthorized persons have had access to the pharmacy since February 2020.

b. Six pharmacy technicians, including the IV pharmacy technician, were present in the "filling area" with only one pharmacist, who was the second pharmacist to arrive. Another pharmacist was in an "order entry" area, a distinctly different area separated by a wall and door. The Board Surveyors were told that additional pharmacy technicians were scheduled that morning to perform non-technician "staging or stocking" duties. However, the Board Surveyors observed that the additional pharmacy technicians that were supposedly scheduled to perform non-technician duties, were filling orders in the "filling area" to be checked by the one pharmacist.

Licensee avers that is does not have sufficient information to admit or deny the Board surveyors' observations, but that company policy requires compliance with required technician-to-pharmacist ratios.

IV.

LAWS

11. Licensee acknowledges the conduct described in section III above constitutes a violation of Minn. Stat. § 151.071, subd. 2(7), and warrants the disciplinary action described below.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

12. The Board **REPRIMANDS** Licensee and imposes a **CIVIL PENALTY** in the amount of $50,000 for the conduct described in section III above. The civil penalty shall be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of entry of this Order.

13. The Board places the following **CONDITION** on Licensee's License: every six months, for a period of three years, Licensee's CEO must certify to the Board's Executive Director that Licensee's licensed pharmacies that provide services to Minnesota residents are in full compliance with all applicable Minnesota statutes and rules.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

14. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Committee may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Committee shall schedule a hearing before the Board. At least 20 days before the hearing, the Committee must mail Licensee a notice of the violation(s) alleged by the Committee. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee shall submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Committee, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Committee and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Committee and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Committee will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations, but may present argument concerning the appropriateness of additional discipline. Pursuant to this process, Licensee waives a hearing before an administrative law judge, discovery, cross-examination of

adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but does not limit the Board's authority to impose discipline for the violation. A decision by the Committee not to seek discipline when it first learns of a violation does not waive the Committee's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's license is in a suspended status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's license, a period of suspension, conditions of reinstatement, or revocation of Licensee's license.

f. Nothing herein limits the Committee's or the Board's right to temporarily suspend Licensee's license as provided in Minnesota Statutes chapters 151 and 214, based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII. ADDITIONAL INFORMATION

15. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

16. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the

investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

17. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter shall constitute the entire record and may be reviewed by the Board in its consideration of this matter.

18. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

19. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

20. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it. If the Board rejects this Stipulation and Consent Order, the parties agree that this Stipulation and Consent Order will not be admissible in any proceedings.

21. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis

of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action, and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

22. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed health professional, and as such, is classified as confidential data pursuant to Minnesota Statutes section 13.41, subdivision 4.

23. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

POLARIS PHARMACY SERVICES OF MINNESOTA, LLC (LICENSEE)

Dated: 12-3-2021

MINNESOTA BOARD OF PHARMACY
COMMITTEE ON PROFESSIONAL STANDARDS

BOARD MEMBER

Dated: 12/8/21

ORDER

Upon consideration of the Stipulation, the Board **REPRIMANDS** Licensee, imposes a **CIVIL PENALTY**, and **CONDITIONS** Licensee's license and adopts all of the terms described above on this 8TH day of December, 2021.

MINNESOTA BOARD OF PHARMACY

CODY WIBERG
Executive Director

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	POLARIS SPECIALTY PHARMACY, LLC
Entity No.:	202205910470
Registration Date:	02/24/2022
Entity Type:	Limited Liability Company - CA
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of August 20, 2024.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 239692639

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at bizfileOnline.sos.ca.gov.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 8/20/2024 Inspector: Philip Wright

Firm: OWL SPECIALTY PHARMACY Phone: (626) 209-8169

Address: 1010 E ARROW HWY City: COVINA Zip: 91724

Ownership: CORPORATION

Permit #: PHY58986 Permit Exp: 11/1/2024 DEA#: FO3651519 DEA Exp: 12/31/2026

Date of Self Assessment Form: 5/16/2024 Other Permit #: N/A Date of DEA Inventory: 5/1/2023

Hours M-F: 9AM-6PM Hours Saturday Closed Hours Sunday: Closed

PIC MICHEAL E GHOBREAL RPH72294 Administrator

RPH Consultant

Staff RPH Name:	License #:
LILLIANA Q NGO	RPH85335
GARY S AUSTIN	RPH49301
MINA M MORKOS	RPH81788
WALEED MESSIAH	RPH66975

Staff Name:	License #:
DANIELA BENITEZ	TCH168122
DIANA L CORTES REYES	TCH159458
EMANUEL BIMBELA	TCH135294
HOA Q NGO	TCH54648
NATHAN A JEROMINO	TCH196832
YURI MUNOZ	TCH56447

Inspector Remarks:

OWL SPECIALTY PHARMACY is an Closed Standalone Business Complex dispensing approximately total 300 prescriptions daily, 80% new and 20% refills per day with 3RPH/4TCH/5CLK. Primary dispensed medications to include mail order infusion therapy general patient populations. There is a no SP-200, Parata, Yayama, CUBEX, MEDFLEX, Omnicell, Dosis Dispensing Machine. There is delivery service (FEDEX/Road Pass), no out of State Delivery, but no specialty services, CII dispensing or compounding.

Today this pharmacy PHY Full Routine

Topics to Educate
1. BPC 4052.04 – Pharmacist may furnish COVID-19 oral therapeutics following a positive test.
   - "COVID-19 oral therapeutics" means drugs that are approved or authorized by the FDA for the treatment of COVID-19 and administered orally.
   - Prior to furnishing COVID-19 oral therapeutics, a pharmacist shall utilize relevant and appropriate evidence-based clinical guidelines published by FDA in providing these patient care services.
   - A pharmacist who furnishes COVID-19 oral therapeutics shall notify patient's PCP or enter appropriate information into patient record system shared with PCP, as permitted by that PCP. If the patient does not have a PCP, the pharmacist shall provide the patient with a written record of the drugs furnished and advise the patient

to consult a physician of the patient's choice.

- Document the kind and amounts of COVID-19 oral therapeutics furnished, as well as any information regarding testing services provided, in the patient's record in the record system maintained by the pharmacy.
- Retain records for 3 years.

2. BPC 4113.1 – Reporting medication errors within 14 days from discovery.
   - Applies to "community pharmacies" – *i.e.,* any pharmacy that dispenses medication to an outpatient (but not including facilities of CDCR).
   - Per the BOP's AB 1286 Implementation Statement, the reporting of medication errors under BPC 4113.1 will not be required until the BOP approves an entity to receive the reports.

Code Section 688 establishes exceptions to the requirement that health care practitioners issue a prescription as an electronic data transmission prescription, including for a prescriber to register annually with the Board of Pharmacy and state their method of qualification, including:
i. Their practice is located in the area of an emergency or disaster declared by a federal, state, or local government.
ii. They issue 100 or fewer prescriptions per calendar year.
iii. They are unable to issue electronic data transmission prescriptions due to circumstances beyond their control.

As of July 2019, all pharmacists must have two hours of board provided law and ethics ce to renew their rph license per ccr 1732.5
January 1, 2024, California licensed pharmacists and pharmacy technicians must complete at least one hour of participation in a cultural competency course, as defined in BPC section 4231, during the two years preceding the application for renewal.

CCR section 1715.65 October 1, 2022. , Inventory Activities and Inventory Reconciliation Reports of Controlled Substances. This amended regulation clarifies what is an "inventory reconciliation" and defines "inventory activities"; identifies four non-Schedule II controlled substances that must be inventoried at least every 12 months; specifies when all other controlled substances must be inventoried; requires individuals in completing the inventory or preparing the report to be identified and the individual who performs the inventory to sign and date it; allows use of a digital, electronic or biometric identifier instead of a physical signature if a printed signed statement confirming the accuracy of the report is retained; and clarifies inventory requirements in hospital settings. The amendments take effect January 1, 2023.
(A)Alprazolam, 1 milligram/unit.
(B)Alprazolam, 2 milligrams/unit.
(C)Tramadol, 50 milligrams/unit.
(D)Promethazine/codeine, 6.25 milligrams of promethazine and 10 milligrams of codeine per 5 milliliters of product.

Reviewed during inspection:
Name tags, names and job title (CCR1793.7c): verified
RPH/INT/TCH/CLK ratios (SB1442/BPC4113.5): verified
Self-Assessment (CCR1715): verified
Hot and Cold running water in sink (CCR1714c), and cleanliness of compounding area: verified
Compounding (Magic mouth Wash/) Training Records, Worksheets, Potency testing annually, test sample submitted ( ): verified N/A
Notice to Consumer (NTC)/Interpretive Services in public view: See discussion
Permits (PHY, RPH, TCH, DEA) (BPC 4058) posted, Original Brown PHY License and Green renewal license

displayed (BPC4058) License Requests (Wall certs) PharmacyLicenseRequest@dca.ca.gov: See Discussion
DSCSA (Drug Supply Chain Security Act)/Drug Take-Back Collection Returned Drugs (CCR1776) Receptacle in front of pharmacy and DEA and State Registered. (No)
Immunizations, education, standing orders, education, CPR Card Current (within 2-yrs): Epi-Pens and Diphenhydramine are not expired, RPH/TCH has completed 1 hour immunization CE as required every 2 years by CCR 1746.4c, CAIR2
Biennial Inventory (Opening/Closing)(CFR1304.11a), and Reconciliation Report (CCR1715.65c) (Every 3 months-Schedule II): verified
Enrolled Transmitting CURES/PDMP: verified
Power of Attorney (if one registrant not): reviewed
Onsite Secure Storage verified
Offsite Storage: N/A
Quality Assurance Documentation (CCR1711d): verified
E-Script complaint (BPC688)/Exemptions: verified
RX signed and dated by prescriber (H&SC11164a1)
DEA 222 endorsed/CSOS forms reviewed
Policy and Procedures Theft (Online/Physically Present): verified
Policy and Procedures Impairment (Online/Physically Present): verified
Policy and Procedures Absence of Pharmacist (Online/Physically Present): verified
Policy and Procedures Interpretive Services (Online/Physically Present): verified
Policy Tech Job Description (Online/Physically Present): verified
Patient Centered Label (Federal Caution, sans serf 12-point font), checked 6 random labels and matched label to drug description, contents, amount and "Generic for" CCR1707.5: verified
Caution Label (BPC 4076.7) Required for Drug Containing an Opioid: verified.
Schedule CII Prescriptions: verified, Reviewed random prescriptions, (identified DX Codes, and attached CURES Report): No CII
Schedule CIII-CV Prescriptions: verified, Reviewed 2 random prescriptions, (identified DX Codes, and attached CURES Report, transmitting and enrolled in PDMP: verified
Dangerous Drugs Prescriptions: verified, Reviewed 2 random prescriptions
Wholesaler Name (WLS): MCK
Reverse Distributor (RD): SMC
Wholesalers/Manufacture Invoices maintained for 3 yrs (BPC4081a): verified
Signed for, reviewed delivery receipt of dangerous drugs by RPH
Pharmacy security (personal bags, lockers, doors, roof, alarms, keys (who has possession): reviewed
Subscriber Alert BOP Email https://www.dca.ca.gov/webapps/pharmacy/subscribe.php :verified
Software and Pharmaceutical References: Clin Pharm., Lexicomp, Epocrates: verified
Outdates: reviewed

Refrigerator
"Controlled cold temperature" means 2 degrees to 8 degrees C (35 degrees to 46 degrees F).
"Controlled freezer temperature" means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F) or at a range otherwise specified by the pharmaceutical manufacturer(s) for that product.
"Controlled room temperature" means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).
Refrigerator (1) 39.3F, Inspector 39.0F
Refrigerator (2) 35.6F, Inspector 41.0F
Refrigerator (3) 36.3F, Inspector 38.0F
Refrigerator (4) 36.6F, Inspector 41.0F

Refrigerator (5) 36.3F, Inspector 41.0F

Freezer (1) Ice packs only
Room: manual check by inspector with electronic thermometer range 75.8F: verified
(Automated Drug Delivery) Required Pharmacy owned Annual Self-Assessment None: verified
ADDS (), Location
APDS (MAX 15) (), - (Located next to pharmacy only refills) Location
AUDS (), Location
Policy and Procedures/Annual Training Reviewed None: verified

Required documents to provide to Inspector Wright:
1) PIC to send picture of Original PHY license and renewal license below in public view, Notice to Consumer (NTC)/Interpretive Services in public

2) PIC to send documentation of CCR section 1715.65 Annual Inventory Reconciliation Reports of Controlled Substances.
(A)Alprazolam, 1 milligram/unit.
(B)Alprazolam, 2 milligrams/unit.
(C)Tramadol, 50 milligrams/unit.
(D)Promethazine/codeine, 6.25 milligrams of promethazine and 10 milligrams of codeine per 5 milliliters of product.

3) PIC to provide updated refrigerator logs (6 total) in lieu of the change to the electronic 24/7 temperature monitoring.

Discussion
1) January 1, 2021 A prescription form that complies with the requirements defined by AB 149, i.e. a valid A prescription form that complies with the requirements defined by AB 149, i.e. a valid
2) B&PC 4125. Pharmacy Quality Assurance Program Required; Records Considered Peer Review Documents
3) HSC 11153. Responsibility for Legitimacy of Prescription; Corresponding Responsibility of Pharmacist; Knowing Violation
4) 1717.3. Preprinted Multiple Checkoff Prescription Blanks.
5) Controlled substance "faxed" RXs- Referred to BOP website to review guidance on filling electronic and faxed controlled substance RXs. Refer to Script Newsletter Fall 2015. Informed PHY faxed CIII-CV RXs required to be taken as a verbal RX by the RPH

In order to complete if any corrective action on inspection send documentation to Inspector Wright within 14 days of this report at philip.wright@dca.ca.gov (Secure Email Only) Cell Phone (626) 476-2017/Fax (626) 938-7081

Licensee Remarks:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) Michael Ghobreal

Inspector (sign) _____

Inspector (print) _____

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

ORDER OF CORRECTION

Date: 8/20/2024 Permit #: PHY58986

Time of Day: 12:45 PM

Name as shown on permit: **OWL SPECIALTY PHARMACY**

Address: 1010 E ARROW HWY City: COVINA

Please be advised it appears there is a failure to comply with the following laws governing the practice of pharmacy, and/or the rules and regulations of the Board of Pharmacy:

1. CCR 1714(b)	Operational Standards and Security. Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy. In that, the refrigerators need to have the temperature log updated in lieu of the change to the electronic 24/7 temperature monitoring.

I have reviewed, discussed, understand and received a copy of this form.

Inspector (sign) _____ Signed _____

Inspector (print) _____ Print Name Michael Ghobreal

Date 8/20/24 Title _____

Pursuant to Business and Professions Code §4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of correction, for an office conference with the board's executive officer to contest the order of correction.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Nevada Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, NV 89521

September 18, 2024

California State Board of Pharmacy License Verification

This document reflects the license status of the person or entity identified below on this date with the California State Board of Pharmacy. It may be used as prima facie evidence of the facts recited below pursuant to California Business and Professions Code section 162.

Licensee Name: OWL SPECIALTY PHARMACY

License Type: PHARMACY

License Number: PHY 58986

Status: ACTIVE

Issue Date: 11/21/2023

Expiration Date: 11/01/2025

Address of Record: 1010 E ARROW HWY COVINA, CA 91724

Disciplinary Action: NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren
Executive Officer

By

Ann Altamirano
Public Inquiry Analyst
(916) 518-3045
Pharmacy.PublicRecords@dca.ca.gov

Jacqueline M. Le

From:	Micheal Ghobreal
Sent:	Wednesday, September 4, 2024 9:47 AM
To:	Jacqueline M. Le
Subject:	FW: Owl Specialty Inspection
Attachments:	IMG_1.heic; IMG_2.heic; IMG_3.heic; IMG_4.heic; CCF_000054.pdf; IMG_010.jpg; IMG_009.jpg; IMG_008.jpg; IMG_007.jpg; IMG_006.jpg; IMG_005.jpg

Micheal Ghobreal | Pharmacist In Charge of Owl Rexall Pharmacy and Owl Specialty Pharmacy
Polaris Pharmacy Services | 837 W. Arrow Hwy, Glendora, CA 91740 / 1010 E Arrow Hwy, Covina, 91724.
o 626-962-1061 x124 | f 626-9621157.

From: Micheal Ghobreal
Sent: Thursday, August 29, 2024 3:58 PM
To: PHILIP.WRIGHT@DCA.CA.GOV
Subject: Owl Specialty Inspection

Hey Inspector Wright,
I would like to express my gratitude for your professionalism and guidance throughout the inspection. The feedback provided during the inspection was beneficial and invaluable. I'll make sure that our operations would always align to all the Board regulatory requirements.
Regarding the observations and the corrections requested, to address them please find attached:

- The pictures of the license and notice to consumer/interpretive Services displayed in public. (IMG 1-4).
- The Tramadol 50mg and Alprazolam 1mg Inventory, please note that we did not dispense or carried in our inventory any Alprazolam 2mg or Promethazine /Codeine. (CCF000054).
- The thermometers installed to all fridges and logs attached to each fridge. (Images 005-010).

It was pleasure dealing with you Sir. Please let me know if you have any questions or if anything else is needed.

Thank you.

Micheal Ghobreal | Pharmacist In Charge of Owl Rexall Pharmacy and Owl Specialty Pharmacy
Polaris Pharmacy Services | 837 W. Arrow Hwy, Glendora, CA 91740 / 1010 E Arrow Hwy, Covina, 91724.
o 626-962-1061 x124 | f 626-9621157.

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 58986

NAME: OWL SPECIALTY PHARMACY

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

1010 E ARROW HWY
COVINA CA 91724
LOS ANGELES COUNTY

ISSUANCE DATE

NOVEMBER 21, 2023

EXPIRATION DATE

NOVEMBER 1, 2025

CURRENT DATE / TIME

SEPTEMBER 10, 2024
7:38:16 AM

LICENSE RELATIONSHIPS

NAME: GHOBREAL, MICHEAL ELHAMY ISSAC

ADDRESS NOT DISCLOSEO

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 72294 **PRIMARY STATUS:** CLEAR

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 58986

NAME: OWL SPECIALTY PHARMACY

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

1010 E ARROW HWY
COVINA CA 91724
LOS ANGELES COUNTY

ISSUANCE DATE

NOVEMBER 21, 2023

EXPIRATION DATE

NOVEMBER 1, 2025

CURRENT DATE / TIME

SEPTEMBER 23, 2024
11:19:3 AM

LICENSE RELATIONSHIPS

NAME: GHOBREAL, MICHEAL ELHAMY ISSAC

ADDRESS NOT DISCLOSED

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 72294 **PRIMARY STATUS:** CLEAR

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FO3651519	12-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	12-07-2023

OWL SPECIALTY PHARMACY
1010 E ARROW HWY
COVINA, CA 91724

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FO3651519	12-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	12-07-2023

OWL SPECIALTY PHARMACY
1010 E ARROW HWY
COVINA, CA 91724

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

Polaris Specialty Pharmacy, LLC DBA Owl Specialty Pharmacy

Officer, Ownership & Manager Detail

1010 E. Arrow Highway
Covina, CA 91724-1020

Officer Name	DOB	SSN
David Rombro (CEO) [redacted]NW 127 Way Parkland, FL 33076 [redacted]	[redacted]	
Robert Meyer (CFO) [redacted]North Ocean 515 Pompano Beach, FL 33062 [redacted]	[redacted]	
Steven Baker (COO) [redacted]N. Ocean Boulevard Unit 1707 Pompano Beach, FL 33062 [redacted]	[redacted]	

Ownership

Polaris Specialty Pharmacy, LLC DBA Owl Specialty Pharmacy

which is owned by: Polaris Specialty Pharmacy, LLC (100%)

which is owned by: Polaris Pharmacy Services of California, LLC (100%)

which is owned by: Polaris Pharmacy Services, LLC (100%)

***all have same officers**

Polaris Pharmacy Services, LLC
2900 NW 60th Street
Ft Lauderdale, FL 33309

FEIN:	47-4098540
Owned by:	Da Pharmacy Guys, LLC (22.03%)
	Enhanced Medical Services (24.30)
	EJJ Pharma, LLC (24.30%)
	PPGRX North Carolina, LLC (29.37%)
Managers:	David W. Rombro, Daniel Galbut, Harold Sussman
Officers:	David W. Rombro (CEO), Robert Meyer (CFO), Steven Baker (COO)

***No one person owns more than 10%**

Managers

David Rombro
[redacted]NW 127 Way
Parkland, FL 33076
[redacted]

Daniel Galbut
[redacted]N. 49th Avenue
Hollywood, FL 33021
[redacted]

Harold Sussman
[redacted]Avenue L
Brooklyn, NY 11230
[redacted]

Responsible Agent for Board Communication
Gina Hunt
Ghunt@polarisrx.com
954-919-1818
2900 NW 60th Street
Ft Lauderdale, FL 33309

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler OWL SPECIALTY PHAMRACY

Pharmacy/Wholesaler License # (if applicable) N/A - NEW APPLICATION

Physical Address 1010 E ARROW HWY

City COVINA State CA Zip 91724

Mailing Address (if different from physical address) SAME AS PHYSICAL ADDRESS

City State Zip

Telephone 626-209-8169 Website WWW.OWLSPECIALTY.COM

Licensing Company Email GHUNT@POLARISRX.COM

Section 2: Personal Information

First MICHEAL Middle ELHAMY ISSAC Last GHOBREAL

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted] E ARROW HWY

City COVINA State CA Zip 91724

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
GERMAN UNIVERSITY IN CAIRO		05/2004-06/2009	
Address	**City**	**State**	**Zip**
Main Entrance El-Tagamoa El-Khames	NEW CAIRO, EGYPT		
Diploma/Degree obtained, if any			
BACHELOR DEGREE IN PHARMACY IN BIOTECHNOLOGY			

School Name		From - To (MM/YY – MM/YY)	
NEFERTARI LANGUAGE SCHOOLS		2001-2004	
Address	**City**	**State**	**Zip**
K.M 22 Cairo-Ismailia Desert Road.	Cairo, Egypt.		
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2024-CURRENT	[redacted] JASMINE AVE	MISSION VIEJO	CA	92692
01/2018-05/2024	[redacted] PARK NEWPORT APT#312	NEWPORT BEACH	CA	92660
01/2016-01/2018	[redacted] PARK NEWPORT APT#343	NEWPORT BEACH	CA	92660
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
OWL SPECIALTY PHARMACY			04/24 - CURRENT	
Business Address		**City**	**State**	**Zip**
1010 E ARROW HWY		COVINA	CA	91724
Phone	**Title**		**Number of Employed Hours**	
626-209-8169	PHARMACIST IN CHARGE		720	
Description of Duties				
MANAGE FULL PHARMACY STAFF, OVERSEE DAY TO DAY OPERATIONS				

Business Name			From - To (MM/YY – MM/YY)	
OWL REXALL DRUG			03/22 - CURRENT	
Business Address		**City**	**State**	**Zip**
837 W ARROW HWY		GLENDORA	CA	91740
Phone	**Title**		**Number of Employed Hours**	
626-962-1061	PHARMACIST IN CHARGE		3780	
Description of Duties				
MANAGE FULL PHARMACY STAFF, DEVELOPED AND IMPLEMENTED STERILE COMPOUNDING POLICY AND PROCEDURES, EVALUATE PATIENT RECORDS FOR ACCURACY AND APPROPRIATNESS				

Business Name			From - To (MM/YY – MM/YY)	
AMERIPHARMA LTC			01/21 - 03/22	
Business Address		**City**	**State**	**Zip**
132 S ANITA DR., 2ND FLOOR		ORANGE	CA	92868
Phone	**Title**		**Number of Employed Hours**	
877-778-0318	STAFF PHARMACIST		1960	
Description of Duties				
CHECKED PRESCRIPTIONS FOR APPROPRIATE DOSAGE, DRUG INTERACTIONS, ALLERGIES, AND CONTRAINDICATIONS BEFORE DISPENSING. VACCINATED MORE THAN 500 PATIENTS AGAINST COVID				

Business Name			From - To (MM/YY – MM/YY)	
OWL WESTERN PHARMACY			2017-2022	
Business Address		**City**	**State**	**Zip**
1009 W SAN BERNARDINO RD.		COVINA	CA	91722
Phone	**Title**		**Number of Employed Hours**	
626-209-8160	STAFF PHARMACIST		6680	
Description of Duties				
CHECKED RXS FOR APPROPRIATE DOSAGE, DRUG INTERACTIONS, ALLERGIES, AND CONTRAINDICATIONS BEFORE DISPENSING. VERIFIED 350+ RX PER DAY WITH 8 POINT CHECK. CONDUCT DURS				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, MICHEAL GHOBREAL, **certify that as the designated representative for**

OWL SPECIALTY PHARMACY,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MG I am at least 21 years of age;
3. MG I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MG I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MG I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MG I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MG I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

MICHEAL GHOBREAL

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/22/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Micheal Ghobreal

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8.22.24

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Micheal Ghobreal, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8.22.24

Date

Subscribed and Sworn to before me this 22nd day of August 2024

Notary Public Signature

Maria Paredes
Notary Public - California
Los Angeles County
Commission #2355245
My Comm. Expires: Apr 22, 2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site OWL SPECIALTY PHARMACY

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 1010 E ARROW HWY

City COVINA State CA Zip 91724

Mailing Address (if different from physical address) SAME AS PHYSICAL ADDRESS

City _____ State _____ Zip _____

Telephone 626-209-8169 Website WWW.OWLSPECIALTY.COM

Licensing Company Email GHUNT@POLARISRX.COM

Section 2: Personal Information

First DAVID Middle _____ Last ROMBRO

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex [redacted]

Mailing Address [redacted] NW 60TH STREET

City FORT LAUDERDALE State FL Zip 33309

Telephone 800-589-9747 Email DROMBRO@POLARISRX.COM

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF MARYLAND, BALTIMORE		05/81	
Address	**City**	**State**	**Zip**
620 W LEXINGTON ST	BALTIMORE	MD	21201
Diploma/Degree obtained, if any			
B.S. OF PHARMACY			

School Name		From - To (MM/YY – MM/YY)	
BALTIMORE POLYTECHNIC INSTITUE			
Address	**City**	**State**	**Zip**
1400 COLD SPRINGS LN	BALTIMORE	MD	21209
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/20 - CURRENT	[redacted]NW 127TH WAY	PARKLAND	FL	33076
06/16 - 09/20	[redacted]NE 28TH TERRACE	FORT LAUDERDALE	FL	33309

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
POLARIS PHARMACY SERVICES			07/15 - CURRENT
Business Address	**City**	**State**	**Zip**
2900 NW 60TH STREET	FORT LAUDERDALE	FL	33309
Phone	**Title**		
954-919-1818	CEO		
Description of Duties			
PLEASE SEE ATTACHED RESUME			

Business Name			From - To (MM/YY – MM/YY)
OMNICARE			06/08 - 04/14
Business Address	**City**	**State**	**Zip**
2955 W CORPORATE LAKES BLVD #600	WESTON	FL	33331
Phone	**Title**		
954-660-5555	GM		
Description of Duties			
PLEASE SEE ATTACHED RESUME			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4, 5, 6. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
02/06/2023	PENDING	CA	LOS ANGELES	LOS ANGELES COUNTY
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
23STCV02582		STANLEY MOSK COURTHOUSE		
Reason/Charge				
BREACH OF CONTRACT				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
MED-PLUS PHARMACY, INC VS ANAHEIM HEALTHCARE			LAWSUIT	
Name of Business/Industry/Entity				
MED-PLUS PHARMACY, INC				

Provide explanation below:

PLEASE SEE ATTACHED

Original Signature (electronic, copies or stamps not accepted)

9/6/24
Date

CASE INFORMATION

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

Case Number: 23STCV02582

MED-PLUS PHARMACY, INC. VS ANAHEIM HEALTHCARE CENTER, LLC, ET AL.

Filing Courthouse: Stanley Mosk Courthouse

Filing Date: 02/06/2023
Case Type: Contract/Warranty Breach - Seller Plaintiff (no fraud/negligence) (General Jurisdiction)
Status: Request for Dismissal - Before Trial not following ADR or more than 60 days since ADR 05/14/2024

Click here to access document images for this case

If this link fails, you may go to the Case Document Images site and search using the case number displayed on this page

FUTURE HEARINGS

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

None

PARTY INFORMATION

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

Click on any of the below link(s) to see Register of Action Items on or before the date indicated:
A - P R - W

ANAHEIM HEALTHCARE CENTER LLC DBA ANAHEIM HEALTHCARE CENTER - Defendant

BARTLETT CARE CENTER LLC DBA FRENCH PARK CARE CENTER - Defendant

BERGMAN ROBERT DAVID - Attorney for Plaintiff

BRUCKER GARY KEITH - Attorney for Defendant

CITRUS NURSING CENTER DBA CITRUS NURSING CENTER - Defendant

COLLEGE VISTA LLC DBA COLLEGE VISTA CARE CENTER - Defendant

COMMUNITY CARE REHAB CENTER LLC DBA COMMUNITY CARE REHABILITATION CENTER - Defendant

COUNTRY OAKS PARTNERS LLC DBA COUNTRY OAKS CARE CENTER - Defendant

DOES 1-20 - Defendant

F. & B. HEALTHCARE DBA EXTENDED CARE HOSPITAL OF RIVERSIDE - Defendant

GARDEN PARK CARE CENTER LLC DBA GARDEN PARK CARE CENTER - Defendant

GIBRALTAR CONVALESCENT HOSPITAL INC. DBA DEL MAR CONVALESCENT HOSPITAL DBA SUNSET MANOR CONVALESCENT HOSPITAL - Defendant

GORDON LANE HEALTHCARE LLC DBA GORDON LANE CARE CENTER - Defendant

HERITAGE MANOR HEALTHCARE LLC DBA HERITAGE MANOR HEALTHCARE - Defendant

INLAND MEDICAL ENTERPRISES INC. DBA ALCOTT REHABILITATION HOSPITAL - Defendant

MED-PLUS PHARMACY LLC DBA MED-PLUS PHARMACY LTC - Plaintiff

MJB PARTNERS LLC DBA POMONA VISTA CARE CENTER - Defendant

MONTERREY PARK CONVALESCENT HOSPITAL INC. DBA MONTERREY PARK CONVALESCENT HOSPITAL - Defendant

PARAMOUNT CONVALESCENT GROUP INC. DBA PARAMOUNT CONVALESCENT HOSPITAL - Defendant

PARK REGENCY CARE LLC DBA PARK REGENCY CARE CENTER - Defendant

PC CARE LLC DBA PACIFIC CONVALESCENT CENTER - Defendant

PUENTE PARTNERS LLC DBA VICTORIA CARE CENTER - Defendant

Click on any of the below link(s) to see Register of Action Items on or before the date indicated:
TOP A - P R - W

RIVERSIDE EQUITIES LLC DBA MISSION CARE CENTER - Defendant

SIERRA VIEW CARE HOLDINGS LLC DBA SIERRA VIEW CARE CENTER - Defendant

SUN MAR HEALTHCARE INC. DBA SUN-MAR NURSING CENTER - Defendant

VILLA RANCHO BERNARDO HEALTH CARE LLC DBA VILLA RANCHO BERNARDO CARE CENTER - Defendant

WYNGATE NURSING CENTER DBA NORTH VALLEY NURSING CENTER - Defendant

Click on any of the below link(s) to see Register of Action Items on or before the date indicated:
TOP A - P R - W

DOCUMENTS FILED

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

Documents Filed (Filing dates listed in descending order)

Click on any of the below link(s) to see Register of Action Items on or before the date indicated:
05/18/2023

05/15/2024 Notice of Case Reassignment and Order for Plaintiff to Give Notice
Filed by Clerk

05/14/2024 Request for Dismissal
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

04/05/2024 Stipulation and Order (TO VACATE TRIAL DATES, [PROPOSED] ORDER)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

01/16/2024 Stipulation and Order (Stipulation and Proposed Order RE Precedential Effect of Plaintiff's Contemplated Initial Motions to Compel Further Discovery Responses)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/12/2024 Undertaking (bond)

01/12/2024 Undertaking (bond)

01/12/2024 Right to Attach Order After Hearing and Order for Issuance of Writ of Attachment
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/12/2024 Right to Attach Order After Hearing and Order for Issuance of Writ of Attachment
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/11/2024 Order Appointing Court Approved Reporter as Official Reporter Pro Tempore
Filed by COMMUNITY CARE REHAB CENTER, LLC (Defendant)

01/11/2024 Decision on applications for right to attach orders: granted in part
Filed by Clerk

01/11/2024 Objection (Evidentiary)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/11/2024 Objection (Evidentiary)
Filed by COMMUNITY CARE REHAB CENTER, LLC (Defendant)

01/11/2024 Minute Order ((Hearing on Application for Writ of Attachment Against Defenda...))
Filed by Clerk

01/08/2024 Proof of Service (not Summons and Complaint)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/08/2024 Objection (Plaintiff's Evidentiary Objections to Declarations and Evidence Filed in Support of Defendant's Opposition to Its Applications for Right to Attach Orders Against Defendants Community Care Rehab Ctr. LLC and Villa Rancho Bernardo Health Care)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/08/2024 Reply (Plaintiff's Reply Brief in Support of Applications for Right to Attach Orders Against Defendants Community Care Rehab Center, LLC and Villa Rancho Bernardo Health Care, LLC)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/04/2024 Declaration (DECLARATION OF ADRIAN DEHGHANMANESH IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TOPLAINTIFF'S APPLICATION__ FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC__)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Objection (DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC's JOINT EVIDENTIARY OBJECTIONS TO DECLARATIONS OF NEIL FARAGE IN SUPPORT OF PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDER AGAINST DEFENDANTS)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration (DECLARATION OF GARY K. BRUCKER, JR. IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Notice of Opposition to Right to Attach Order and Claim of Exemption
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Notice of Opposition to Right to Attach Order and Claim of Exemption
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration (DECLARATION OF ADRIAN DEHGHANMANESH IN SUPPORT OF DEFENDANT COMMUNITY CARE REHAB CENTER, LLC'S NOTICE OF OPPOSITION TO RIGHT TO ATTACH ORDER AND CLAIM OF EXEMPTION)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration (DECLARATION OF ADRIAN DEHGHANMANESH IN SUPPORT OF DEFENDANT VILLA RANCHO BERNARDO HEALTH CARE, LLC'SNOTICE OF OPPOSITION TO RIGHT TO ATTACH ORDER AND CLAIM OF EXEMPTION)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Proof of Service (not Summons and Complaint)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration (DECLARATION OF MICAH RHEAD IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration (DECLARATION OF JORDAN MADER IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATION FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Opposition (DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

01/04/2024 Stipulation and Order (Stipulation and Proposed Order Amending the Complaint)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/03/2024 Proof of Service (not Summons and Complaint)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Application for Right to Attach Order, Temporary Protective Order, etc.
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Proof of Service by Mail
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Memorandum of Points & Authorities
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Memorandum of Points & Authorities
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Proof of Service by Mail
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Application for Right to Attach Order, Temporary Protective Order, etc.
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

07/27/2023 Notice of Ruling
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

07/14/2023 Certificate of Mailing for ((Non-Appearance Case Review) of 07/14/2023)
Filed by Clerk

07/14/2023 Minute Order ((Non-Appearance Case Review))
Filed by Clerk

06/29/2023 Decision on Applications for Right to Attach Orders
Filed by Clerk

06/29/2023 Objections to Declaration of Adrian Dehghanmanesh Submitted in Opposition to Applications for Right to Attach Orders
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/29/2023 Minute Order ((Hearing on Application for Writ of Attachment against (1) Def...))
Filed by Clerk

06/27/2023 Objection (to Decl. of A. Dehghanmanesh Submitted in Opp to Appl. for Right to Attach Order)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/27/2023 Reply (Brief ISO Application for Right to Attach Order)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/22/2023 Declaration (Declaration Of John Kimball In Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Declaration (Declaration Of Channon Balana Yin Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Declaration (Declaration Of Adrian Dehghanmanesh In Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Objection (Defendants Anaheim Healthcare Center, LLC And Bartlett Care Center, LLC Joint Evidentiary Objections To Declarations Of Neil Farage In Support Of Plaintiffs Applications For Right To Attach Order Against Defendants)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Notice of Opposition to Right to Attach Order and Claim of Exemption
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

06/22/2023 Notice of Opposition to Right to Attach Order and Claim of Exemption
Filed by BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Opposition (To Plaintiffs Application For Right To Attach Orders Against Defendants Anaheim Healthcare Center, LLC And Bartlett Care Center, LLC)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/06/2023 Application for Right to Attach Order, Temporary Protective Order, etc.
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/06/2023 Memorandum of Points & Authorities
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/06/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/06/2023 Application for Right to Attach Order, Temporary Protective Order, etc.
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/06/2023 Memorandum of Points & Authorities
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/06/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

05/31/2023 Certificate of Mailing for ((Non-Appearance Case Review) of 05/31/2023)
Filed by Clerk

05/31/2023 Minute Order ((Non-Appearance Case Review))
Filed by Clerk

05/24/2023 Case Management Statement
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

05/23/2023 Case Management Statement
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

05/19/2023 Minute Order ((Hearing on Ex Parte Application of Plaintiff for Temporary Pr...))
Filed by Clerk

Click on any of the below link(s) to see Register of Action Items on or before the date indicated:
TOP 05/18/2023

05/18/2023 Opposition (Opposition To Plaintiffs Ex Parte Applications For Temporary Protective Orders Against Defendants Anaheim Healthcare Center And Bartlett Care Center; Declaration Of Gary K. Brucker, Jr.)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

05/18/2023 Declaration (of Richard Fond re Ex Parte for Temporary Protective Order)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

05/18/2023 Declaration (In support of Temporary Protective Order)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

05/18/2023 Ex Parte Application (for Temporary Protective Order)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

03/30/2023 Answer
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

03/01/2023 Proof of Service (not Summons and Complaint)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

03/01/2023 Notice and Acknowledgment of Receipt
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

02/15/2023 Notice (of Case Management Conference)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

02/10/2023 Notice of Case Management Conference
Filed by Clerk

02/06/2023 Notice of Case Assignment - Unlimited Civil Case
Filed by Clerk

02/06/2023 Voluntary Efficient Litigation Stipulation Packet
Filed by Clerk

02/06/2023 First Amended General Order re: Mandatory Electronic Filing
Filed by Clerk

02/06/2023 Alternate Dispute Resolution Packet
Filed by Clerk

02/06/2023 Summons (on Complaint)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

02/06/2023 Civil Case Cover Sheet
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

02/06/2023 Complaint
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

Click on any of the below link(s) to see Register of Action Items on or before the date indicated:
TOP 05/18/2023

PROCEEDINGS HELD

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

Proceedings Held (Proceeding dates listed in descending order)

06/25/2024 at 08:30 AM in Department 39
Trial Setting Conference - **Not Held - Vacated by Court**

06/24/2024 at 08:30 AM in Department 39
Post-Mediation Status Conference - **Not Held - Vacated by Court**

01/11/2024 at 09:30 AM in Department 85, James C. Chalfant, Presiding
Hearing on Application for Writ of Attachment (CCP 484.040) - **Held - Motion Granted**

01/11/2024 at 09:30 AM in Department 85
Hearing on Application for Writ of Attachment (CCP 484.040) - **Held - Motion Granted**

07/26/2023 at 08:30 AM in Department 39
Case Management Conference - **Not Held - Advanced and Vacated**

07/14/2023 at 3:41 PM in Department 39, Stephen I. Goorvitch, Presiding
Non-Appearance Case Review

06/29/2023 at 09:30 AM in Department 85, James C. Chalfant, Presiding
Hearing on Application for Writ of Attachment (CCP 484.040) - **Held - Motion Denied**

06/08/2023 at 08:30 AM in Department 39
Case Management Conference - **Not Held - Advanced and Continued - by Court**

05/31/2023 at 2:34 PM in Department 39, Stephen I. Goorvitch, Presiding
Non-Appearance Case Review

05/19/2023 at 08:30 AM in Department 85, James C. Chalfant, Presiding
Hearing on Ex Parte Application (In support of Temporary Protective Order) - **Held - Motion Denied**

REGISTER OF ACTIONS

05/20/2024 Case reassigned to Stanley Mosk Courthouse in Department 39 - Hon. Tony L. Richardsoneffective 05/20/2024; Reason: Inventory Transfer

05/15/2024 Notice of Case Reassignment and Order for Plaintiff to Give Notice; Filed by: Clerk

05/14/2024 On the Complaint filed by MED-PLUS PHARMACY, INC. on 02/06/2023, entered Request for Dismissal with prejudice filed by MED-PLUS PHARMACY, LLC as to the entire action

05/14/2024 Request for Dismissal; Filed by: MED-PLUS PHARMACY, LLC (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

05/14/2024 Order to Show Cause re: Payment of Waived Fees; by:

05/14/2024 Trial Setting Conference scheduled for 06/25/2024 at 08:30 AM in Stanley Mosk Courthouse at Department 39 Not Held - Vacated by Court on 05/14/2024

04/05/2024 Trial Setting Conference scheduled for 06/25/2024 at 08:30 AM in Stanley Mosk Courthouse at Department 39

04/05/2024 Stipulation and Order TO VACATE TRIAL DATES; [PROPOSED] ORDER; Signed and Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant); COLLEGE VISTA, LLC (Defendant); COUNTRY OAKS PARTNERS, LLC (Defendant); COMMUNITY CARE REHAB CENTER, LLC (Defendant); F. & B. HEALTHCARE (Defendant); GARDEN PARK CARE CENTER, LLC (Defendant); GIBRALTAR CONVALESCENT HOSPITAL, INC. (Defendant); GORDON LANE HEALTHCARE, LLC (Defendant); HERITAGE MANOR HEALTHCARE, LLC (Defendant); INLAND MEDICAL ENTERPRISES, INC. (Defendant); MJB PARTNERS, LLC (Defendant); MONTERREY PARK CONVALESCENT HOSPITAL, INC. (Defendant); PARAMOUNT CONVALESCENT GROUP, INC. (Defendant); PARK REGENCY CARE, LLC (Defendant); PC CARE, LLC (Defendant); PUENTE PARTNERS, LLC (Defendant); RIVERSIDE EQUITIES, LLC (Defendant); SIERRA VIEW CARE HOLDINGS, LLC (Defendant); SUN MAR HEALTHCARE, INC. (Defendant); VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant); WYNGATE NURSING CENTER

04/05/2024 Updated -- Stipulation and Order TO VACATE TRIAL DATES; [PROPOSED] ORDER: Filed By: COLLEGE VISTA, LLC (Defendant),CITRUS NURSING CENTER (Defendant),BARTLETT CARE CENTER, LLC (Defendant),ANAHEIM HEALTHCARE CENTER, LLC (Defendant),GARDEN PARK CARE CENTER, LLC (Defendant),F. & B. HEALTHCARE (Defendant),COMMUNITY CARE REHAB CENTER, LLC (Defendant),COUNTRY OAKS PARTNERS, LLC (Defendant),SIERRA VIEW CARE HOLDINGS, LLC (Defendant),RIVERSIDE EQUITIES, LLC (Defendant),PUENTE PARTNERS, LLC (Defendant),PC CARE, LLC (Defendant),WYNGATE NURSING CENTER (Defendant),VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant),SUN MAR HEALTHCARE, INC. (Defendant),INLAND MEDICAL ENTERPRISES, INC. (Defendant),HERITAGE MANOR HEALTHCARE, LLC (Defendant),GORDON LANE HEALTHCARE, LLC (Defendant),GIBRALTAR CONVALESCENT HOSPITAL, INC. (Defendant),PARK REGENCY CARE, LLC (Defendant),PARAMOUNT CONVALESCENT GROUP, INC. (Defendant),MONTERREY PARK CONVALESCENT HOSPITAL, INC. (Defendant),MJB PARTNERS, LLC (Defendant);

04/05/2024 Post-Mediation Status Conference scheduled for 06/24/2024 at 08:30 AM in Stanley Mosk Courthouse at Department 39 Not Held - Vacated by Court on 04/05/2024

04/05/2024 Final Status Conference scheduled for 10/18/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 39 Not Held - Vacated by Court on 04/05/2024

04/05/2024 Jury Trial scheduled for 10/29/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 39 Not Held - Vacated by Court on 04/05/2024

01/16/2024 Stipulation and Order Stipulation and Proposed Order RE Precedential Effect of Plaintiff's Contemplated Initial Motions to Compel Further Discovery Responses; Signed and Filed by: MED-PLUS PHARMACY, LLC (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

01/16/2024 Updated -- Stipulation and Order Stipulation and Proposed Order RE Precedential Effect of Plaintiff's Contemplated Initial Motions to Compel Further Discovery Responses: Filed By: MED-PLUS PHARMACY, LLC (Plaintiff); Result: Granted ; Result Date: 01/16/2024

01/12/2024 Right to Attach Order After Hearing and Order for Issuance of Writ of Attachment; Signed and Filed by: MED-PLUS PHARMACY, LLC (Plaintiff)

01/12/2024 Updated -- Right to Attach Order After Hearing and Order for Issuance of Writ of Attachment: As To Parties: VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant)

01/12/2024 Right to Attach Order After Hearing and Order for Issuance of Writ of Attachment; Signed and Filed by: MED-PLUS PHARMACY, LLC (Plaintiff); As to: COMMUNITY CARE REHAB CENTER, LLC (Defendant)

01/12/2024 Undertaking bond; Filed by:

01/12/2024 Undertaking bond; Filed by:

01/11/2024 Objection Evidentiary; Filed by: COMMUNITY CARE REHAB CENTER, LLC (Defendant)

01/11/2024 Objection Evidentiary; Filed by: MED-PLUS PHARMACY, LLC (Plaintiff)

01/11/2024 Decision on applications for right to attach orders: granted in part; Filed by: Clerk

01/11/2024 Order Appointing Court Approved Reporter as Official Reporter Pro Tempore; Filed by: COMMUNITY CARE REHAB CENTER, LLC (Defendant)

01/11/2024 Minute Order (Hearing on Application for Writ of Attachment Against Defenda...)

01/11/2024 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 01/11/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 85 updated: Result Date to 01/11/2024; Result Type to Held - Motion Granted

01/11/2024 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 01/11/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 85 updated: Result Date to 01/11/2024; Result Type to Held - Motion Granted

01/08/2024 Reply Plaintiff's Reply Brief In Support of Applications for Right to Attach Orders Against Defendants Community Care Rehab Center, LLC and Villa Rancho Bernardo Health Care, LLC; Filed by: MED-PLUS PHARMACY, LLC (Plaintiff)

01/08/2024 Objection Plaintiff's Evidentiary Objections to Declarations and Evidence Filed in Support of Defendant's Opposition to Its Applications for Right to Attach Orders Against Defendants Community Care Rehab Ctr, LLC and Villa Rancho Bernardo Health Care; Filed by: MED-PLUS PHARMACY, LLC (Plaintiff)

01/08/2024 Proof of Service (not Summons and Complaint); Filed by: MED-PLUS PHARMACY, LLC (Plaintiff); As to: MED-PLUS PHARMACY, LLC (Plaintiff); ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant) et al.

01/05/2024 Updated -- MED-PLUS PHARMACY, LLC (Plaintiff): Organization Name changed from MED-PLUS PHARMACY, INC. to MED-PLUS PHARMACY, LLC

01/04/2024 Opposition DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

01/04/2024 Declaration DECLARATION OF JORDAN MADER IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATION FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration DECLARATION OF MICAH RHEAD IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Proof of Service (not Summons and Complaint); Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration DECLARATION OF ADRIAN DEHGHANMANESH IN SUPPORT OF DEFENDANT VILLA RANCHO BERNARDO HEALTH CARE, LLC'SNOTICE OF OPPOSITION TO RIGHT TO ATTACH ORDER AND CLAIM OF EXEMPTION; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration DECLARATION OF ADRIAN DEHGHANMANESH IN SUPPORT OF DEFENDANT COMMUNITY CARE REHAB CENTER, LLC'S NOTICE OF OPPOSITION TO RIGHT TO ATTACH ORDER AND CLAIM OF EXEMPTION; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Notice of Opposition to Right to Attach Order and Claim of Exemption; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Notice of Opposition to Right to Attach Order and Claim of Exemption; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration DECLARATION OF GARY K. BRUCKER, JR. IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Objection DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC's JOINT EVIDENTIARY OBJECTIONS TO DECLARATIONS OF NEIL FARAGE IN SUPPORT OF PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDER AGAINST DEFENDANTS; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration DECLARATION OF ADRIAN DEHGHANMANESH IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TOPLAINTIFF'S APPLICATION__ FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC__; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Stipulation and Order Stipulation and Proposed Order Amending the Complaint; Signed and Filed by: MED-PLUS PHARMACY, LLC (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

01/04/2024 Updated -- Stipulation and Order Stipulation and Proposed Order Amending the Complaint: Filed By: MED-PLUS PHARMACY, INC. (Plaintiff); Result: Granted , Result Date: 01/04/2024

01/03/2024 Proof of Service (not Summons and Complaint); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

11/07/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Application for Right to Attach Order, Temporary Protective Order, etc. Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: COMMUNITY CARE REHAB CENTER, LLC (Defendant)

11/07/2023 Proof of Service by Mail; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: COMMUNITY CARE REHAB CENTER, LLC (Defendant); After Substituted Service of Summons and Complaint ?: No

11/07/2023 Memorandum of Points & Authorities; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 01/11/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 85

11/07/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Memorandum of Points & Authorities; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Proof of Service by Mail; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant); After Substituted Service of Summons and Complaint ?: No

11/07/2023 Application for Right to Attach Order, Temporary Protective Order, etc. Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant)

11/07/2023 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 01/11/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 85

07/27/2023 Notice of Ruling; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

07/14/2023 Final Status Conference scheduled for 10/18/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 39

07/14/2023 Jury Trial scheduled for 10/29/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 39

07/14/2023 Post-Mediation Status Conference scheduled for 06/24/2024 at 08:30 AM in Stanley Mosk Courthouse at Department 39

07/14/2023 Minute Order (Non-Appearance Case Review)

07/14/2023 Certificate of Mailing for (Non-Appearance Case Review) of 07/14/2023; Filed by: Clerk

07/14/2023 On the Court's own motion, Case Management Conference scheduled for 07/26/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 39 Not Held - Advanced and Vacated on 07/14/2023

06/29/2023 Objections to Declaration of Adrian Dehghanmanesh Submitted in Opposition to Applications for Right to Attach Orders; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/29/2023 Decision on Applications for Right to Attach Orders; Filed by: Clerk

06/29/2023 Minute Order (Hearing on Application for Writ of Attachment against (1) Def...)

06/29/2023 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 06/29/2023 at 09:30 AM in Stanley Mosk Courthouse at Department 85 updated: Result Date to 06/29/2023; Result Type to Held - Motion Denied

06/27/2023 Reply Brief ISO Application for Right to Attach Order; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/27/2023 Objection to Decl. of A. Dehghanmanesh Submitted in Opp to Appl. for Right to Attach Order; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/22/2023 Opposition To Plaintiffs Application For Right To Attach Orders Against Defendants Anaheim Healthcare Center, LLC And Bartlett Care Center, LLC; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Notice of Opposition to Right to Attach Order and Claim of Exemption; Filed by: BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Notice of Opposition to Right to Attach Order and Claim of Exemption; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

06/22/2023 Objection Defendants Anaheim Healthcare Center, LLC And Bartlett Care Center, LLC Joint Evidentiary Objections To Declarations Of Neil Farage In Support Of Plaintiffs Applications For Right To Attach Order Against Defendants; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Declaration Declaration Of Adrian Dehghanmanesh In Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Declaration Declaration Of Channon Balana Yin Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Declaration Declaration Of John Kimball In Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/06/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/06/2023 Memorandum of Points & Authorities; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/06/2023 Application for Right to Attach Order, Temporary Protective Order, etc. Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

06/06/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/06/2023 Memorandum of Points & Authorities; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/06/2023 Application for Right to Attach Order, Temporary Protective Order, etc. Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: BARTLETT CARE CENTER, LLC (Defendant)

06/06/2023 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 06/29/2023 at 09:30 AM in Stanley Mosk Courthouse at Department 85

05/31/2023 Minute Order (Non-Appearance Case Review)

05/31/2023 Certificate of Mailing for (Non-Appearance Case Review) of 05/31/2023; Filed by: Clerk

05/31/2023 Updated -- Gary Keith Brucker (Attorney): Organization Name: Lewis Brisbois Bisgaard & Smith LLP: Middle Name changed from K. to Keith

05/31/2023 Address for Gary Keith Brucker (Attorney) null

05/31/2023 On the Court's own motion, Case Management Conference scheduled for 06/08/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 39 Not Held - Advanced and Continued - by Court was rescheduled to 07/26/2023 08:30 AM

05/24/2023 Case Management Statement; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant); COLLEGE VISTA, LLC (Defendant); COUNTRY OAKS PARTNERS, LLC (Defendant); COMMUNITY CARE REHAB CENTER, LLC (Defendant); F. & B. HEALTHCARE (Defendant); GARDEN PARK CARE CENTER, LLC (Defendant); GIBRALTAR CONVALESCENT HOSPITAL, INC. (Defendant); GORDON LANE HEALTHCARE, LLC (Defendant); HERITAGE MANOR HEALTHCARE, LLC (Defendant); INLAND MEDICAL ENTERPRISES, INC. (Defendant); MJB PARTNERS, LLC (Defendant); MONTERREY PARK CONVALESCENT HOSPITAL, INC. (Defendant); PARAMOUNT CONVALESCENT GROUP, INC. (Defendant); PARK REGENCY CARE, LLC (Defendant); PC CARE, LLC (Defendant);

PUENTE PARTNERS, LLC (Defendant); RIVERSIDE EQUITIES, LLC (Defendant); SIERRA VIEW CARE HOLDINGS, LLC (Defendant); SUN MAR HEALTHCARE, INC. (Defendant); VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant); WYNGATE NURSING CENTER (Defendant)

05/23/2023 Case Management Statement; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

05/19/2023 Updated -- Ex Parte Application for Temporary Protective Order: Name Extension changed from In support of Temporary Protective Order to for Temporary Protective Order ; As To Parties changed from ANAHEIM HEALTHCARE CENTER, LLC (Defendant) to ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

05/19/2023 Updated -- Ex Parte Application for Temporary Protective Order: Filed By: MED-PLUS PHARMACY, INC. (Plaintiff); Result: Denied ; Result Date: 05/19/2023

05/19/2023 Minute Order (Hearing on Ex Parte Application of Plaintiff for Temporary Pr...)

05/19/2023 Hearing on Ex Parte Application In support of Temporary Protective Order scheduled for 05/19/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 85 updated: Result Date to 05/19/2023; Result Type to Held - Motion Denied

05/18/2023 Ex Parte Application In support of Temporary Protective Order; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

05/18/2023 Declaration In support of Temporary Protective Order; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

05/18/2023 Declaration of Richard Fond re Ex Parte for Temporary Protective Order; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

05/18/2023 Hearing on Ex Parte Application In support of Temporary Protective Order scheduled for 05/19/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 85

05/18/2023 Opposition Opposition To Plaintiffs Ex Parte Applications For Temporary Protective Orders Against Defendants Anaheim Healthcare Center And Bartlett Care Center; Declaration Of Gary K. Brucker, Jr. Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant); COLLEGE VISTA, LLC (Defendant); COUNTRY OAKS PARTNERS, LLC (Defendant); COMMUNITY CARE REHAB CENTER, LLC (Defendant); F. & B. HEALTHCARE (Defendant); GARDEN PARK CARE CENTER, LLC (Defendant); GIBRALTAR CONVALESCENT HOSPITAL, INC. (Defendant); GORDON LANE HEALTHCARE, LLC (Defendant); HERITAGE MANOR HEALTHCARE, LLC (Defendant); INLAND MEDICAL ENTERPRISES, INC. (Defendant); MJB PARTNERS, LLC (Defendant); MONTERREY PARK CONVALESCENT HOSPITAL, INC. (Defendant); PARAMOUNT CONVALESCENT GROUP, INC. (Defendant); PARK REGENCY CARE, LLC (Defendant); PC CARE, LLC (Defendant); PUENTE PARTNERS, LLC (Defendant); RIVERSIDE EQUITIES, LLC (Defendant); SIERRA VIEW CARE HOLDINGS, LL

03/30/2023 Answer; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant); COLLEGE VISTA, LLC (Defendant); COUNTRY OAKS PARTNERS, LLC (Defendant); COMMUNITY CARE REHAB CENTER, LLC (Defendant); F. & B. HEALTHCARE (Defendant); GARDEN PARK CARE CENTER, LLC (Defendant); GIBRALTAR CONVALESCENT HOSPITAL, INC. (Defendant); GORDON LANE HEALTHCARE, LLC (Defendant); HERITAGE MANOR HEALTHCARE, LLC (Defendant); INLAND MEDICAL ENTERPRISES, INC. (Defendant); MJB PARTNERS, LLC (Defendant); MONTERREY PARK CONVALESCENT HOSPITAL, INC. (Defendant); PARAMOUNT CONVALESCENT GROUP, INC. (Defendant); PARK REGENCY CARE, LLC (Defendant); PC CARE, LLC (Defendant); PUENTE PARTNERS, LLC (Defendant); RIVERSIDE EQUITIES, LLC (Defendant); SIERRA VIEW CARE HOLDINGS, LLC (Defendant); SUN MAR HEALTHCARE, INC. (Defendant); VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant); WYNGATE NURSING CENTER (Defendant); As to: MED-PLUS PHARMACY, INC. (Plaintiff)

03/01/2023 Notice and Acknowledgment of Receipt; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

03/01/2023 Proof of Service (not Summons and Complaint); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

02/15/2023 Notice of Case Management Conference; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

02/10/2023 Case Management Conference scheduled for 06/08/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 39

02/10/2023 Case Management Conference scheduled for 07/26/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 39

02/10/2023 Address for Robert David Bergman (Attorney) updated

02/10/2023 Notice of Case Management Conference; Filed by: Clerk

02/07/2023 Case assigned to Hon. Stephen I. Goorvitch in Department 39 Stanley Mosk Courthouse

02/06/2023 Complaint; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

02/06/2023 Civil Case Cover Sheet; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

02/06/2023 Summons on Complaint; Issued and Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

02/06/2023 Alternate Dispute Resolution Packet; Filed by: Clerk

02/06/2023 First Amended General Order re: Mandatory Electronic Filing; Filed by: Clerk

02/06/2023 Voluntary Efficient Litigation Stipulation Packet; Filed by: Clerk

02/06/2023 Notice of Case Assignment - Unlimited Civil Case; Filed by: Clerk

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4, 5, 6. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
02/15/2023	PENDING	DE	WILMINGTON	NEW CASTLE COUNTY

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
N23C-02-128	NEW CASTLE SUPERIOR COURT

Reason/Charge
BREACH OF CONTRACT

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
POLARIS PHARMACY SERVICES VS BONAMOUR HEALTH	LAWSUIT

Name of Business/Industry/Entity
POLARIS PHARMACY SERVICES OF PENNSYLVANIA

Provide explanation below:

Please see attached.

Original Signature (electronic, copies or stamps not accepted)

9/11/24
Date

Report Selection Criteria

Case ID: N23C-02-128
Docket Start Date:
Docket Ending Date:

Case Description

Case ID: N23C-02-128 - POLARIS PHARM SERV V BONAMOUR HEALTH
Filing Date: Wednesday, February 15th, 2023
Type: C2 - CCLD: COMPLEX COM LIT DIVISION
Status: BANRUPTCY - BANKRUPTCY

Related Cases

No related cases were found.

Case Event Schedule

Event	Date/Time	Room	Location	Judge
PRE-TRIAL CONFERENCE	27-SEP-2024 10:00 AM	SCN COURTROOM TBD	SUPERIOR CT NEW CASTLE COUNTY	ADAMS, MEGHAN A
JURY SELECTION	28-OCT-2024 09:30 AM	SCN COURTROOM TBD	SUPERIOR CT NEW CASTLE COUNTY	ADAMS, MEGHAN A
TRIAL (CIVIL)	28-OCT-2024 09:30 AM	SCN COURTROOM TBD	SUPERIOR CT NEW CASTLE COUNTY	ADAMS, MEGHAN A

Case Parties

Seq #	Assoc	Party End Date	Type	ID	Name
1	2		PLAINTIFF	@3764760	**POLARIS PHARMACY SERVICES**
Address:	*unavailable*		**Aliases:**	*none*	
2	1		ATTORNEY FOR PLAINTIFF	004356	**FIRTH III, WILLIAM R**
Address:	COHEN SEGLIAS PALLAS GREENHALL 500 DELAWARE AVENUE, SUITE 730		**Aliases:**	*none*	

	WILMINGTON DE 198010000				
3	7		DEFENDANT	@3764761	**BONAMOUR HEALTH GROUP**
Address:	*unavailable*		**Aliases:**	*none*	
4		09-MAY-2023	JUDGE	004673	**LEGROW, ABIGAIL M**
Address:	SUPERIOR COURT 500 NORTH KING STREET SUITE 11400 WILMINGTON DE 19801 (302)651-3963		**Aliases:**	*none*	
5			SHERIFF	KCSHRF	**KENT COUNTY, SHERIFF**
Address:	*unavailable*		**Aliases:**	*none*	
6			SHERIFF	NCSHRF	**NEW CASTLE COUNTY, SHERIFF**
Address:	87 READS WAY NEW CASTLE DE 19720		**Aliases:**	*none*	
7	3		ATTORNEY FOR DEFENDANT	003496	**FASIC, G. KEVIN**
Address:	OFFIT KURMAN 222 DELAWARE AVENUE SUITE 1105 WILMINGTON DE 19801		**Aliases:**	FASIC, G KEVIN	
8		10-MAY-2023	JUDGE	TBAJ	**JUDGE, TO BE ASSIGNED**
Address:	*unavailable*		**Aliases:**	*none*	
9			JUDGE	004981	**ADAMS, MEGHAN A**
Address:	SUPERIOR COURT LEONARD L. WILLIAMS JUSTICE CT 500 NORTH KING		**Aliases:**	*none*	

	STREET WILMINGTON DE 19801		

Docket Entries

Filing Date	Description	Name	Monetary
15-FEB-2023 01:26 PM	INIT FILING CCLD	FIRTH III, WILLIAM R	
Entry:	INITIAL FILING CCLD - COMPLEX COMMERCIAL LITIGATION DIVISION DATE DOCKETED: FEBRUARY 18, 2023		
15-FEB-2023 01:26 PM	INITIAL COMPLAINT	FIRTH III, WILLIAM R	
Entry:	INITIAL COMPLAINT DATE DOCKETED: FEBRUARY 18, 2023 COMPLAINT CASE INFORMATION STATEMENT EXHIBIT A TO COMPLAINT EXHIBIT B TO COMPLAINT EXHIBIT C TO COMPLAINT EXHIBIT D TO COMPLAINT EXHIBIT E TO COMPLAINT EXHIBIT F TO COMPLAINT EXHIBIT G TO COMPLAINT PRAECIPE TO COMPLAINT SUMMONS TO COMPLAINT ACCEPTED BY: JDB TRANSACTION ID: 69155555		
21-FEB-2023 03:32 PM	WRIT ISSUED		
Entry:	WRIT(S) ISSUED ON DATE DOCKETED: FEBRUARY 22, 2023 (1) WRIT ISSUED ON 2-20-23, CHECK #5611 $30.00, TO NEW CASTLE COUNTY SHERIFF ACCEPTED BY: RH TRANSACTION ID: 69188972		
27-FEB-2023 09:16 AM	WRIT RETURN (GENERIC)	NEW CASTLE COUNTY, SHERIFF	
Entry:	WRIT RETURNED: DATE DOCKETED: MARCH 1, 2023 ENTITY - BONAMOUR HEALTH GROUP, LLC. ON 2/22/2023 AT 12:14 PM A COPY OF THE WITHIN WRIT TOGETHER WITH A COPY OF THE SUMMONS AND COMPLAINT WERE SERVED UPON LITIGATION MANAGEMENT REPRESENTATIVE, A REPRESENTATIVE FOR THE REGISTERED AGENT CORPORATION SERVICE COMPANY 251 LITTLE FALLS DRIVE WILMINGTON, DE 19808. ACCEPTED BY: RH TRANSACTION ID: 69223030		
14-MAR-2023 11:55 AM	ANSWER & COUNTERCLAIM	FASIC, G. KEVIN	
Entry:	ANSWER AND COUNTERCLAIM DATE DOCKETED: MARCH 15, 2023 DEFENDANT'S ANSWER WITH COUNTERCLAIMS CERTIFICATE OF SERVICE TO DEFENDANT'S ANSWER WITH COUNTERCLAIMS CASE INFORMATION STATEMENT TO DEFENDANT'S ANSWER WITH COUNTERCLAIMS ENTRY OF		

	APPEARANCE OF G. KEVIN FASIC ON BEHALF OF DEFENDANT ACCEPTED BY: SD TRANSACTION ID: 69336247		
16-MAR-2023 08:28 AM	REFERRED TO CASE SCHEDULING		
Entry:	REFERRED TO CASE SCHEDULING DATE DOCKETED: MARCH 16, 2023		
30-MAR-2023 12:57 PM	ANSWER TO COUNTERCLAIM	FIRTH III, WILLIAM R	
Entry:	ANSWER TO COUNTERCLAIM DATE DOCKETED: MARCH 31, 2023 PLAINTIFF'S ANSWER TO DEFENDANT'S COUNTERCLAIM CERTIFICATE OF SERVICE TO PLAINTIFF'S ANSWER TO DEFENDANT'S COUNTERCLAIM ACCEPTED BY: TNW TRANSACTION ID: 69693405		
11-MAY-2023 01:45 PM	LETTER		
Entry:	LETTER DATE DOCKETED: MAY 12, 2023 THE ABOVE CAPTIONED CASE HAS BEEN REASSIGNED TO JUDGE MEGHAN A ADAMS. PLEASE REMEMBER THAT ON ALL FUTURE DOCUMENTS AND FILINGS ON THIS CASE, COUNSEL MUST REFERENCE THE ASSIGNED JUDGE BY INCLUDING THE JUDGE'S INITIALS (MAA-CCLD) AS A SUFFIX TO THE CIVIL ACTION NUMBER. ACCEPTED BY: TNW TRANSACTION ID: 69996405		
19-MAY-2023 10:13 AM	NOTICE	ADAMS, MEGHAN A	
Entry:	NOTICE DATE DOCKETED: MAY 20, 2023 ORDER SIGNED BY: ADAMS, MEGHAN PER THE EMAIL CORRESPONDENCE BETWEEN CHAMBERS AND COUNSEL ON 5-19-23, A STATUS CONFERENCE WILL BE HELD ON MAY 19TH, 2023 AT 10:45 A.M. VIA ZOOM ACCEPTED BY: TRANSACTION ID: 70046520		
19-MAY-2023 02:39 PM	JUDICIAL ACTION FORM		
Entry:	JUDICIAL ACTION FORM DATE DOCKETED: MAY 20, 2023 JUDICIAL ACTION FORM FROM STATUS CONFERENCE HELD ON FRIDAY, MAY 19, 2023 AT 10:45 A.M. VIA ZOOM ACCEPTED BY: SR TRANSACTION ID: 70050068		
06-JUN-2023 12:23 PM	STIPULATION	FASIC, G. KEVIN	
Entry:	STIPULATION DATE DOCKETED: JUNE 7, 2023 JOINT STIPULATED CASE MANAGEMENT ORDER ACCEPTED BY: SR TRANSACTION ID: 70148008		

08-JUN-2023 07:42 PM	ORDER	ADAMS, MEGHAN A	
Entry:	ORDER DATE DOCKETED: JUNE 10, 2023 ORDER SIGNED BY: ADAMS, MEGHAN GRANTED (JOINT STIPULATED CASE MANAGEMENT ORDER) ADAMS, J. 6-8-23. ACCEPTED BY: SR TRANSACTION ID: 70168936		
29-JUN-2023 10:45 AM	LETTER	FIRTH III, WILLIAM R	
Entry:	LETTER DATE DOCKETED: JUNE 30, 2023 LETTER TO JUDICIAL CASE MANAGER FOR JUDGE ADAMS DATED JUNE 29, 2023 FROM WILLIAM R. FIRTH, III, ESQUIRE RE: NEW ADDRESS AND CONTACT INFORMATION ACCEPTED BY: SR TRANSACTION ID: 70283800		
29-JUN-2023 11:14 AM	NOTICE SRV REQUEST PRODUCTION	FIRTH III, WILLIAM R	
Entry:	NOTICE OF SERVICE OF REQUEST FOR PRODUCTION DATE DOCKETED: JUNE 30, 2023 NOTICE OF SERVICE OF POLARIS PHARMACY SERVICES OF PENNSYLVANIA, LLC'S FIRST REQUEST FOR PRODUCTION OF DOCUMENTS DIRECTED TO DEFENDANT - SERVED VIA EMAIL ON JUNE 29, 2023 ACCEPTED BY: SR TRANSACTION ID: 70284205		
30-JUN-2023 01:37 PM	NOTICE SRV REQUEST PRODUCTION	FASIC, G. KEVIN	
Entry:	NOTICE OF SERVICE OF REQUEST FOR PRODUCTION DATE DOCKETED: JULY 2, 2023 NOTICE OF SERVICE FOR DEFENDANT'S REQUEST FOR FIRST SET OF INTERROGATORIES AND REQUESTS FOR PRODUCTION OF DOCUMENTS TO PLAINTIFF CERTIFICATE OF SERVICE TO NOTICE OF SERVICE FOR DEFENDANT'S REQUEST FOR FIRST SET OF INTERROGATORIES AND REQUESTS FOR PRODUCTION OF DOCUMENTS TO PLAINTIFF ACCEPTED BY: VP TRANSACTION ID: 70293778		
22-AUG-2023 11:22 AM	NOTICE SRV OF INTERROGATORIES	FIRTH III, WILLIAM R	
Entry:	NOTICE OF SERVICE OF INTERROGATORIES DATE DOCKETED: AUGUST 23, 2023 NOTICE OF SERVICE OF POLARIS PHARMACY SERVICES OF PENNSYLVANIA, LLC'S FIRST SET OF INTERROGATORIES DIRECTED TO DEFENDANT - SERVED VIA EMAIL ON AUGUST 22, 2023 ACCEPTED BY: OA TRANSACTION ID: 70689234		
22-AUG-2023 12:59 PM	LETTER FOR JUDICIAL REVIEW	FASIC, G. KEVIN	
Entry:	LETTER FOR JUDICIAL REVIEW DATE DOCKETED: AUGUST 24, 2023 LETTER TO THE HONORABLE JUDGE ADAMS REGARDING THE PARTIES CONFIDENTIALITY STIPULATION AND ORDER STIPULATION AND PROPOSED		

	ORDER GOVERNING THE PRODUCTION AND EXCHANGE OF CONFIDENTIAL AND HIGHLY CONFIDENTIAL INFORMATION AGREEMENT TO DISCOVERY CONFIDENTIALITY STIPULATION AND ORDER ACCEPTED BY: TRANSACTION ID: 70690752		
23-AUG-2023 10:55 AM	ORDER	ADAMS, MEGHAN A	
Entry:	ORDER DATE DOCKETED: AUGUST 24, 2023 ORDER SIGNED BY: ADAMS, MEGHAN GRANTED (STIPULATION AND PROPOSED ORDER GOVERNING THE PRODUCTION AND EXCHANGE OF CONFIDENTIAL AND HIGHLY CONFIDENTIAL INFORMATION) ACCEPTED BY: OA TRANSACTION ID: 70698845		
30-OCT-2023 05:05 PM	LETTER FOR JUDICIAL REVIEW	FASIC, G. KEVIN	
Entry:	LETTER FOR JUDICIAL REVIEW DATE DOCKETED: NOVEMBER 2, 2023 LETTER TO THE HONORABLE MEGHAN A. ADAMS REGARDING STIPULATION A PROPOSED ORDER TO EXTEND DOCUMENT PRODUCTION DEADLINE PROPOSED STIPULATION AND AMENDED CASE MANAGEMENT ORDER ACCEPTED BY: TRANSACTION ID: 71234189		
01-NOV-2023 02:15 PM	ORDER	ADAMS, MEGHAN A	
Entry:	ORDER DATE DOCKETED: NOVEMBER 3, 2023 ORDER SIGNED BY: ADAMS, MEGHAN DENIED IN PART - STIPULATION AND AMENDED CASE MANAGEMENT ORDER. ADAMS, J. NOVEMBER 1, 2023 ACCEPTED BY: AK TRANSACTION ID: 71282675		
08-NOV-2023 10:31 AM	NOTICE OF SERVICE	FASIC, G. KEVIN	
Entry:	NOTICE OF SERVICE DATE DOCKETED: NOVEMBER 9, 2023 NOTICE OF SERVICE OF DISCOVERY RESPONSES DIRECTED TO PLAINTIFF CERTIFICATE OF SERVICE TO THE NOTICE OF SERVICE OF DISCOVERY RESPONSES DIRECTED TO PLAINTIFF ACCEPTED BY: OA TRANSACTION ID: 71355583		
17-NOV-2023 02:28 PM	NOTICE SRV ANS INTERROGATORIES	FIRTH III, WILLIAM R	
Entry:	NOTICE OF SERVICE OF ANSWERS TO INTERROGATORIES DATE DOCKETED: NOVEMBER 18, 2023 NOTICE OF SERVICE OF PLAINTIFF POLARIS PHARMACY SERVICES OF PENNSYLVANIA, LLC'S RESPONSES TO DEFENDANT'S FIRST SET OF INTERROGATORY REQUESTS CERTIFICATE OF SERVICE ACCEPTED BY: OA TRANSACTION ID: 71440418		

11-JAN-2024 02:17 PM	NOTICE OF SERVICE	FIRTH III, WILLIAM R	
Entry:	NOTICE OF SERVICE DATE DOCKETED: JANUARY 13, 2024 NOTICE OF SERVICE OF SUBPOENA DUCES TECUM ON SPECIALTY RX PA HOLDINGS, LLC CERTIFICATE OF SERVICE ACCEPTED BY: OA TRANSACTION ID: 71792059		
11-JAN-2024 02:20 PM	NOTICE OF SERVICE	FIRTH III, WILLIAM R	
Entry:	NOTICE OF SERVICE DATE DOCKETED: JANUARY 13, 2024 NOTICE OF SERVICE OF SUBPOENA DUCES TECUM ON SPECIALTY RX INC. CERTIFICATE OF SERVICE ACCEPTED BY: OA TRANSACTION ID: 71792122		
06-FEB-2024 02:41 PM	NOTICE OF DEPOSITION	FIRTH III, WILLIAM R	
Entry:	NOTICE OF DEPOSITION OF DATE DOCKETED: FEBRUARY 8, 2024 PLAINTIFF POLARIS PHARMACY SERVICES OF PENNSYLVANIA, LLC'S NOTICE OF DEPOSITION OF DEFENDANT BONAMOUR HEALTH GROUP, LLC'S CORPORATE DESIGNEE ON FEBRUARY 28, 2024 AT 9:30 A.M. CERTIFICATE OF SERVICE ACCEPTED BY: OA TRANSACTION ID: 71964550		
13-FEB-2024 01:33 PM	MOTION FOR PRO HAC VICE	FIRTH III, WILLIAM R	
Entry:	MOTION FOR PRO HAC VICE DATE DOCKETED: FEBRUARY 14, 2024 MOTION FOR ADMISSION PRO HAC VICE OF GERARD J. GAENG, ESQUIRE AND CERTIFICATE OF SERVICE CERTIFICATION OF GERARD J. GAENG, ESQUIRE IN SUPPORT OF PRO HAC VICE ADMISSION NOTICE OF MOTION FOR ADMISSION PRO HAC VICE OF GERARD J. GAENG, ESQUIRE GAENG, GERARD J.: PROPOSED ORDER GRANTING ADMISSION PRO HAC VICE OF GERARD J. GAENG, ESQUIRE ACCEPTED BY: AK TRANSACTION ID: 72028188		
14-FEB-2024 11:17 AM	ORDER - PRO HAC VICE	ADAMS, MEGHAN A	
Entry:	ORDER - PRO HAC VICE DATE DOCKETED: FEBRUARY 15, 2024 ORDER SIGNED BY: ADAMS, MEGHAN GRANTED (GAENG, GERARD J.: PROPOSED ORDER GRANTING ADMISSION PRO HAC VICE OF GERARD J. GAENG, ESQUIRE) ACCEPTED BY: OA TRANSACTION ID: 72035735		
14-FEB-2024 02:54 PM	LETTER FOR JUDICIAL REVIEW	FASIC, G. KEVIN	
Entry:	LETTER FOR JUDICIAL REVIEW DATE DOCKETED: FEBRUARY 15, 2024 LETTER TO THE HONORABLE MEGHAN ADAMS REGARDING SECOND STIPULATION AND PROPOSED ORDER AMENDING CASE MANAGEMENT		

	ORDER SECOND STIPULATION AND PROPOSED ORDER AMENDING CASE MANAGEMENT ORDER ACCEPTED BY: OA TRANSACTION ID: 72039799		
15-FEB-2024 11:15 AM	ORDER	ADAMS, MEGHAN A	
Entry:	ORDER DATE DOCKETED: FEBRUARY 16, 2024 ORDER SIGNED BY: ADAMS, MEGHAN GRANTED (SECOND STIPULATION AND PROPOSED ORDER AMENDING CASE MANAGEMENT ORDER) ACCEPTED BY: OA TRANSACTION ID: 72046867		
26-FEB-2024 01:20 PM	MOTION	FASIC, G. KEVIN	
Entry:	MOTION DATE DOCKETED: FEBRUARY 27, 2024 MOTION TO WITHDRAW AS COUNSEL NOTICE OF MOTION TO WITHDRAW AS COUNSEL PROPOSED ORDER TO MOTION TO WITHDRAW AS COUNSEL CERTIFICATE OF SERVICE TO MOTION TO WITHDRAW AS COUNSEL ACCEPTED BY: KC TRANSACTION ID: 72147092		
04-MAR-2024 01:04 PM	RE-NOTICE	FASIC, G. KEVIN	
Entry:	RE-NOTICE DATE DOCKETED: MARCH 5, 2024 RE-NOTICE OF MOTION TO WITHDRAW AS COUNSEL SCHEDULED FOR THURSDAY, MARCH 14, 2024 AT 9:15 AM CERTIFICATE OF SERVICE TO RE-NOTICE OF MOTION TO WITHDRAW AS COUNSEL SCHEDULED FOR THURSDAY, MARCH 14, 2024 AT 9:15 AM ACCEPTED BY: KC TRANSACTION ID: 72230740		
07-MAR-2024 02:06 PM	RESPONSE	FIRTH III, WILLIAM R	
Entry:	RESPONSE DATE DOCKETED: MARCH 8, 2024 RESPONSE OF PLAINTIFF POLARIS PHARMACY SERVICES OF PENNSYLVANIA, LLC TO MOTION TO WITHDRAW AS COUNSEL PROPOSED ORDER CERTIFICATE OF SERVICE ACCEPTED BY: KC TRANSACTION ID: 72326050		
14-MAR-2024 09:27 AM	ORDER	ADAMS, MEGHAN A	
Entry:	ORDER DATE DOCKETED: MARCH 15, 2024 ORDER SIGNED BY: ADAMS, MEGHAN GRANTED WITH AMENDMENTS (PROPOSED ORDER TO MOTION TO WITHDRAW AS COUNSEL) ACCEPTED BY: KC TRANSACTION ID: 72514416		
14-MAR-2024 09:33 AM	JUDICIAL ACTION FORM		
Entry:	JUDICIAL ACTION FORM DATE DOCKETED: MARCH 15, 2024 JUDICIAL ACTION FORM FROM MARCH 14, 2024 DEFENDANTS MOTION TO WITHDRAW.		

	MOTION IS GRANTED. ACCEPTED BY: KC TRANSACTION ID: 72514430		
14-MAR-2024 02:58 PM	NOTICE OF SERVICE	FASIC, G. KEVIN	
Entry:	NOTICE OF SERVICE DATE DOCKETED: MARCH 15, 2024 NOTICE OF SERVICE OF ORDER GRANTING OFFIT KURMAN, P.A. TO WITHDRAW AS COUNSEL ACCEPTED BY: KC TRANSACTION ID: 72522130		
22-APR-2024 02:29 PM	LETTER FOR JUDICIAL REVIEW	FIRTH III, WILLIAM R	
Entry:	LETTER FOR JUDICIAL REVIEW DATE DOCKETED: APRIL 23, 2024 LETTER FROM WILLIAM R FIRTH, ESQ. TO THE HONORABLE MEGHAN A. ADAMS RE; POLARIS V. BONAMOUR MOTION FOR DEFAULT JUDGMENT AND DEFENDANT'S INVOLUNTARY CHAPTER 7 BANKRUPTCY FILING EXHIBIT A CERTIFICATE OF SERVICE ACCEPTED BY: ERM TRANSACTION ID: 72798811		
25-APR-2024 11:11 AM	SO NOTED	ADAMS, MEGHAN A	
Entry:	SO NOTED DATE DOCKETED: APRIL 27, 2024 ORDER SIGNED BY: ADAMS, MEGHAN SO NOTED (LETTER FROM WILLIAM R FIRTH, ESQ. TO THE HONORABLE MEGHAN A. ADAMS RE; POLARIS V. BONAMOUR MOTION FOR DEFAULT JUDGMENT AND DEFENDANT'S INVOLUNTARY CHAPTER 7 BANKRUPTCY FILING) ACCEPTED BY: JH TRANSACTION ID: 72828630		
23-JUL-2024 02:23 PM	BANKRUPTCY LETTER		
Entry:	BANKRUPTCY LETTER DATE DOCKETED: JULY 24, 2024 BANKRUPTCY DORMANT DOCKET LETTER TO COUNSEL ON JULY 23, 2024. ACCEPTED BY: AK TRANSACTION ID: 73771556		

Report Selection Criteria

Case ID: N23C-02-128
Docket Start Date:
Docket Ending Date:

Case Description

Case ID: N23C-02-128 - POLARIS PHARM SERV V BONAMOUR HEALTH
Filing Date: Wednesday, February 15th, 2023
Type: C2 - CCLD: COMPLEX COM LIT DIVISION
Status: CSO - CASE SCHEDULING ORDER

Related Cases

No related cases were found.

Case Event Schedule

Event	Date/Time	Room	Location	Judge
PRE-TRIAL CONFERENCE	27-SEP-2024 10:00 AM	SCN COURTROOM TBD	SUPERIOR CT NEW CASTLE COUNTY	ADAMS, MEGHAN A
JURY SELECTION	28-OCT-2024 09:30 AM	SCN COURTROOM TBD	SUPERIOR CT NEW CASTLE COUNTY	ADAMS, MEGHAN A
TRIAL (CIVIL)	28-OCT-2024 09:30 AM	SCN COURTROOM TBD	SUPERIOR CT NEW CASTLE COUNTY	ADAMS, MEGHAN A

Case Parties

Seq #	Assoc	Party End Date	Type	ID	Name

Search Home | New Search | Report Selection | Case Description
Related Cases | Event Schedule | Case Parties | Docket Entries

© 2019 Avenu Insights & Analytics, LLC. All rights reserved. Contexte and the accompanying logos are trademarks of Avenu Insights & Analytics, LLC in the United States and/or other countries. This material contains trade secrets and other confidential information and is subject to a confidentiality agreement. The unauthorized use, reproduction, distribution, display, or disclosure of this material or the information contained herein is prohibited. User Accepts/Agrees to Disclaimer. Not for official use.

	09:30 AM	COURTROOM TBD	NEW CASTLE COUNTY	

Case Parties

Seq #	Assoc	Party End Date	Type	ID	Name
1	2		PLAINTIFF	@3764760	POLARIS PHARMACY SERVICES
Address:	*unavailable*		Aliases:	*none*	
2	1		ATTORNEY FOR PLAINTIFF	004356	FIRTH III, WILLIAM R
Address:	COHEN SEGLIAS PALLAS GREENHALL 500 DELAWARE AVENUE, SUITE 730 WILMINGTON DE 198010000		Aliases:	*none*	
3	7		DEFENDANT	@3764761	BONAMOUR HEALTH GROUP
Address:	*unavailable*		Aliases:	*none*	
4		09-MAY-2023	JUDGE	004673	LEGROW, ABIGAIL M
Address:	SUPERIOR COURT 500 NORTH KING STREET SUITE 11400 WILMINGTON DE 19801 (302)651-3963		Aliases:	*none*	

Search Home | New Search | Report Selection | Case Description
Related Cases | Event Schedule | Case Parties | Docket Entries

© 2019 Avenu Insights & Analytics, LLC. All rights reserved. Contexte and the accompanying logos are trademarks of Avenu Insights & Analytics, LLC in the United States and/or other countries. This material contains trade secrets and other confidential information and is subject to a confidentiality agreement. The unauthorized use, reproduction, distribution, display, or disclosure of this material or the information contained herein is prohibited. User Accepts/Agrees to Disclaimer. Not for official use.

3	7		DEFENDANT	@3764761	BONAMOUR HEALTH GROUP
Address:	*unavailable*		Aliases:	*none*	
4		09-MAY-2023	JUDGE	004673	LEGROW, ABIGAIL M
Address:	SUPERIOR COURT 500 NORTH KING STREET SUITE 11400 WILMINGTON DE 19801 (302)651-3963		Aliases:	*none*	
5			SHERIFF	KCSHRF	KENT COUNTY, SHERIFF
Address:	*unavailable*		Aliases:	*none*	
6			SHERIFF	NCSHRF	NEW CASTLE COUNTY, SHERIFF
Address:	87 READS WAY NEW CASTLE DE 19720		Aliases:	*none*	
7	3		ATTORNEY FOR DEFENDANT	003496	FASIC, G. KEVIN
Address:	OFFIT KURMAN 222 DELAWARE AVENUE SUITE 1105 WILMINGTON DE 19801		Aliases:	FASIC, G KEVIN	
8		10-MAY-2023	JUDGE	TBAJ	JUDGE, TO BE ASSIGNED

Search Home | New Search | Report Selection | Case Description
Related Cases | Event Schedule | Case Parties | Docket Entries

©2019 Avenu Insights & Analytics, LLC. All rights reserved. Contexte and the accompanying logos are trademarks of Avenu Insights & Analytics, LLC in the United States and/or other countries. This material contains trade secrets and other confidential information and is subject to a confidentiality agreement. The unauthorized use, reproduction, distribution, display, or disclosure of this material or the information contained herein is prohibited. User Accepts/Agrees to Disclaimer. Not for official use.

	AVENUE SUITE 1105 WILMINGTON DE 19801				
8		10-MAY-2023	JUDGE	TBAJ	JUDGE, TO BE ASSIGNED
Address:	*unavailable*		Aliases:	*none*	
9			JUDGE	004981	ADAMS, MEGHAN A
Address:	SUPERIOR COURT LEONARD L. WILLIAMS JUSTICE CT 500 NORTH KING STREET WILMINGTON DE 19801		Aliases:	*none*	

Docket Entries

Filing Date	Description	Name	Monetary
15-FEB-2023 01:26 PM	INIT FILING CCLD	FIRTH III, WILLIAM R	
Entry:	INITIAL FILING CCLD - COMPLEX COMMERCIAL LITIGATION DIVISION DATE DOCKETED: FEBRUARY 18, 2023		
15-FEB-2023 01:26 PM	INITIAL COMPLAINT	FIRTH III, WILLIAM R	
Entry:	INITIAL COMPLAINT DATE DOCKETED: FEBRUARY 18, 2023 COMPLAINT CASE INFORMATION STATEMENT EXHIBIT A TO COMPLAINT EXHIBIT B TO COMPLAINT EXHIBIT C TO COMPLAINT EXHIBIT D TO COMPLAINT EXHIBIT E TO COMPLAINT EXHIBIT F TO COMPLAINT EXHIBIT G TO COMPLAINT PRAECIPE TO COMPLAINT SUMMONS TO COMPLAINT ACCEPTED BY: JDB		

Search Home | New Search | Report Selection | Case Description
Related Cases | Event Schedule | Case Parties | Docket Entries

© 2019 Avenu Insights & Analytics, LLC. All rights reserved. Contexte and the accompanying logos are trademarks of Avenu Insights & Analytics, LLC in the United States and/or other countries. This material contains trade secrets and other confidential information and is subject to a confidentiality agreement. The unauthorized use, reproduction, distribution, display, or disclosure of this material or the information contained herein is prohibited. User Accepts/Agrees to Disclaimer. Not for official use.

15-FEB-2023 01:26 PM	INITIAL COMPLAINT	FIRTH III, WILLIAM R	
Entry:	INITIAL COMPLAINT DATE DOCKETED: FEBRUARY 18, 2023 COMPLAINT CASE INFORMATION STATEMENT EXHIBIT A TO COMPLAINT EXHIBIT B TO COMPLAINT EXHIBIT C TO COMPLAINT EXHIBIT D TO COMPLAINT EXHIBIT E TO COMPLAINT EXHIBIT F TO COMPLAINT EXHIBIT G TO COMPLAINT PRAECIPE TO COMPLAINT SUMMONS TO COMPLAINT ACCEPTED BY: JDB TRANSACTION ID: 69155555		
21-FEB-2023 03:32 PM	WRIT ISSUED		
Entry:	WRIT(S) ISSUED ON DATE DOCKETED: FEBRUARY 22, 2023 (1) WRIT ISSUED ON 2-20-23, CHECK #5611 $30.00, TO NEW CASTLE COUNTY SHERIFF ACCEPTED BY: RH TRANSACTION ID: 69188972		
27-FEB-2023 09:16 AM	WRIT RETURN (GENERIC)	NEW CASTLE COUNTY, SHERIFF	
Entry:	WRIT RETURNED: DATE DOCKETED: MARCH 1, 2023 ENTITY - BONAMOUR HEALTH GROUP, LLC. ON 2/22/2023 AT 12:14 PM A COPY OF THE WITHIN WRIT TOGETHER WITH A COPY OF THE SUMMONS AND COMPLAINT WERE SERVED UPON LITIGATION MANAGEMENT REPRESENTATIVE, A REPRESENTATIVE FOR THE REGISTERED AGENT CORPORATION SERVICE COMPANY 251 LITTLE FALLS DRIVE WILMINGTON, DE 19808. ACCEPTED BY: RH TRANSACTION ID: 69223030		
14-MAR-2023 11:55 AM	ANSWER & COUNTERCLAIM.	FASIC, G. KEVIN	
Entry:	ANSWER AND COUNTERCLAIM DATE DOCKETED: MARCH 15, 2023 DEFENDANT'S ANSWER WITH COUNTERCLAIMS CERTIFICATE OF SERVICE TO DEFENDANT'S ANSWER WITH COUNTERCLAIMS CASE INFORMATION STATEMENT TO DEFENDANT'S ANSWER WITH COUNTERCLAIMS ENTRY OF APPEARANCE OF G. KEVIN FASIC ON BEHALF OF DEFENDANT ACCEPTED BY: SD TRANSACTION ID: 69336247		

Search Home | New Search | Report Selection | Case Description
Related Cases | Event Schedule | Case Parties | Docket Entries

©2019 Avenu Insights & Analytics, LLC. All rights reserved. Contexte and the accompanying logos are trademarks of Avenu Insights & Analytics, LLC in the United States and/or other countries. This material contains trade secrets and other confidential information and is subject to a confidentiality agreement. The unauthorized use, reproduction, distribution, display, or disclosure of this material or the information contained herein is prohibited. User Accepts/Agrees to Disclaimer. Not for official use.

Entry:	ANSWER AND COUNTERCLAIM DATE DOCKETED: MARCH 15, 2023 DEFENDANT'S ANSWER WITH COUNTERCLAIMS CERTIFICATE OF SERVICE TO DEFENDANT'S ANSWER WITH COUNTERCLAIMS CASE INFORMATION STATEMENT TO DEFENDANT'S ANSWER WITH COUNTERCLAIMS ENTRY OF APPEARANCE OF G. KEVIN FASIC ON BEHALF OF DEFENDANT ACCEPTED BY: SD TRANSACTION ID: 69336247		
16-MAR-2023 08:28 AM	REFERRED TO CASE SCHEDULING		
Entry:	REFERRED TO CASE SCHEDULING DATE DOCKETED: MARCH 16, 2023		
30-MAR-2023 12:57 PM	ANSWER TO COUNTERCLAIM	FIRTH III, WILLIAM R	
Entry:	ANSWER TO COUNTERCLAIM DATE DOCKETED: MARCH 31, 2023 PLAINTIFF'S ANSWER TO DEFENDANT'S COUNTERCLAIM CERTIFICATE OF SERVICE TO PLAINTIFF'S ANSWER TO DEFENDANT'S COUNTERCLAIM ACCEPTED BY: TNW TRANSACTION ID: 69693405		
11-MAY-2023 01:45 PM	LETTER		
Entry:	LETTER DATE DOCKETED: MAY 12, 2023 THE ABOVE CAPTIONED CASE HAS BEEN REASSIGNED TO JUDGE MEGHAN A ADAMS. PLEASE REMEMBER THAT ON ALL FUTURE DOCUMENTS AND FILINGS ON THIS CASE, COUNSEL MUST REFERENCE THE ASSIGNED JUDGE BY INCLUDING THE JUDGE'S INITIALS (MAA-CCLD) AS A SUFFIX TO THE CIVIL ACTION NUMBER. ACCEPTED BY: TNW TRANSACTION ID: 69996405		
19-MAY-2023 10:13 AM	NOTICE	ADAMS, MEGHAN A	
Entry:	NOTICE DATE DOCKETED: MAY 20, 2023 ORDER SIGNED BY: ADAMS, MEGHAN PER THE EMAIL CORRESPONDENCE BETWEEN CHAMBERS AND COUNSEL ON 5-19-23, A STATUS CONFERENCE WILL BE HELD ON MAY 19TH, 2023 AT 10:45 A.M. VIA ZOOM ACCEPTED BY: TRANSACTION ID: 70046520		

Search Home | New Search | Report Selection | Case Description
Related Cases | Event Schedule | Case Parties | Docket Entries

© 2019 Avenu Insights & Analytics, LLC. All rights reserved. Contexte and the accompanying logos are trademarks of Avenu Insights & Analytics, LLC in the United States and/or other countries. This material contains trade secrets and other confidential information and is subject to a confidentiality agreement. The unauthorized use, reproduction, distribution, display, or disclosure of this material or the information contained herein is prohibited. User Accepts/Agrees to Disclaimer. Not for official use.

Entry:	REMEMBER THAT ON ALL FUTURE DOCUMENTS AND FILINGS ON THIS CASE, COUNSEL MUST REFERENCE THE ASSIGNED JUDGE BY INCLUDING THE JUDGE'S INITIALS (MAA-CCLD) AS A SUFFIX TO THE CIVIL ACTION NUMBER. ACCEPTED BY: TNW TRANSACTION ID: 69996405		
19-MAY-2023 10:13 AM	NOTICE	ADAMS, MEGHAN A	
Entry:	NOTICE DATE DOCKETED: MAY 20, 2023 ORDER SIGNED BY: ADAMS, MEGHAN PER THE EMAIL CORRESPONDENCE BETWEEN CHAMBERS AND COUNSEL ON 5-19-23, A STATUS CONFERENCE WILL BE HELD ON MAY 19TH, 2023 AT 10:45 A.M. VIA ZOOM ACCEPTED BY: TRANSACTION ID: 70046520		
19-MAY-2023 02:39 PM	JUDICIAL ACTION FORM		
Entry:	JUDICIAL ACTION FORM DATE DOCKETED: MAY 20, 2023 JUDICIAL ACTION FORM FROM STATUS CONFERENCE HELD ON FRIDAY, MAY 19, 2023 AT 10:45 A.M. VIA ZOOM ACCEPTED BY: SR TRANSACTION ID: 70050068		
06-JUN-2023 12:23 PM	STIPULATION	FASIC, G. KEVIN	
Entry:	STIPULATION DATE DOCKETED: JUNE 7, 2023 JOINT STIPULATED CASE MANAGEMENT ORDER ACCEPTED BY: SR TRANSACTION ID: 70148008		
08-JUN-2023 07:42 PM	ORDER	ADAMS, MEGHAN A	
Entry:	ORDER DATE DOCKETED: JUNE 10, 2023 ORDER SIGNED BY: ADAMS, MEGHAN GRANTED (JOINT STIPULATED CASE MANAGEMENT ORDER) ADAMS, J. 6-8-23. ACCEPTED BY: SR TRANSACTION ID: 70168936		
29-JUN-2023 10:45 AM	LETTER	FIRTH III, WILLIAM R	
	LETTER DATE DOCKETED: JUNE 30, 2023 LETTER TO JUDICIAL CASE		

Search Home | New Search | Report Selection | Case Description
Related Cases | Event Schedule | Case Parties | Docket Entries

© 2019 Avenu Insights & Analytics, LLC. All rights reserved. Contexte and the accompanying logos are trademarks of Avenu Insights & Analytics, LLC in the United States and/or other countries. This material contains trade secrets and other confidential information and is subject to a confidentiality agreement. The unauthorized use, reproduction, distribution, display, or disclosure of this material or the information contained herein is prohibited. User Accepts/Agrees to Disclaimer. Not for official use.

06-JUN-2023 12:23 PM	STIPULATION	FASIC, G. KEVIN	
Entry:	STIPULATION DATE DOCKETED: JUNE 7, 2023 JOINT STIPULATED CASE MANAGEMENT ORDER ACCEPTED BY: SR TRANSACTION ID: 70148008		
08-JUN-2023 07:42 PM	ORDER	ADAMS, MEGHAN A	
Entry:	ORDER DATE DOCKETED: JUNE 10, 2023 ORDER SIGNED BY: ADAMS, MEGHAN GRANTED (JOINT STIPULATED CASE MANAGEMENT ORDER) ADAMS, J. 6-8-23. ACCEPTED BY: SR TRANSACTION ID: 70168936		
29-JUN-2023 10:45 AM	LETTER	FIRTH III, WILLIAM R	
Entry:	LETTER DATE DOCKETED: JUNE 30, 2023 LETTER TO JUDICIAL CASE MANAGER FOR JUDGE ADAMS DATED JUNE 29, 2023 FROM WILLIAM R. FIRTH, III, ESQUIRE RE: NEW ADDRESS AND CONTACT INFORMATION ACCEPTED BY: SR TRANSACTION ID: 70283800		
29-JUN-2023 11:14 AM	NOTICE SRV REQUEST PRODUCTION	FIRTH III, WILLIAM R	
Entry:	NOTICE OF SERVICE OF REQUEST FOR PRODUCTION DATE DOCKETED: JUNE 30, 2023 NOTICE OF SERVICE OF POLARIS PHARMACY SERVICES OF PENNSYLVANIA, LLC'S FIRST REQUEST FOR PRODUCTION OF DOCUMENTS DIRECTED TO DEFENDANT - SERVED VIA EMAIL ON JUNE 29, 2023 ACCEPTED BY: SR TRANSACTION ID: 70284205		
30-JUN-2023 01:37 PM	NOTICE SRV REQUEST PRODUCTION	FASIC, G. KEVIN	
Entry:	NOTICE OF SERVICE OF REQUEST FOR PRODUCTION DATE DOCKETED: JULY 2, 2023 NOTICE OF SERVICE FOR DEFENDANT'S REQUEST FOR FIRST SET OF INTERROGATORIES AND REQUESTS FOR PRODUCTION OF DOCUMENTS TO PLAINTIFF CERTIFICATE OF SERVICE TO NOTICE OF		

Search Home | New Search | Report Selection | Case Description
Related Cases | Event Schedule | Case Parties | Docket Entries

© 2019 Avenu Insights & Analytics, LLC. All rights reserved. Contexte and the accompanying logos are trademarks of Avenu Insights & Analytics, LLC in the United States and/or other countries. This material contains trade secrets and other confidential information and is subject to a confidentiality agreement. The unauthorized use, reproduction, distribution, display, or disclosure of this material or the information contained herein is prohibited. User Accepts/Agrees to Disclaimer. Not for official use.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4, 5, 6. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
03/19/2019	12/08/2021	MN	MINNEAPOLIS	RAMSEY
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
265679		MINNESOTA BOARD OF PHARMACY		
Reason/Charge				
PHARMACY WAS ALLOWING REMOTE ORDER ENTRY				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
PLEASE SEE ATTACHED			HEARING	
Name of Business/Industry/Entity				
POLARIS PHARMACY SERVICES OF MINNESOTA, LLC				

Provide explanation below:

CEO

Original Signature (electronic, copies or stamps not accepted)

9/11/24

Date

Challenges Polaris Faced in Minnesota

Polaris entered the Minnesota market in November 2018. The company operates only one pharmacy in Minnesota, which is located at 5220 Park Glen Road, St. Louis Park. Polaris' early experience in Minnesota was not without its challenges, but the company has made a good faith effort to address its challenges and is constantly looking to improve.

When Polaris entered the Minnesota market, it was surprised to find a labor market (particularly for pharmacy technicians) that was much tighter than other markets in which Polaris operates and experienced more staff turnover in Minnesota than it is accustomed to in other markets. The Covid-19 pandemic obviously put an incredible amount of stress on every stakeholder in the pharmacy industry, and Polaris was no exception. The pandemic made it even more difficult for Polaris to recruit, hire, and retain talented staff.

Polaris continues to believe it did not engage in central services by having Minnesota-licensed technicians located in Florida perform remote order entry tasks in connection with prescription orders filled in Minnesota. In letters to the Board dated July 19, 2019, Polaris explained why it began using Minnesota-licensed technicians based in Florida to assist Polaris Minnesota with order entry tasks.

In sum, during its initial months of operation, Polaris faced an unanticipated and unacceptable backlog of prescription orders that needed to be filled in Minnesota. The backlog resulted largely from Polaris' inability to recruit and retain enough capable pharmacy technicians in Minnesota during the early months of operation. To address the backlog and ensure the timely delivery of prescriptions to Minnesota patients, Polaris initially had Minnesota-licensed technicians based in Florida perform order entry services on behalf of Polaris Minnesota. These technicians were experienced technicians who were licensed in Minnesota before they performed order entry work for Polaris Minnesota. Further, while performing remote order entry work from a Polaris Florida location, these technicians were connected virtually to Polaris Minnesota's physical workspace through Polaris' FrameworkLTC software platform, which is commonly used across the long-term care pharmacy industry. At all times, the work of these technicians was overseen by a licensed pharmacist at the Florida pharmacy (where the data was entered into FrameworkLTC), as well as a Minnesota-licensed pharmacist in the Minnesota pharmacy, who ultimately controlled and was responsible for the technicians' work and any prescriptions filled in connection with data they entered into the system. Additionally, until May 2019, Polaris had IND Consulting and its "Team X" do some remote order entry work for Polaris Minnesota. Aside from the order entry function, Polaris Minnesota's prescription processing and filling functions have always taken place entirely in the Minnesota pharmacy. Polaris has at times relied on similar remote order entry processes in other states without triggering central service pharmacy requirements.

Accordingly, when Polaris started using this process to help deal with the Minnesota backlog, it did not anticipate that it might be triggering central services pharmacy requirements. For this reason, Polaris initially did not submit or seek approval from the Board for a central prescription drug processing policy or procedure. In March 2019, after Board staff expressed a

view that Polaris' use of Minnesota-licensed technicians based in Florida to perform remote entry work constituted an unauthorized central service arrangement, Polaris took immediate steps to address the issue. Polaris initially flew Minnesota-licensed technicians from Florida to Minnesota, so they could be physically present in the Polaris Minnesota pharmacy while performing the same order entry functions they had been performing in Florida.

Finally, Polaris sought Board approval of several remote order entry variances, with the goal of being authorized to resume using Minnesota-licensed technicians based in Florida to perform remote order entry for Polaris Minnesota, and particularly to deal with emergencies or backlogs. When Board staff initially raised this issue in March 2019, Polaris did not believe it could immediately shift all order entry functions to its limited staff in Minnesota without compromising patient safety and welfare. At the time, Polaris was still working through the backlog, onboarding new care facilities, and working hard to locate, hire, train, and retain technicians and other staff in Minnesota in a challenging labor market. Under the circumstances, Polaris determined it was necessary to continue using Minnesota licensed, Florida-based technicians for a period of time in order to deal with the backlog and continue filling prescriptions in a timely manner for patients who needed them, while simultaneously building up its Minnesota workforce and making the changes necessary to meet the expectations of Board staff. As soon as Polaris was staffed and equipped to perform all order entry functions in Minnesota, it stopped utilizing technicians who were not physically located in Minnesota altogether. Accordingly, from June 2019 to the present, Polaris has only used Minnesota-licensed technicians physically located in the Polaris Minnesota pharmacy to perform order entry work on prescription orders filled in Minnesota. Polaris took concerns raised by Board staff over remote order entry issues seriously, and it believes it acted reasonably under the circumstances to address those concerns, while also maintaining high levels of patient care.

Polaris remained committed to working cooperatively with the Board to better understand what it must do in order to utilize remote order entry processes in the future. Polaris would always attempt to rely on technicians physically located in its Minnesota pharmacy to perform data entry and other prescription filling functions. The Board acknowledged granting variance requests to many pharmacy chains and health-systems that authorize the use of remote order entry processes. In March 2020, the Board also issued Covid-19 related guidance acknowledging that pharmacists and technicians could perform various prescription drug filling functions while working remotely—including data entry of prescriptions and orders; verifying prescriptions; certifying data entry and the finished prescriptions (i.e., the product check); conducting profile and prospective drug utilization reviews; and stage-checking for compounding—so long as affiliated pharmacies were using adequate computer software and hardware for the tasks being performed. While the Board's Covid-19 guidance evolved after Governor Walz's Peacetime Emergency declaration was rescinded, Polaris continues to believe remote order entry processes like those implemented during the first few months of Polaris' operations in Minnesota were safe, effective, and should have a place in the delivery of modern pharmacy services.

The Board approved the central services variance #265679-010 on July 13, 2022 between Polaris Pharmacy Services of Minnesota, LLC and both the Polaris Pharmacies located in Tampa and Ft. Lauderdale Florida for urgent or emergent needs.

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Polaris Pharmacy Services of Minnesota, LLC
License No. 265679

STIPULATION AND CONSENT ORDER

STIPULATION

Polaris Pharmacy Services of Minnesota, LLC ("Licensee") and the Minnesota Board of Pharmacy Committee on Professional Standards ("Committee") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to license and regulate pharmacies and to take disciplinary action as appropriate.

2. Licensee holds a pharmacy license from the Board and is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On August 18, 2021, Licensee met with the Committee to discuss the allegations described in a Notice of Conference. Board members Kendra Metz and Stuart Williams comprised the Committee. The Board's Executive Director, Cody Wiberg; Deputy Director, Jennell Bilek; and staff attorney, Brian Park, were also present. Alex Mountain, Assistant Attorney General, represented the Committee. Brian A. Dillon, of Lathrop GPM LLP, represented licensee and was

accompanied by Licensee's Pharmacist-in-Charge, Neil Uitto; Polaris' Chief Operating Officer, Steven Baker; and Polaris' Executive Vice President of Operations, Todd Zisek.

III.

FACTS

4. On or about November 1, 2018, the Board licensed Licensee as a pharmacy in Minnesota.

5. Licensee is a closed door, long-term care ("LTC") pharmacy that prepares sterile and non-sterile compounded drug products for dispensing.

6. Licensee has two affiliated pharmacy locations in Florida, both licensed by the Board as follows:

a. On or about July 8, 2016, the Board issued Polaris Rx, located in Fort Lauderdale, Florida ("Pharmacy 1"), non-resident pharmacy license #265101.

b. On or about December 5, 2018, the Board issued Polaris Pharmacy Services of Tampa, located in Tampa, Florida ("Pharmacy 2"), non-resident pharmacy license #265721.

7. On or about March 19, 2019, two Board Surveyors visited Licensee for the purpose of completing a routine inspection, met with the pharmacist-in-charge, and identified the following:

a. Seven pharmacy technicians registered by the Board and employed by Pharmacy 1 and Pharmacy 2, were living in Florida but listed their current physical address as Licensee's address in Minnesota.

b. During the inspection, the Board Surveyors cited Licensee for engaging in central services with Pharmacy 1 and Pharmacy 2, by allowing pharmacy technicians working in Florida to remotely perform data entry of prescription drug information for Minnesota patients into

Licensee's Frameworks LTC prescription processing and dispensing software system ("FW-LTC"), followed by verification of the data entry by Licensee's pharmacist staff members working in Minnesota ("Central Service").

c. Prior to beginning Central Service, Licensee failed to submit a copy of its policy and procedure manual and failed to obtain Board approval to participate in a Central Service arrangement with Pharmacy 1 and Pharmacy 2.

d. Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the March 2019 citation.

e. Licensee's nonsterile compounding records failed to include an assigned beyond use date ("BUD") for the final compounded drug product, or included a BUD exceeding those recommended within United States Pharmacopeia, General Chapter 795 for Pharmaceutical Compounding - Nonsterile Preparations ("USP 795"), without documentation of a reference for literature or a stability study applicable to the specific drug product allowing for extension of the BUD. Licensee avers that it responded to these findings by providing education to its staff to ensure compounded components included lot numbers, expiration dates, and BUDs, along with noting the supporting reference sources. Licensee states that it Is not aware of any other issues regarding its compliance with BUD requirements since 2019.

8. On or about March 20, 2019, the Board received a complaint alleging that Licensee was utilizing pharmacy technicians from outside of Minnesota to enter prescription data. On or about April 9, 2019, a Board Surveyor reminded Licensee, after expanding its operations to 24-

hours, that pharmacy technicians working outside of its Minnesota location could not be used to help with covering the additional hours that the pharmacy is open, due to the lack of Board approved policies for Central Services with Pharmacy 1 and Pharmacy 2. As noted above, Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the Board's concern regarding the use of out-of-state technicians to enter prescription data.

9. On June 11, 2019, two Board Surveyors visited Licensee for the purpose of an investigation, met with representatives of the Licensee, and identified the following:

a. The pharmacist-in-charge stated that, as far as she was aware, Pharmacy 1 and Pharmacy 2, both located in Florida, were the only two locations providing Central Services for Licensee.

b. Licensee utilized a company named IND Consulting ("IND") for emergency kit ("E-kit") billing and entry of patient information when pharmacy services are initiated in a new LTC facility. IND's website states its staff are able to provide services including, but not limited to, billing services, medical record entry, and data entry solutions, with guaranteed staffing in fully operational data centers that are open 24 hours a day and 365 days a year, located within or outside of the United States across the globe in Mexico, India, the Philippines, and Florida. During the conference with the Committee, Licensee admitted that IND consulting had been used to enter prescription data for prescription drug orders ultimately dispensed by its

Minnesota pharmacy. Licensee cannot definitively state where individuals affiliated with IND were licensed or physically located when entering such data.

c. At the end of the visit, the Board Surveyor's provided an Investigative Report requesting additional information and reminding Licensee again that it cannot engage in Central Services without Board approval.

10. On February 12, 2020, two Board Surveyors visited Licensee for the purposes of an investigation, met with representatives of Licensee, and identified the following:

a. After arriving at 4:36 a.m., one of the Board Surveyors observed two of Licensee's pharmacy technicians were allowed badge access to the pharmacy entrance prior to the arrival of RPh 3 at around 5:55 a.m. One technician was found to be working in the sterile compounding area and another was logged into Licensee's computer. A representative of Licensee later stated that three pharmacy technicians had been given keys and passcodes to access Licensee's pharmacy. During its conference with the Committee, Licensee admitted that this allegation is true, but stated that senior management took corrective action upon learning of the situation, including immediately revoking the access code of all non-pharmacists and physically rekeying all doors within the pharmacy. Licensees avers that periodic security assessments confirm that no unauthorized persons have had access to the pharmacy since February 2020.

b. Six pharmacy technicians, including the IV pharmacy technician, were present in the "filling area" with only one pharmacist, who was the second pharmacist to arrive. Another pharmacist was in an "order entry" area, a distinctly different area separated by a wall and door. The Board Surveyors were told that additional pharmacy technicians were scheduled that morning to perform non-technician "staging or stocking" duties. However, the Board Surveyors observed that the additional pharmacy technicians that were supposedly scheduled to perform non-technician duties, were filling orders in the "filling area" to be checked by the one pharmacist.

Licensee avers that is does not have sufficient information to admit or deny the Board surveyors' observations, but that company policy requires compliance with required technician-to-pharmacist ratios.

IV.

LAWS

11. Licensee acknowledges the conduct described in section III above constitutes a violation of Minn. Stat. § 151.071, subd. 2(7), and warrants the disciplinary action described below.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

12. The Board **REPRIMANDS** Licensee and imposes a **CIVIL PENALTY** in the amount of $50,000 for the conduct described in section III above. The civil penalty shall be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of entry of this Order.

13. The Board places the following **CONDITION** on Licensee's License: every six months, for a period of three years, Licensee's CEO must certify to the Board's Executive Director that Licensee's licensed pharmacies that provide services to Minnesota residents are in full compliance with all applicable Minnesota statutes and rules.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

14. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Committee may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Committee shall schedule a hearing before the Board. At least 20 days before the hearing, the Committee must mail Licensee a notice of the violation(s) alleged by the Committee. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee shall submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Committee, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Committee and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Committee and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Committee will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations, but may present argument concerning the appropriateness of additional discipline. Pursuant to this process, Licensee waives a hearing before an administrative law judge, discovery, cross-examination of

adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but does not limit the Board's authority to impose discipline for the violation. A decision by the Committee not to seek discipline when it first learns of a violation does not waive the Committee's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's license is in a suspended status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's license, a period of suspension, conditions of reinstatement, or revocation of Licensee's license.

f. Nothing herein limits the Committee's or the Board's right to temporarily suspend Licensee's license as provided in Minnesota Statutes chapters 151 and 214, based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII. ADDITIONAL INFORMATION

15. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

16. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the

investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

17. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter shall constitute the entire record and may be reviewed by the Board in its consideration of this matter.

18. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

19. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

20. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it. If the Board rejects this Stipulation and Consent Order, the parties agree that this Stipulation and Consent Order will not be admissible in any proceedings.

21. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis

of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action, and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

22. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed health professional, and as such, is classified as confidential data pursuant to Minnesota Statutes section 13.41, subdivision 4.

23. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

POLARIS PHARMACY SERVICES OF MINNESOTA, LLC (LICENSEE)

Dated: 12-3-2021

MINNESOTA BOARD OF PHARMACY
COMMITTEE ON PROFESSIONAL STANDARDS

BOARD MEMBER

Dated: 12/8/21

ORDER

Upon consideration of the Stipulation, the Board **REPRIMANDS** Licensee, imposes a **CIVIL PENALTY**, and **CONDITIONS** Licensee's license and adopts all of the terms described above on this 8TH day of December, 2021.

MINNESOTA BOARD OF PHARMACY

CODY WIBERG
Executive Director

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Rombro

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/11/24

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/11/24

Date

Subscribed and Sworn to before me this 11 day of Sep 2024.

Notary Public Signature

IVOR STEWART
Notary Public - State of Florida
Commission # HH 339460
My Comm. Expires Apr 2, 2027
Bonded through National Notary Assn.

(Seal)

David Rombro

2900 NW 60th St., Fort Lauderdale, FL 33309
Phone: 561-212-5728 • Email: drombro@polarisrx.com

C-Level Senior Executive

Results-driven, highly accomplished senior level operational professional with the demonstrated ability to streamline business operations, execute solid decision-making that drives growth and increases efficiency while developing talent that improves customer relations that increases the bottom line within multi-billion dollar and small business organizations.

Professional Experience

Polaris Pharmacy Services, LLC.

Chief Executive Officer and Member, (2015 - present)

Overall leadership and vision for of the business.

Selected Achievements:

- Successfully led a startup in 2015 to an $800 million dollar company in 2023.
- Leveraged experience and team members to become the 6th largest long term care pharmacy in the US.

Omnicare, Inc., Cincinnati, OH
General Manager – Weston, Florida (2009-2014)

Selected Achievements:

- Led the largest pharmacy in Florida with over 21,000 licensed beds.

First Choice Pharmacy, Hollywood, Florida
Chief Executive Officer and Owner (2005-2009)

Selected Achievements:

- Led the pharmacy from start up to 7500 licensed beds and eventually sold to Omnicare.

Education

Bachelor of Science, Pharmacy, University of Maryland

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site OWL SPECIALTY PHARMACY

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 1010 E ARROW HWY

City COVINA State CA Zip 91724

Mailing Address (if different from physical address) SAME AS PHYSICAL ADDRESS

City _____ State _____ Zip _____

Telephone 626-209-8171 Website WWW.OWLSPECIALTY.COM

Licensing Company Email GHUNT@POLARISRX.COM

Section 2: Personal Information

First STEVEN Middle _____ Last BAKER

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex [redacted]

Mailing Address [redacted] NW 60TH STREET

City FORT LAUDERDALE State FL Zip 33309

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
VCU SCHOOL OF PHARMACY		08/89 - 06/92	
Address	**City**	**State**	**Zip**
410 NORTH 12TH STREET	RICHMOND	VA	23298
Diploma/Degree obtained, if any			
BS PHARMACY			

School Name		From - To (MM/YY – MM/YY)	
SOUTHWEST VIRGINIA COMMUNITY COLLEGE		08/87 - 06/89	
Address	**City**	**State**	**Zip**
635 COMMUNITY COLLEGE ROAD	CEDAR BLUFF	VA	24609
Diploma/Degree obtained, if any			
ASSOCIATES DEGREE			

School Name		From - To (MM/YY – MM/YY)	
RICHLANDS HIGH SCHOOL		08/83 - 06/87	
Address	**City**	**State**	**Zip**
138 TORNADO ALLEY	RICHLANDS	VA	28574
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/22 - CURRENT	[redacted]N OCEAN BLVD, UNIT 1707	POMPANO BEACH	FL	33062
02/20 - 02/22	[redacted]SE 2ND AVE, UNIT 416	DELRAY BEACH	FL	33443
02/19 - 02/20	[redacted]NE 5TH AVE, UNIT 214	DELRAY BEACH	FL	33483
02/18 - 02/19	[redacted]W CAMINO REAL	BOCA RATON	FL	33486
02/16 - 02/18	[redacted]PORT ROYALE DR. S	FORT LAUDERDALE	FL	33308
02/14 - 02/16	[redacted]SE 5TH AVE	FORT LAUDERDALE	FL	33301
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
POLARIS PHARMACY SERVICES			11/15 - CURRENT
Business Address	**City**	**State**	**Zip**
2900 NW 60TH STREET	FORT LAUDERDALE	FL	33309
Phone	**Title**		
954-919-1818	COO		
Description of Duties			
OVER SEE DAY-TO-DAY OPERATIONS OF PHARMACIES AND CUSTOMER RETENTION.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

STEVEN BAKER

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/11/2024

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/11/2024

Date

Subscribed and Sworn to before me this 11 day of Sep 2024.

Notary Public Signature

IVOR STEWART
Notary Public - State of Florida
Commission # HH 339460
My Comm. Expires Apr 2, 2027
Bonded through National Notary Assn.

(Seal)

Challenges Polaris Faced in Minnesota

Polaris entered the Minnesota market in November 2018. The company operates only one pharmacy in Minnesota, which is located at 5220 Park Glen Road, St. Louis Park. Polaris' early experience in Minnesota was not without its challenges, but the company has made a good faith effort to address its challenges and is constantly looking to improve.

When Polaris entered the Minnesota market, it was surprised to find a labor market (particularly for pharmacy technicians) that was much tighter than other markets in which Polaris operates and experienced more staff turnover in Minnesota than it is accustomed to in other markets. The Covid-19 pandemic obviously put an incredible amount of stress on every stakeholder in the pharmacy industry, and Polaris was no exception. The pandemic made it even more difficult for Polaris to recruit, hire, and retain talented staff.

Polaris continues to believe it did not engage in central services by having Minnesota-licensed technicians located in Florida perform remote order entry tasks in connection with prescription orders filled in Minnesota. In letters to the Board dated July 19, 2019, Polaris explained why it began using Minnesota-licensed technicians based in Florida to assist Polaris Minnesota with order entry tasks.

In sum, during its initial months of operation, Polaris faced an unanticipated and unacceptable backlog of prescription orders that needed to be filled in Minnesota. The backlog resulted largely from Polaris' inability to recruit and retain enough capable pharmacy technicians in Minnesota during the early months of operation. To address the backlog and ensure the timely delivery of prescriptions to Minnesota patients, Polaris initially had Minnesota-licensed technicians based in Florida perform order entry services on behalf of Polaris Minnesota. These technicians were experienced technicians who were licensed in Minnesota before they performed order entry work for Polaris Minnesota. Further, while performing remote order entry work from a Polaris Florida location, these technicians were connected virtually to Polaris Minnesota's physical workspace through Polaris' FrameworkLTC software platform, which is commonly used across the long-term care pharmacy industry. At all times, the work of these technicians was overseen by a licensed pharmacist at the Florida pharmacy (where the data was entered into FrameworkLTC), as well as a Minnesota-licensed pharmacist in the Minnesota pharmacy, who ultimately controlled and was responsible for the technicians' work and any prescriptions filled in connection with data they entered into the system. Additionally, until May 2019, Polaris had IND Consulting and its "Team X" do some remote order entry work for Polaris Minnesota. Aside from the order entry function, Polaris Minnesota's prescription processing and filling functions have always taken place entirely in the Minnesota pharmacy. Polaris has at times relied on similar remote order entry processes in other states without triggering central service pharmacy requirements.

Accordingly, when Polaris started using this process to help deal with the Minnesota backlog, it did not anticipate that it might be triggering central services pharmacy requirements. For this reason, Polaris initially did not submit or seek approval from the Board for a central prescription drug processing policy or procedure. In March 2019, after Board staff expressed a

view that Polaris' use of Minnesota-licensed technicians based in Florida to perform remote entry work constituted an unauthorized central service arrangement, Polaris took immediate steps to address the issue. Polaris initially flew Minnesota-licensed technicians from Florida to Minnesota, so they could be physically present in the Polaris Minnesota pharmacy while performing the same order entry functions they had been performing in Florida.

Finally, Polaris sought Board approval of several remote order entry variances, with the goal of being authorized to resume using Minnesota-licensed technicians based in Florida to perform remote order entry for Polaris Minnesota, and particularly to deal with emergencies or backlogs. When Board staff initially raised this issue in March 2019, Polaris did not believe it could immediately shift all order entry functions to its limited staff in Minnesota without compromising patient safety and welfare. At the time, Polaris was still working through the backlog, onboarding new care facilities, and working hard to locate, hire, train, and retain technicians and other staff in Minnesota in a challenging labor market. Under the circumstances, Polaris determined it was necessary to continue using Minnesota licensed, Florida-based technicians for a period of time in order to deal with the backlog and continue filling prescriptions in a timely manner for patients who needed them, while simultaneously building up its Minnesota workforce and making the changes necessary to meet the expectations of Board staff. As soon as Polaris was staffed and equipped to perform all order entry functions in Minnesota, it stopped utilizing technicians who were not physically located in Minnesota altogether. Accordingly, from June 2019 to the present, Polaris has only used Minnesota-licensed technicians physically located in the Polaris Minnesota pharmacy to perform order entry work on prescription orders filled in Minnesota. Polaris took concerns raised by Board staff over remote order entry issues seriously, and it believes it acted reasonably under the circumstances to address those concerns, while also maintaining high levels of patient care.

Polaris remained committed to working cooperatively with the Board to better understand what it must do in order to utilize remote order entry processes in the future. Polaris would always attempt to rely on technicians physically located in its Minnesota pharmacy to perform data entry and other prescription filling functions. The Board acknowledged granting variance requests to many pharmacy chains and health-systems that authorize the use of remote order entry processes. In March 2020, the Board also issued Covid-19 related guidance acknowledging that pharmacists and technicians could perform various prescription drug filling functions while working remotely—including data entry of prescriptions and orders; verifying prescriptions; certifying data entry and the finished prescriptions (i.e., the product check); conducting profile and prospective drug utilization reviews; and stage-checking for compounding—so long as affiliated pharmacies were using adequate computer software and hardware for the tasks being performed. While the Board's Covid-19 guidance evolved after Governor Walz's Peacetime Emergency declaration was rescinded, Polaris continues to believe remote order entry processes like those implemented during the first few months of Polaris' operations in Minnesota were safe, effective, and should have a place in the delivery of modern pharmacy services.

The Board approved the central services variance #265679-010 on July 13, 2022 between Polaris Pharmacy Services of Minnesota, LLC and both the Polaris Pharmacies located in Tampa and Ft. Lauderdale Florida for urgent or emergent needs.

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Polaris Pharmacy Services of Minnesota, LLC
License No. 265679

STIPULATION AND CONSENT ORDER

STIPULATION

Polaris Pharmacy Services of Minnesota, LLC ("Licensee") and the Minnesota Board of Pharmacy Committee on Professional Standards ("Committee") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to license and regulate pharmacies and to take disciplinary action as appropriate.

2. Licensee holds a pharmacy license from the Board and is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On August 18, 2021, Licensee met with the Committee to discuss the allegations described in a Notice of Conference. Board members Kendra Metz and Stuart Williams comprised the Committee. The Board's Executive Director, Cody Wiberg; Deputy Director, Jennell Bilek; and staff attorney, Brian Park, were also present. Alex Mountain, Assistant Attorney General, represented the Committee. Brian A. Dillon, of Lathrop GPM LLP, represented licensee and was

accompanied by Licensee's Pharmacist-in-Charge, Neil Uitto; Polaris' Chief Operating Officer, Steven Baker; and Polaris' Executive Vice President of Operations, Todd Zisek.

III.

FACTS

4. On or about November 1, 2018, the Board licensed Licensee as a pharmacy in Minnesota.

5. Licensee is a closed door, long-term care ("LTC") pharmacy that prepares sterile and non-sterile compounded drug products for dispensing.

6. Licensee has two affiliated pharmacy locations in Florida, both licensed by the Board as follows:

a. On or about July 8, 2016, the Board issued Polaris Rx, located in Fort Lauderdale, Florida ("Pharmacy 1"), non-resident pharmacy license #265101.

b. On or about December 5, 2018, the Board issued Polaris Pharmacy Services of Tampa, located in Tampa, Florida ("Pharmacy 2"), non-resident pharmacy license #265721.

7. On or about March 19, 2019, two Board Surveyors visited Licensee for the purpose of completing a routine inspection, met with the pharmacist-in-charge, and identified the following:

a. Seven pharmacy technicians registered by the Board and employed by Pharmacy 1 and Pharmacy 2, were living in Florida but listed their current physical address as Licensee's address in Minnesota.

b. During the inspection, the Board Surveyors cited Licensee for engaging in central services with Pharmacy 1 and Pharmacy 2, by allowing pharmacy technicians working in Florida to remotely perform data entry of prescription drug information for Minnesota patients into

Licensee's Frameworks LTC prescription processing and dispensing software system ("FW-LTC"), followed by verification of the data entry by Licensee's pharmacist staff members working in Minnesota ("Central Service").

c. Prior to beginning Central Service, Licensee failed to submit a copy of its policy and procedure manual and failed to obtain Board approval to participate in a Central Service arrangement with Pharmacy 1 and Pharmacy 2.

d. Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the March 2019 citation.

e. Licensee's nonsterile compounding records failed to include an assigned beyond use date ("BUD") for the final compounded drug product, or included a BUD exceeding those recommended within United States Pharmacopeia, General Chapter 795 for Pharmaceutical Compounding - Nonsterile Preparations ("USP 795"), without documentation of a reference for literature or a stability study applicable to the specific drug product allowing for extension of the BUD. Licensee avers that it responded to these findings by providing education to its staff to ensure compounded components included lot numbers, expiration dates, and BUDs, along with noting the supporting reference sources. Licensee states that it is not aware of any other issues regarding its compliance with BUD requirements since 2019.

8. On or about March 20, 2019, the Board received a complaint alleging that Licensee was utilizing pharmacy technicians from outside of Minnesota to enter prescription data. On or about April 9, 2019, a Board Surveyor reminded Licensee, after expanding its operations to 24-

hours, that pharmacy technicians working outside of its Minnesota location could not be used to help with covering the additional hours that the pharmacy is open, due to the lack of Board approved policies for Central Services with Pharmacy 1 and Pharmacy 2. As noted above, Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the Board's concern regarding the use of out-of-state technicians to enter prescription data.

9. On June 11, 2019, two Board Surveyors visited Licensee for the purpose of an investigation, met with representatives of the Licensee, and identified the following:

a. The pharmacist-in-charge stated that, as far as she was aware, Pharmacy 1 and Pharmacy 2, both located in Florida, were the only two locations providing Central Services for Licensee.

b. Licensee utilized a company named IND Consulting ("IND") for emergency kit ("E-kit") billing and entry of patient information when pharmacy services are initiated in a new LTC facility. IND's website states its staff are able to provide services including, but not limited to, billing services, medical record entry, and data entry solutions, with guaranteed staffing in fully operational data centers that are open 24 hours a day and 365 days a year, located within or outside of the United States across the globe in Mexico, India, the Philippines, and Florida. During the conference with the Committee, Licensee admitted that IND consulting had been used to enter prescription data for prescription drug orders ultimately dispensed by its

Minnesota pharmacy. Licensee cannot definitively state where individuals affiliated with IND were licensed or physically located when entering such data.

c. At the end of the visit, the Board Surveyor's provided an Investigative Report requesting additional information and reminding Licensee again that it cannot engage in Central Services without Board approval.

10. On February 12, 2020, two Board Surveyors visited Licensee for the purposes of an investigation, met with representatives of Licensee, and identified the following:

a. After arriving at 4:36 a.m., one of the Board Surveyors observed two of Licensee's pharmacy technicians were allowed badge access to the pharmacy entrance prior to the arrival of RPh 3 at around 5:55 a.m. One technician was found to be working in the sterile compounding area and another was logged into Licensee's computer. A representative of Licensee later stated that three pharmacy technicians had been given keys and passcodes to access Licensee's pharmacy. During its conference with the Committee, Licensee admitted that this allegation is true, but stated that senior management took corrective action upon learning of the situation, including immediately revoking the access code of all non-pharmacists and physically rekeying all doors within the pharmacy. Licensees avers that periodic security assessments confirm that no unauthorized persons have had access to the pharmacy since February 2020.

b. Six pharmacy technicians, including the IV pharmacy technician, were present in the "filling area" with only one pharmacist, who was the second pharmacist to arrive. Another pharmacist was in an "order entry" area, a distinctly different area separated by a wall and door. The Board Surveyors were told that additional pharmacy technicians were scheduled that morning to perform non-technician "staging or stocking" duties. However, the Board Surveyors observed that the additional pharmacy technicians that were supposedly scheduled to perform non-technician duties, were filling orders in the "filling area" to be checked by the one pharmacist.

Licensee avers that is does not have sufficient information to admit or deny the Board surveyors' observations, but that company policy requires compliance with required technician-to-pharmacist ratios.

IV.

LAWS

11. Licensee acknowledges the conduct described in section III above constitutes a violation of Minn. Stat. § 151.071, subd. 2(7), and warrants the disciplinary action described below.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

12. The Board **REPRIMANDS** Licensee and imposes a **CIVIL PENALTY** in the amount of $50,000 for the conduct described in section III above. The civil penalty shall be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of entry of this Order.

13. The Board places the following **CONDITION** on Licensee's License: every six months, for a period of three years, Licensee's CEO must certify to the Board's Executive Director that Licensee's licensed pharmacies that provide services to Minnesota residents are in full compliance with all applicable Minnesota statutes and rules.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

14. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Committee may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Committee shall schedule a hearing before the Board. At least 20 days before the hearing, the Committee must mail Licensee a notice of the violation(s) alleged by the Committee. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee shall submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Committee, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Committee and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Committee and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Committee will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations, but may present argument concerning the appropriateness of additional discipline. Pursuant to this process, Licensee waives a hearing before an administrative law judge, discovery, cross-examination of

adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but does not limit the Board's authority to impose discipline for the violation. A decision by the Committee not to seek discipline when it first learns of a violation does not waive the Committee's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's license is in a suspended status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's license, a period of suspension, conditions of reinstatement, or revocation of Licensee's license.

f. Nothing herein limits the Committee's or the Board's right to temporarily suspend Licensee's license as provided in Minnesota Statutes chapters 151 and 214, based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII. ADDITIONAL INFORMATION

15. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

16. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the

investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

17. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter shall constitute the entire record and may be reviewed by the Board in its consideration of this matter.

18. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

19. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

20. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it. If the Board rejects this Stipulation and Consent Order, the parties agree that this Stipulation and Consent Order will not be admissible in any proceedings.

21. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis

of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action, and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

22. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed health professional, and as such, is classified as confidential data pursuant to Minnesota Statutes section 13.41, subdivision 4.

23. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

POLARIS PHARMACY SERVICES OF MINNESOTA, LLC (LICENSEE)

Dated: 12-3-2021

MINNESOTA BOARD OF PHARMACY
COMMITTEE ON PROFESSIONAL STANDARDS

BOARD MEMBER

Dated: 12/8/21

ORDER

Upon consideration of the Stipulation, the Board **REPRIMANDS** Licensee, imposes a **CIVIL PENALTY**, and **CONDITIONS** Licensee's license and adopts all of the terms described above on this 8TH day of December, 2021.

MINNESOTA BOARD OF PHARMACY

CODY WIBERG
Executive Director

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site OWL SPECIALTY PHARMACY

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 1010 E ARROW HWY

City COVINA State CA Zip 91724

Mailing Address (if different from physical address) SAME AS PHYSICAL ADDRESS

City _____ State _____ Zip _____

Telephone 626-209-8169 Website WWW.OWLSPECIALTY.COM

Licensing Company Email GHUNT@POLARISRX.COM

Section 2: Personal Information

First ROBERT Middle _____ Last MEYER

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]NW 60TH STREET

City FORT LAUDERDALE State FL Zip 33309

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF CINCINNATI		1988-1993	
Address	**City**	**State**	**Zip**
2600 CLIFTON AVE	CINCINNATI	OH	45221
Diploma/Degree obtained, if any			
B.S. IN ACCOUNTING, B.S. IN REAL ESTATE			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
	[redacted]N OCEAN BLVD, UNIT 515	POMPANO BEACH	FL	33062
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years:

Business Name			From - To (MM/YY – MM/YY)	
POLARIS PHARMACY SERVICES			2019 - CURRENT	
Business Address		**City**	**State**	**Zip**
2900 NW 60TH STREET		FORT LAUDERDALE	FL	33309
Phone	**Title**			
800-589-9747	CFO			
Description of Duties				
OVERSEE FINANCIAL REPORTING, PLANNING (BUDGETING), TREASURY AND CAPITAL STRUCTURE.				

Business Name			From - To (MM/YY – MM/YY)	
WELLFOUNT PHARMACY			2015 - 2019	
Business Address		**City**	**State**	**Zip**
5751 W 73RD ST		INDIANAPOLIS	IN	46278
Phone	**Title**			
	CFO AND PRESIDENT, LTC DIVISION			
Description of Duties				
DIRECT A TEAM ENCOMPASSING CONTROLLERSHIP, BUSINESS OPERATIONS, DECISON SUPPORT, FINANCIAL PLANNING AND ANALYSIS, SALES REPORTING, REAL ESTATE, BUSINESS SYSTEMS, AND HR.				

Business Name			From - To (MM/YY – MM/YY)	
ORIONRX, LLC			2014 - 2015	
Business Address		**City**	**State**	**Zip**
13100 MAGISTERIAL DRIVE, SUITE 102		PRESIDENT & CFO	KY	
Phone	**Title**			
502-213-8444	PRESIDENT & CFO			
Description of Duties				
EVALUATED AREA OPERATIONS TO IDENTIFY OPPORTUNITIES FOR DECREASED EXPENSES, IMPLEMENT PLANS FOR OPERATIONAL INFRASTRUCTURE OF SYSTEMS, PROCESSES, AND PERSONNEL.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4, 5, 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
03/19/2019	12/08/2021	MN	MINNEAPOLIS	RAMSEY
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
265679		MINNESOTA BOARD OF PHARMACY		
Reason/Charge				
PHARMACY WAS ALLOWING REMOTE ORDER ENTRY.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
PLEASE SEE ATTACHED.			HEARING	
Name of Business/Industry/Entity				
POLARIS SPECIALTY SERVICES OF MINNESOTA, LLC				

Provide explanation below:

PLEASE SEE ATTACHED.

Original Signature (electronic, copies or stamps not accepted)

9/11/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Meyer

Print Name (First, Last)

Robert Meyer

Original Signature (electronic, copies or stamps not accepted)

9/11/24

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Robert Meyer

Original Signature

9/11/24

Date

Subscribed and Sworn to before me this 11 day of Sep 2024.

Notary Public Signature

IVOR STEWART
Notary Public - State of Florida
Commission # HH 339460
My Comm. Expires Apr 2, 2027
Bonded through National Notary Assn.

(Seal)

Challenges Polaris Faced in Minnesota

Polaris entered the Minnesota market in November 2018. The company operates only one pharmacy in Minnesota, which is located at 5220 Park Glen Road, St. Louis Park. Polaris' early experience in Minnesota was not without its challenges, but the company has made a good faith effort to address its challenges and is constantly looking to improve.

When Polaris entered the Minnesota market, it was surprised to find a labor market (particularly for pharmacy technicians) that was much tighter than other markets in which Polaris operates and experienced more staff turnover in Minnesota than it is accustomed to in other markets. The Covid-19 pandemic obviously put an incredible amount of stress on every stakeholder in the pharmacy industry, and Polaris was no exception. The pandemic made it even more difficult for Polaris to recruit, hire, and retain talented staff.

Polaris continues to believe it did not engage in central services by having Minnesota-licensed technicians located in Florida perform remote order entry tasks in connection with prescription orders filled in Minnesota. In letters to the Board dated July 19, 2019, Polaris explained why it began using Minnesota-licensed technicians based in Florida to assist Polaris Minnesota with order entry tasks.

In sum, during its initial months of operation, Polaris faced an unanticipated and unacceptable backlog of prescription orders that needed to be filled in Minnesota. The backlog resulted largely from Polaris' inability to recruit and retain enough capable pharmacy technicians in Minnesota during the early months of operation. To address the backlog and ensure the timely delivery of prescriptions to Minnesota patients, Polaris initially had Minnesota-licensed technicians based in Florida perform order entry services on behalf of Polaris Minnesota. These technicians were experienced technicians who were licensed in Minnesota before they performed order entry work for Polaris Minnesota. Further, while performing remote order entry work from a Polaris Florida location, these technicians were connected virtually to Polaris Minnesota's physical workspace through Polaris' FrameworkLTC software platform, which is commonly used across the long-term care pharmacy industry. At all times, the work of these technicians was overseen by a licensed pharmacist at the Florida pharmacy (where the data was entered into FrameworkLTC), as well as a Minnesota-licensed pharmacist in the Minnesota pharmacy, who ultimately controlled and was responsible for the technicians' work and any prescriptions filled in connection with data they entered into the system. Additionally, until May 2019, Polaris had IND Consulting and its "Team X" do some remote order entry work for Polaris Minnesota. Aside from the order entry function, Polaris Minnesota's prescription processing and filling functions have always taken place entirely in the Minnesota pharmacy. Polaris has at times relied on similar remote order entry processes in other states without triggering central service pharmacy requirements.

Accordingly, when Polaris started using this process to help deal with the Minnesota backlog, it did not anticipate that it might be triggering central services pharmacy requirements. For this reason, Polaris initially did not submit or seek approval from the Board for a central prescription drug processing policy or procedure. In March 2019, after Board staff expressed a

view that Polaris' use of Minnesota-licensed technicians based in Florida to perform remote entry work constituted an unauthorized central service arrangement, Polaris took immediate steps to address the issue. Polaris initially flew Minnesota-licensed technicians from Florida to Minnesota, so they could be physically present in the Polaris Minnesota pharmacy while performing the same order entry functions they had been performing in Florida.

Finally, Polaris sought Board approval of several remote order entry variances, with the goal of being authorized to resume using Minnesota-licensed technicians based in Florida to perform remote order entry for Polaris Minnesota, and particularly to deal with emergencies or backlogs. When Board staff initially raised this issue in March 2019, Polaris did not believe it could immediately shift all order entry functions to its limited staff in Minnesota without compromising patient safety and welfare. At the time, Polaris was still working through the backlog, onboarding new care facilities, and working hard to locate, hire, train, and retain technicians and other staff in Minnesota in a challenging labor market. Under the circumstances, Polaris determined it was necessary to continue using Minnesota licensed, Florida-based technicians for a period of time in order to deal with the backlog and continue filling prescriptions in a timely manner for patients who needed them, while simultaneously building up its Minnesota workforce and making the changes necessary to meet the expectations of Board staff. As soon as Polaris was staffed and equipped to perform all order entry functions in Minnesota, it stopped utilizing technicians who were not physically located in Minnesota altogether. Accordingly, from June 2019 to the present, Polaris has only used Minnesota-licensed technicians physically located in the Polaris Minnesota pharmacy to perform order entry work on prescription orders filled in Minnesota. Polaris took concerns raised by Board staff over remote order entry issues seriously, and it believes it acted reasonably under the circumstances to address those concerns, while also maintaining high levels of patient care.

Polaris remained committed to working cooperatively with the Board to better understand what it must do in order to utilize remote order entry processes in the future. Polaris would always attempt to rely on technicians physically located in its Minnesota pharmacy to perform data entry and other prescription filling functions. The Board acknowledged granting variance requests to many pharmacy chains and health-systems that authorize the use of remote order entry processes. In March 2020, the Board also issued Covid-19 related guidance acknowledging that pharmacists and technicians could perform various prescription drug filling functions while working remotely—including data entry of prescriptions and orders; verifying prescriptions; certifying data entry and the finished prescriptions (i.e., the product check); conducting profile and prospective drug utilization reviews; and stage-checking for compounding—so long as affiliated pharmacies were using adequate computer software and hardware for the tasks being performed. While the Board's Covid-19 guidance evolved after Governor Walz's Peacetime Emergency declaration was rescinded, Polaris continues to believe remote order entry processes like those implemented during the first few months of Polaris' operations in Minnesota were safe, effective, and should have a place in the delivery of modern pharmacy services.

The Board approved the central services variance #265679-010 on July 13, 2022 between Polaris Pharmacy Services of Minnesota, LLC and both the Polaris Pharmacies located in Tampa and Ft. Lauderdale Florida for urgent or emergent needs.

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of Polaris Pharmacy Services of Minnesota, LLC License No. 265679	STIPULATION AND CONSENT ORDER

STIPULATION

Polaris Pharmacy Services of Minnesota, LLC ("Licensee") and the Minnesota Board of Pharmacy Committee on Professional Standards ("Committee") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to license and regulate pharmacies and to take disciplinary action as appropriate.

2. Licensee holds a pharmacy license from the Board and is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On August 18, 2021, Licensee met with the Committee to discuss the allegations described in a Notice of Conference. Board members Kendra Metz and Stuart Williams comprised the Committee. The Board's Executive Director, Cody Wiberg; Deputy Director, Jennell Bilek; and staff attorney, Brian Park, were also present. Alex Mountain, Assistant Attorney General, represented the Committee. Brian A. Dillon, of Lathrop GPM LLP, represented licensee and was

accompanied by Licensee's Pharmacist-in-Charge, Neil Uitto; Polaris' Chief Operating Officer, Steven Baker; and Polaris' Executive Vice President of Operations, Todd Zisek.

III.

FACTS

4. On or about November 1, 2018, the Board licensed Licensee as a pharmacy in Minnesota.

5. Licensee is a closed door, long-term care ("LTC") pharmacy that prepares sterile and non-sterile compounded drug products for dispensing.

6. Licensee has two affiliated pharmacy locations in Florida, both licensed by the Board as follows:

a. On or about July 8, 2016, the Board issued Polaris Rx, located in Fort Lauderdale, Florida ("Pharmacy 1"), non-resident pharmacy license #265101.

b. On or about December 5, 2018, the Board issued Polaris Pharmacy Services of Tampa, located in Tampa, Florida ("Pharmacy 2"), non-resident pharmacy license #265721.

7. On or about March 19, 2019, two Board Surveyors visited Licensee for the purpose of completing a routine inspection, met with the pharmacist-in-charge, and identified the following:

a. Seven pharmacy technicians registered by the Board and employed by Pharmacy 1 and Pharmacy 2, were living in Florida but listed their current physical address as Licensee's address in Minnesota.

b. During the inspection, the Board Surveyors cited Licensee for engaging in central services with Pharmacy 1 and Pharmacy 2, by allowing pharmacy technicians working in Florida to remotely perform data entry of prescription drug information for Minnesota patients into

Licensee's Frameworks LTC prescription processing and dispensing software system ("FW-LTC"), followed by verification of the data entry by Licensee's pharmacist staff members working in Minnesota ("Central Service").

c. Prior to beginning Central Service, Licensee failed to submit a copy of its policy and procedure manual and failed to obtain Board approval to participate in a Central Service arrangement with Pharmacy 1 and Pharmacy 2.

d. Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the March 2019 citation.

e. Licensee's nonsterile compounding records failed to include an assigned beyond use date ("BUD") for the final compounded drug product, or included a BUD exceeding those recommended within United States Pharmacopeia, General Chapter 795 for Pharmaceutical Compounding - Nonsterile Preparations ("USP 795"), without documentation of a reference for literature or a stability study applicable to the specific drug product allowing for extension of the BUD. Licensee avers that it responded to these findings by providing education to its staff to ensure compounded components included lot numbers, expiration dates, and BUDs, along with noting the supporting reference sources. Licensee states that it is not aware of any other issues regarding its compliance with BUD requirements since 2019.

8. On or about March 20, 2019, the Board received a complaint alleging that Licensee was utilizing pharmacy technicians from outside of Minnesota to enter prescription data. On or about April 9, 2019, a Board Surveyor reminded Licensee, after expanding its operations to 24-

hours, that pharmacy technicians working outside of its Minnesota location could not be used to help with covering the additional hours that the pharmacy is open, due to the lack of Board approved policies for Central Services with Pharmacy 1 and Pharmacy 2. As noted above, Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the Board's concern regarding the use of out-of-state technicians to enter prescription data.

9. On June 11, 2019, two Board Surveyors visited Licensee for the purpose of an investigation, met with representatives of the Licensee, and identified the following:

a. The pharmacist-in-charge stated that, as far as she was aware, Pharmacy 1 and Pharmacy 2, both located in Florida, were the only two locations providing Central Services for Licensee.

b. Licensee utilized a company named IND Consulting ("IND") for emergency kit ("E-kit") billing and entry of patient information when pharmacy services are initiated in a new LTC facility. IND's website states its staff are able to provide services including, but not limited to, billing services, medical record entry, and data entry solutions, with guaranteed staffing in fully operational data centers that are open 24 hours a day and 365 days a year, located within or outside of the United States across the globe in Mexico, India, the Philippines, and Florida. During the conference with the Committee, Licensee admitted that IND consulting had been used to enter prescription data for prescription drug orders ultimately dispensed by its

Minnesota pharmacy. Licensee cannot definitively state where individuals affiliated with IND were licensed or physically located when entering such data.

c. At the end of the visit, the Board Surveyor's provided an Investigative Report requesting additional information and reminding Licensee again that it cannot engage in Central Services without Board approval.

10. On February 12, 2020, two Board Surveyors visited Licensee for the purposes of an investigation, met with representatives of Licensee, and identified the following:

a. After arriving at 4:36 a.m., one of the Board Surveyors observed two of Licensee's pharmacy technicians were allowed badge access to the pharmacy entrance prior to the arrival of RPh 3 at around 5:55 a.m. One technician was found to be working in the sterile compounding area and another was logged into Licensee's computer. A representative of Licensee later stated that three pharmacy technicians had been given keys and passcodes to access Licensee's pharmacy. During its conference with the Committee, Licensee admitted that this allegation is true, but stated that senior management took corrective action upon learning of the situation, including immediately revoking the access code of all non-pharmacists and physically rekeying all doors within the pharmacy. Licensees avers that periodic security assessments confirm that no unauthorized persons have had access to the pharmacy since February 2020.

b. Six pharmacy technicians, including the IV pharmacy technician, were present in the "filling area" with only one pharmacist, who was the second pharmacist to arrive. Another pharmacist was in an "order entry" area, a distinctly different area separated by a wall and door. The Board Surveyors were told that additional pharmacy technicians were scheduled that morning to perform non-technician "staging or stocking" duties. However, the Board Surveyors observed that the additional pharmacy technicians that were supposedly scheduled to perform non-technician duties, were filling orders in the "filling area" to be checked by the one pharmacist.

Licensee avers that is does not have sufficient information to admit or deny the Board surveyors' observations, but that company policy requires compliance with required technician-to-pharmacist ratios.

IV.

LAWS

11. Licensee acknowledges the conduct described in section III above constitutes a violation of Minn. Stat. § 151.071, subd. 2(7), and warrants the disciplinary action described below.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

12. The Board **REPRIMANDS** Licensee and imposes a **CIVIL PENALTY** in the amount of $50,000 for the conduct described in section III above. The civil penalty shall be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of entry of this Order.

13. The Board places the following **CONDITION** on Licensee's License: every six months, for a period of three years, Licensee's CEO must certify to the Board's Executive Director that Licensee's licensed pharmacies that provide services to Minnesota residents are in full compliance with all applicable Minnesota statutes and rules.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

14. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Committee may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Committee shall schedule a hearing before the Board. At least 20 days before the hearing, the Committee must mail Licensee a notice of the violation(s) alleged by the Committee. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee shall submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Committee, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Committee and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Committee and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Committee will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations, but may present argument concerning the appropriateness of additional discipline. Pursuant to this process, Licensee waives a hearing before an administrative law judge, discovery, cross-examination of

adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but does not limit the Board's authority to impose discipline for the violation. A decision by the Committee not to seek discipline when it first learns of a violation does not waive the Committee's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's license is in a suspended status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's license, a period of suspension, conditions of reinstatement, or revocation of Licensee's license.

f. Nothing herein limits the Committee's or the Board's right to temporarily suspend Licensee's license as provided in Minnesota Statutes chapters 151 and 214, based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII. ADDITIONAL INFORMATION

15. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

16. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the

investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

17. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter shall constitute the entire record and may be reviewed by the Board in its consideration of this matter.

18. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

19. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

20. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it. If the Board rejects this Stipulation and Consent Order, the parties agree that this Stipulation and Consent Order will not be admissible in any proceedings.

21. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis

of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action, and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

22. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed health professional, and as such, is classified as confidential data pursuant to Minnesota Statutes section 13.41, subdivision 4.

23. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

POLARIS PHARMACY SERVICES OF MINNESOTA, LLC (LICENSEE)

Dated: 12-3-2021

MINNESOTA BOARD OF PHARMACY
COMMITTEE ON PROFESSIONAL STANDARDS

BOARD MEMBER

Dated: 12/8/21

ORDER

Upon consideration of the Stipulation, the Board **REPRIMANDS** Licensee, imposes a **CIVIL PENALTY**, and **CONDITIONS** Licensee's license and adopts all of the terms described above on this 8TH day of December, 2021.

MINNESOTA BOARD OF PHARMACY

CODY WIBERG
Executive Director

8B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

4

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH PH03813	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: FP6189725 ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Postmeds Inc. dba Truepill

Physical Address: 3121 Diablo Ave.

City: Hayward State: CA Zip: 94545

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 650-353-5495 Toll Free # (NAC 639.708, NRS 639.23286): 855-910-8606

Fax: _____ Contact Email: compliance@truepill.com

Website: https://www.truepill.com/

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Christopher Lau

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21371

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.):

Name: Christopher Lau	NV Pharmacist Registration #: 21371
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Truepill, Inc.

Corporation/Organization Name: Postmeds, Inc.

Mailing Address: 3121 Diablo Ave.

City: Hayward State: CA Zip: 94545

Telephone: 650-353-5495 Email: compliance@truepill.com

Contact Person Name: Samantha Gabbard

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO/President/Secretary (title) for Postmeds Inc. dba Truepill (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Paul Greenall

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

9/19/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Paul Greenall hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CEO/President/Secretary (title) for Postmeds Inc. dba Truepill (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

_____
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this _____ day of _____, 20_____

California
Jurat Attatched

_____
Notary Public

California
Jurat Attatched

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Paul Greenall

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

9/19/24

Date

Board Use Only	Date Received: _____	Amount: 500.00 / ## 1046883

CALIFORNIA JURAT WITH AFFIANT STATEMENT GOVERNMENT CODE § 8202

☑ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], *not* Notary)

1 _____
2 _____
3 _____
4 _____
5 _____

Signature of Document Signer No. 1 *Signature of Document Signer No. 2 (if any)*

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Marin

LILIA RIVAS CRESCENCIO
COMM. # 2442906
NOTARY PUBLIC-CALIFORNIA
MARIN COUNTY
My Comm. Expires APR. 27, 2027

Subscribed and sworn to (or affirmed) before me on this 19 day of September, 2024,
Date *Month* *Year*
by
(1) Paul Greenall
(and (2) _____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature Lilia Rivas
Signature of Notary Public

Seal
Place Notary Seal Above

OPTIONAL

Though this section is optional, completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: _____ Document Date: _____

Number of Pages: _____ Signer(s) Other Than Named Above: _____

©2016 National Notary Association • www.NationalNotary.org • 1-800-US NOTARY (1-800-876-6827) Item #5910

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THAT "POSTMEDS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE NOT HAVING BEEN CANCELLED OR DISSOLVED SO FAR AS THE RECORDS OF THIS OFFICE SHOW AND IS DULY AUTHORIZED TO TRANSACT BUSINESS.

THE FOLLOWING DOCUMENTS HAVE BEEN FILED:

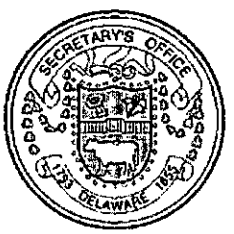
CERTIFICATE OF INCORPORATION, FILED THE TWENTIETH DAY OF MAY, A.D. 2015, AT 5:18 O`CLOCK P.M.

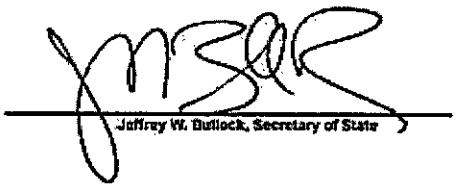
RESTATED CERTIFICATE, FILED THE NINTH DAY OF AUGUST, A.D. 2018, AT 9:12 O`CLOCK P.M.

CERTIFICATE OF CHANGE OF REGISTERED AGENT, FILED THE SEVENTH DAY OF JUNE, A.D. 2019, AT 8:26 O`CLOCK A.M.

RESTATED CERTIFICATE, FILED THE EIGHTH DAY OF AUGUST, A.D. 2022, AT 8:01 O`CLOCK A.M.

CERTIFICATE OF CHANGE OF REGISTERED AGENT, FILED THE THIRD DAY OF NOVEMBER, A.D. 2022, AT 12:35 O`CLOCK P.M.





5751427 8310

SR# 20243581488

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204295652

Date: 09-03-24

Delaware

The First State

AND I DO HEREBY FURTHER CERTIFY THAT THE AFORESAID CERTIFICATES ARE THE ONLY CERTIFICATES ON RECORD OF THE AFORESAID CORPORATION, "POSTMEDS, INC.".

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

5751427 8310

SR# 20243581488

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204295652

Date: 09-03-24

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 5/2/2024 Inspector: Kavita Nankani

Firm: TRUEPILL Phone: (650) 353-5495

Address: 3121 DIABLO AVE City: HAYWARD Zip: 94545

Ownership: CORPORATION

Permit #: PHY58585 Permit Exp: 3/1/2025 DEA#: FP6189725 DEA Exp: 11/30/2025

Date of Self Assessment Form: 5/3/2023 Other Permit #: N/A Date of DEA Inventory: 3/31/2024

Hours M-F: 24Hr Hours Saturday: 24Hr Hours Sunday: 24Hr

PIC RICHARD J HAGAN MYERS RPH62320 Administrator

RPH Consultant

Staff RPH Name:	License #:
HOWARD KO	RPH58900
ARTHUR LUKAS Y KWONG	RPH83850
ANGELINE H LE	RPH86994
KAYLA PHUONG U TRAN	RPH71488
HA N TRINH	RPH72002
DANA L CHAU	RPH56397
ALEXUS JERARD V HERMOGI	RPH79237
RAJI RAJAN	RPH64706
KRISTIN R XIE	RPH68135
DIANA M LUONG	RPH71888
RUBY NGOC DAO	RPH79724
MAGGIE S GONG	RPH57624
TZE-YU LO	RPH65139
ARIELLE A MADISON	RPH77431
YI L YAO	RPH83724
KARUNDRA BEN ABRAHAM	RPH74044
JOHN J HWANG	RPH56696
KIEU T HO	RPH80597
HYO E KIM	RPH77257
CHRISTOPHER S LAU	RPH73514
EMILY PHAN	RPH77553
FLORA Y WONG	RPH44357
ARTI K MULCHANDANI	RPH77631
DAVID TRUONG	RPH74245
KHALED A ELSAIAD	RPH74423
TIFFANY N LE	RPH85307

Staff Name:	License #:
ALEXIS Y ALEJANDRO	TCH171199
ALICIA YOUNG	TCH110224
ANDREW J WIRJADISASTRA	TCH168996
ARESHNA A DEVI	TCH150606
BHAVANIBEN G PATEL	TCH158562
CARINA L ORTEGA-ROMERO	TCH179809
CHAD G SWAN	TCH168362
CHEYENNE B DOMINGUEZ	TCH151816
DEBRA MAE D SANCHEZ	TCH156582
DONLY E LAMBETH	TCH163701
FRANCHESKA C HUMARANG	TCH174164
FRANK O WUSTNER	TCH132600
JAMIKA L ACEVES	TCH134278
JENIFER S PASCUA	TCH152429
JONATHAN H NGUYEN	TCH164623
JOSEPH K BANISCH	TCH175943
KISHA A JONES-PETERSON	TCH134944
KY H NGUYEN	TCH133825
MARTA WONG	TCH154922
MEI YAN ZENG	TCH167473
MINETTE T MATEO	TCH24146
MOHYMAN A AWWAD	TCH167840
MOLLIE J JORDAN	TCH92038
RICARDO V PELAYO	TCH119174

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

VIDA PEJMAN	RPH49739	RODERICK M LEWIS	TCH159131
CURTIS D ANCAR	RPH57345	TERIESA N DASS	TCH185842
TRAVIS J PAU	RPH70260	TIFFANI K HAWKINS	TCH65856
DANA M NG	RPH78086	TIFFANY S ROQUE	TCH162790
VU L TRAN	RPH52752	VINCENT MATHEW C MUNIZ	TCH165168
JESSICA NGO	RPH81042		
ZHIHUA SHI	RPH73964		
JULIE V TRAN	RPH85217		
APRIL N ADAMS	RPH49949		
SHRUTHY ALEX	RPH77746		
NHATANH D NGO	RPH51783		
DAVID WILLIAM C KNIGHT	RPH78846		
PAULINA T NGUYEN	RPH48806		
LIEN T TRUONG	RPH74962		
DONNY Q NGUYEN	RPH85712		

Inspector Remarks:

ROUTINE PHARMACY INSPECTION

Retail pharmacy - majority mail order, very rare pickup of medications from customers
RX Volume approx. ~2000-2,500 prescriptions/day
Licensed in and mails Rxs to all 50 states
No compounding
No immunizations
No controlled substance dispensing since ~10/2022
24 hours pharmacy - closed from 7pm to 8:45pm
Partners with >20 companies. Major partners: Blink, Lilly, Phil, Wisp, Found, Duration, etc.
Mail carriers used: mostly USPS, FedEx for refrigerated medications, and UPS
Other TruePill locations in NY, OH, and FL
Assisted by RPH Elsaiad - pharmacy operations manager, Mr. Cathric Yaga - director of pharmacy operations, RPH Trinh - regulatory pharmacy operations supervisor.

Wholesaler: Afaxys, Agile, Anda, Aurobindo, Bausch & Lomb, Camber, Cardinal, Dr. Reddy, Evofem, Hikma, HRA, IBSA, IPC, Keysource, Lexicon, Lupin, Mayne, McKesson, Parmed, Phathom, Prasco, Primus, Sun, TopRx, WWS
Reverse Distributor: Inmar

REVIEWED:

**Consultation: written notification of consultation provided to every patient
NTC poster, Point to Your Language Sign posted
DEA registration, BOP original license/renewal posted
Community pharmacy self-assessment, DEA biennial controlled substance inventory, POA
Pharmacy security, badge access for pharmacist/technician, alarm access with select pharmacists
Pharmacy records storage in pharmacy
HIPAA disposal bins in pharmacy, locked and secured, keys in lockbox
Three drug rooms + overstock drug room + second overstock drug room dedicated to one vendor (i.e. Mark Cuban) - badge access by Rph/Tch, for overstock room - there is only key access at this time, key in the lockbox, lockbox key with supervisor
CS locked safe - currently empty with one expired medication quarantined for destruction, safe access with PIC and RPH Trinh

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

BOP emails, CURES access
sample invoices
All prescriptions are received electronically and maintained electronically
Schedule 2 Reconciliation Inventory Report, last 03/31/2024 - no CS in stock at this time
name badges for staff, tech ratio discussed with RPH Trinh
Rph receives and signs for order from wholesaler
No 340b drugs
No bubble packs or unit dose packaging
Does not dispense to physicians' offices for office use
No delivery services
Refrigerated items are packaged in insulated package with multiple ice packs and shipped via FedEx
Pharmacy performs cold chain testing 2x/year
Pharmacy has no automatic refill program; dispense medications pursuant to new prescription or refill request through contracted companies
SmartSense continuous digital monitoring system for ambient, refrigerator, and freezer; out of range alerts are sent via email to managers and leads
manual temperature logs also maintained and logged twice a day
sink with hot and cold running water
Prescription process - current inventory; filling/verification process observed by Rph/Tch; shipping area
Automated Dispensing Devices: 5 Parata Max and 4 Parata Mini - all of the automated dispensing devices have been decommissioned as of 2023/2024 and labeled as such, with the exception of 1 Parata Mini
Reviewed Parata Mini cells - labeled with drug name, strength, lot number, NDC, expiration dates
Kirby Lester counting machine
Recall process, quarantined from active inventory, documentation maintained on Google drive
Expired medications process, quarantined from active inventory
sample prescription labels - patient centered, description of tabs/caps, requirement for patient-centered label "generic for ___"
Reviewed QA reporting system on TruePill error/quality tracker on Google sheets, last QA reported on 04/23/2024, viewed sample report from 01/29/2024
Computer system: mostly use TruePill operating system, sometimes use Pioneer for specific vendor

Policy/Procedures: maintained in a binder and available online. Reviewed:

- Automatic prescription refill/renewal program; licensed employee, Theft or impairment; Inventory Reconciliation Report of CS; Language Line Solutions for access to an interpreter; Reporting of Errors, Issues, & Complaints of Clinical Significance

EDUCATION/DISCUSSION:

1. CCR 1714(c) - in that pharmacy sink drain was dirty. Ensure pharmacy kept in a clean and orderly condition, including sink.
2. At the time of inspection, found a large container with expired medications from a previous vendor, that was quarantined in the cage. Please ensure expired medications are returned to the reverse distributor.

EDUCATIONAL TOPIC FOR DISCUSSION

1. BPC 4052.04 – Pharmacist may furnish COVID-19 oral therapeutics following a positive test.
   - "COVID-19 oral therapeutics" means drugs that are approved or authorized by the FDA for the treatment of COVID-19 and administered orally.
   - Prior to furnishing COVID-19 oral therapeutics, a pharmacist shall utilize relevant and appropriate evidence-based clinical guidelines published by FDA in providing these patient care services.
   - A pharmacist who furnishes COVID-19 oral therapeutics shall notify patient's PCP or enter appropriate information into patient record system shared with PCP, as permitted by that PCP. If the patient does not have a PCP, the pharmacist shall provide the patient with a written record of the drugs furnished and advise the patient to consult a physician of the patient's choice.

INSPECTION REPORT

- Document the kind and amounts of COVID-19 oral therapeutics furnished, as well as any information regarding testing services provided, in the patient's record in the record system maintained by the pharmacy.
- Retain records for 3 years.

2. BPC 4113 – PIC authority to make staffing decisions
   - PIC may make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely.
   - If PIC is not available, a pharmacist on duty may adjust staffing according to workload if needed.
   - PIC or pharmacist on duty shall immediately notify the store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. If the conditions are not resolved within 24 hours, the PIC or RPH on duty shall ensure the BOP is timely notified. Conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff include, but are not limited to:
     - Workplace safety and health hazards that present an immediate risk of death, illness or irreparable harm to patients, personnel, or pharmacy staff.
     - Sustained temperatures that could impact ambient temperature drug stability according to manufacturer data on acceptable drug storage conditions.
     - Vermin infestation that poses a risk to the safety or efficacy of medicine.
3. BPC 4113.1 – Reporting medication errors within 14 days from discovery.
   - Applies to "community pharmacies" – *i.e.,* any pharmacy that dispenses medication to an outpatient (but not including facilities of CDCR).
   - Per the BOP's AB 1286 Implementation Statement, the reporting of medication errors under BPC 4113.1 will not be required until the BOP approves an entity to receive the reports.
4. BPC 4113.6 – Chain community pharmacy subject to BPC 4113.5 must be staffed at all times with at least one clerk or pharmacy technician fully dedicated to performing pharmacy-related services. The BOP will not take action against a pharmacy for violation of this staffing requirement if any of the following conditions apply:
   - RPH on duty waives the requirement in writing during specified hours based on workload need.
   - The pharmacy is open beyond normal business hours (*i.e.,* before 8am, after 7pm). During the hours before 8am and after 7pm, the staffing requirement shall not apply.
   - The pharmacy's prescription volume per day on average is less than 75 prescriptions per day based on the average daily prescription volume for the past calendar year. However, if the pharmacist is also expected to provide additional pharmacy services (such as immunizations or CLIA-waived tests) this exception does not apply.

   When staffing of pharmacist hours within a chain community pharmacy does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted, and included on the outgoing telephone message.
5. BPC 4115 – Pharmacy technician may, under the direct supervision and control of a pharmacy, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are CLIA waived, receive prescription transfers, and accept clarification on prescriptions under certain specified conditions.
6. BPC 4231 – CE required for pharmacists to renew their pharmacist license must now include at least one hour of participation in a cultural competency course which meets specified requirements.
7. The Board has posted on its website the FAQ's to address the changes in pharmacy law related to AB1286, dated 12/21/2023. Here's the link: https://pharmacy.ca.gov/publications/ab1286_faqs.pdf

DISCLAIMER:
Any issues referenced/discussed in this report are not intended to be an all-inclusive list of issues that may exist at your facility. Your facility is responsible for investigating and determining the causes of any issues and items to be corrected and for preventing their recurrence. Further review of items provided at inspection, may result in further communication after this report.

Kavita Nankani, Board Inspector

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Phone 408-515-7416
Fax 510-683-0103
Email: kavita.nankani@dca.ca.gov

Licensee Remarks:

. have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) Khaled Elsaiad

Pharmacist (print) Khaled Elsaiad

Inspector (sign) Kavita Nankani

Inspector (print) Kavita NanKani

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Renewal Certificate

Retail Pharmacy Permit

LICENSE NO. PHY 58585
RECEIPT NO. 00190516

VALID UNTIL MARCH 01, 2025

TRUEPILL
3121 DIABLO AVE
HAYWARD CA 94545

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown and is subject to the rules and regulations of the California State Board of Pharmacy.
This permit is non transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change), administrator or pharmacist in charge.
This permit is valid only at the address shown.

/26/24
/26/24

The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHPHY (09/30/19) PH

3610

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 58585

NAME: TRUEPILL

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

3121 DIABLO AVE
HAYWARD CA 94545
ALAMEDA COUNTY

ISSUANCE DATE

MARCH 1, 2022

EXPIRATION DATE

MARCH 1, 2025

CURRENT DATE / TIME

AUGUST 29, 2024
8:9:44 AM

LICENSE RELATIONSHIPS

NAME: HAGAN MYERS, RICHARD JAMES

ADDRESS NOT DISCLOSED

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 62320 **PRIMARY STATUS:** CLEAR

3611

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler POSTMEDS INC.

Pharmacy/Wholesaler License # (if applicable) PH03813

Physical Address 3121 Diablo Ave

City Hayward State CA Zip 94545

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 650-353-5495 Website WWW.TRUEPILL.COM

Licensing Company Email support@truepill.com, CHRIS.LAU@TRUEPILL.COM, rick.hagan@truepill.com

Section 2: Personal Information

First CHRISTOPHER Middle SHUNSUN Last LAU

Alias(es, nicknames, name changes, etc.) CHRIS LAU

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] STACY ST

City OAKLAND State CA Zip 94605

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)		Yes	No
1.	Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2.	Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
PACIFIC UNIVERSITY OREGON SCHOOL OF PHARMACY			08/11-05/14	
Address	City		State	Zip
222 SE 8th Ave	Hillsboro		OR	97123
Diploma/Degree obtained, if any				
DOCTOR OF PHARMACY				
School Name			From - To (MM/YY – MM/YY)	
UNIVERSITY OF CALIFORNIA SAN DIEGO			09/02-06/06	
Address	City		State	Zip
9500 Gilman Dr	LAJOLLA		CA	92093
Diploma/Degree obtained, if any				
BA - ECONOMICS				
School Name			From - To (MM/YY – MM/YY)	
WILCOX HIGH SCHOOL			08/98-06/02	
Address	City		State	Zip
3250 Monroe St.	SANTA CLARA		CA	95051
Diploma/Degree obtained, if any				
HIGH SCHOOL DIPLOMA				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/19-09/24	[redacted]STACY ST.	OAKLAND	CA	94605
11/17-09/19	[redacted]E. DUANE AVE	SUNNYVALE	CA	94085
11/13-11/17	[redacted]SW BARLOW RD.	BEAVERTON	OR	97008
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
POSTMEDS INC.			12/17-09/24	
Business Address		**City**	**State**	**Zip**
3121 DIABLO AVE.		HAYWARD	CA	94545
Phone	**Title**		**Number of Employed Hours**	
650-353-5495	PHARMACIST		13,700	
Description of Duties				
LICENSED DISPENSING PHARMACIST DUTIES, PATIENT CARE, PHARMACY TRAINING, ADMINISTRATIVE DUTIES				

Business Name			From - To (MM/YY – MM/YY)	
PROVIDENCE HEALTH & SERVICES ST. VINCENT MOB PHARMACY			07/15-11/17	
Business Address		**City**	**State**	**Zip**
9205 SW Barnes Rd		PORTLAND	OR	97225
Phone	**Title**		**Number of Employed Hours**	
(503) 216-1234	PHARMACIST		4,700	
Description of Duties				
LICENSED DISPENSING PHARMACIST DUTIES, CLINICAL PATIENT CARE				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations		Yes	No
1.	Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2.	If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3.	Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4.	Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5.	Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6.	Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7.	Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8.	Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9.	Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10.	Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, CHRISTOPHER S. LAU, **certify that as the designated representative for**

POSTMEDS INC.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CSL I am at least 21 years of age;
3. CSL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CSL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CSL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CSL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CSL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

CHRISTOPHER LAU

Print Name (First, ~~Last~~)

Original Signature (electronic, copies or stamps not accepted)

9/13/2024.

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

CHRISTOPHER LAU

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/13/2024

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Alameda

I, Christopher Lau, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/13/2024

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

(Seal)

CALIFORNIA JURAT WITH AFFIANT STATEMENT **GOVERNMENT CODE § 8202**

☑ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], not Notary)

1 _____
2 _____
3 _____
4 _____
5 _____
6 _____

Signature of Document Signer No. 1 *Signature of Document Signer No. 2 (if any)*

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of ALAMEDA

Subscribed and sworn to (or affirmed) before me

on this 13th day of September, 2024,
Date *Month* *Year*

by (1) CHRISTOPHER SHUN-SUN LAU

(and (2) _____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

RUPINDER GREWAL
Notary Public - California
Alameda County
Commission # 2362757
My Comm. Expires Jul 1, 2025

Place Notary Seal and/or Stamp Above

Signature Rupinder Grewal
Signature of Notary Public

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: Nevada State Board of PHARMACY

Document Date: 9/13/2024 Number of Pages: 10

Signer(s) Other Than Named Above: None

©2019 National Notary Association

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Postmeds Inc

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): CA PHY58585

Physical Address: 3121 Diablo Ave

City: Hayward State: CA Zip: 94545

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 650-353-5495 Website: n/a

Licensing Company Email: compliance@truepill.com

Section 2: Personal Information

First: Paul Middle: James Last: Greenall

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] Benjamin Way

City: Healdsburg State: CA Zip: 95448

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)		Yes	No
1.	Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2.	Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Bayes Business School, University of London			10/98 - 07/02	
Address		City	State	Zip
106 Bunhill Row		London	UK	EC1Y 8TZ
Diploma/Degree obtained, if any				
BSC Business Management				
School Name			From - To (MM/YY – MM/YY)	
Abbotsfield School			09/91-07/98	
Address		City	State	Zip
Clifton Gardens		Hillingdon	UK	UB10 0EX
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/20-Date	[redacted]Benjamin Way	Healdsburg	CA	95448
09/11 - 07/20	[redacted]Church St, Apt H	San Francisco	CA	94114
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Postmeds Inc D/B/A Truepill			07/22 - Date
Business Address	**City**	**State**	**Zip**
3121 Diablo Ave	Hayward	CA	94545
Phone	**Title**		
855-910-8606	CEO		

Description of Duties
Managing the overall resources and operations of company, making major corporate decisions, and acting as the main point of contact between the board of directors, employees, and the public.

Business Name			From - To (MM/YY – MM/YY)
Prophet Brand Strategy LLC			04/19 - 06/22
Business Address	**City**	**State**	**Zip**
150 Spear St Ste 1300	San Francisco	CA	94105
Phone	**Title**		
(415) 518-5692	Senior Partner, Chief Strategy Officer		

Description of Duties
Primary responsibility for strategy formulation and management, including developing the corporate vision and strategy, overseeing strategic planning, and leading strategic initiatives, including M&A, transformation, partnerships, and costs

Business Name			From - To (MM/YY – MM/YY)
McKesson Corporation			07/09-12/18
Business Address	**City**	**State**	**Zip**
1 Post Street	San Francisco	CA	94104
Phone	**Title**		
415-983-8300	Sr Vice President, Enterprise Strategy		

Description of Duties
Primary responsibility for strategy formulation and management, including developing the corporate vision and strategy, overseeing strategic planning, and leading strategic initiatives, including M&A, transformation, partnerships, and costs

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.		Yes	No
1.	Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2.	If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3.	Have you ever had a civil or criminal record expunged or sealed by a court order?	✓	
4.	Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5.	Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6.	Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7.	Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8.	Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9.	Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10.	Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 & 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
06/01/2007	06/01/2007	MN	Metropolitan Airport	Hennepin
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
225001		Metropolitan Airport		
Reason/Charge				
Petty Misdemeanor - Airport Ordinance Violation				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Self		N/A		
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

Petty Misdemeanor Airport Ordinance Violation with $300 fine, expunged 9/27/2021 by State Statute. Original documentation unavailable due to fire loss.

MN Statute 609.2 - "Petty misdemeanor" a petty offense which is prohibited by ordinance or statute, which does not constitute a crime and for which a sentence of a fine of not more than $300 may be imposed.

Original Signature (electronic, copies or stamps not accepted)

9/19/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Paul Greenall

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/19/24

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

California All-Purpose Acknowledgment Attached

(Seal)

CALIFORNIA ALL-PURPOSE ACKNOWLEDGEMENT

A Notary Public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Marin

On September 19, 2024, before me, Lilia Rivas Crescencio, Notary Public,
personally appeared Paul Greenall

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of State of California that the foregoing paragraph is true and correct.

LILIA RIVAS CRESCENCIO
COMM. # 2442906
NOTARY PUBLIC-CALIFORNIA
MARIN COUNTY
My Comm. Expires APR. 27, 2027

PLACE NOTARY SEAL ABOVE

WITNESS my hand and official seal.

SIGNATURE Lilia Rivas

Though the information below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent removal and reattachment of this form to another document.

Description of attached document

Title or type of document: Personal History Application

Document Date: _____ Number of Pages: _____

Signer(s) Other than Named Above: _____

POSTMEDS, INC. DBA TRUEPILL DISCIPLINARY SUMMARY

California resident license PHY 58585
California old resident license PHY 56100

Illinois Board of Pharmacy

The Illinois Board issued the pharmacy (non-resident license #054.022249) a Consent Order of Discipline effective **August 8, 2024** resolving alleged violations of the Illinois Pharmacy Practice Act stemming from disciplinary actions by proper licensing authority of another state. As per the terms of the Consent Order, Pharmacy has agreed to pay a $5,000 administrative fine to the Illinois State Board of Pharmacy.

Alaska Board of Pharmacy

The Alaska Board issued the pharmacy (non resident license #166601) a Consent Order of Discipline effective **February 15, 2024** resolving alleged violations of the Alaska Pharmacy Practice Act stemming from disciplinary actions by proper licensing authority of another state. As per the terms of the Consent Order, Pharmacy has agreed to pay a $5,000 administrative fine to the Alaska State Board of Pharmacy.

Pennsylvania Board of Pharmacy

The Pennsylvania Board issued the pharmacy (non resident license #NP000931) a Consent Order of Discipline effective **November 7, 2023** resolving alleged violations of the Pennsylvania Pharmacy Practice Act stemming from disciplinary actions by proper licensing authority of another state. As per the terms of the Consent Order, Pharmacy has agreed to pay a $3,500 administrative fine to the Pennsylvania State Board of Pharmacy.

DEA Memorandum of Agreement

On December 15, 2022, the federal Drug Enforcement Agency ("DEA") issued Postmeds, Inc ("Truepill-Hayward") an administrative Order to Show Cause ("OSC") regarding revocation of its DEA registration FP6189725. **On September 28, 2023**, Truepill-Hayward and DEA reached a non-monetary resolution of the OSC proceedings through a Memorandum of Agreement ("MOA"). Under the MOA, Truepill-Hayward will maintain its active DEA registration without paying a fine and without suspension or revocation of its registration, while making certain agreed changes to its processes and procedures going forward. The MOA is specific to Truepill-Hayward and does not involve other Truepill pharmacies commonly owned by or affiliated with Truepill-Hayward.

Alabama Board of Pharmacy

The Alabama Board issued the pharmacy (non resident license #114861) a Consent Order of Discipline dated **June 6, 2023**. The Pharmacy has resolved alleged violations of the Alabama Pharmacy Practice Act through entry of a Consent Order with the Alabama State Board of Pharmacy on June 8, 2023. As per the terms of the Consent Order, Pharmacy has agreed to pay a $3,000 administrative fine to the Alabama State Board of Pharmacy.

Kansas Board of Pharmacy

The Kansas Board of Pharmacy issued the pharmacy (non resident license #22-117859) an amended Summary Order effective **February 8, 2023**. The pharmacy did not report the change of ownership in a

timely manner, and paid a fine. The Kansas Board of Pharmacy approved the change of ownership application, and issued license 22-117859 on May 20, 2022.

Louisiana Board of Pharmacy

The Louisiana Board of Pharmacy issued the pharmacy (non resident license #PHY.007761-NR) a Consent Order of Discipline dated **May 11, 2022.** The pharmacy did not report the change of ownership in a timely manner. The Louisiana Board of Pharmacy approved the change of ownership application with a new permit number PHY.008479-NR as a successor to permit number PHY.007761-NR.

North Carolina Board of Pharmacy

The North Carolina Board of Pharmacy issued the pharmacy a Consent Order of Discipline dated **March 8, 2022.** The pharmacy made inaccurate statements about its ownership and officers on its initial application in November 2017 and did not correct this until November 2021. The North Carolina Board of Pharmacy approved the change of ownership application with a new permit number 14900 as a successor to permit number 13413.

Maine Board of Pharmacy

The Maine Board of Pharmacy notified the pharmacy on **March 30, 2022** that its non-resident license (#MO40002429) was terminated effective November 6, 2019 for reporting deficiencies related to its ownership. The pharmacy submitted a change of ownership application for licensure, and has been issued a new pharmacy license (#MO40003167) on November 2, 2022.

California Board of Pharmacy

The California Board of Pharmacy issued the pharmacy (former license #PHY 56100) a letter of admonishment CI 2019 84877 dated **January 23, 2020,** concluding an investigation that found the pharmacy shipped a prescription to the wrong patient and shipped two prescriptions with the wrong return address.

The California Board of Pharmacy issued the pharmacy (former license #PHY 56100) a modified citation and fine CI 2019 78633 dated **June 16, 2020,** with the fine amount of $0.00. In 2018, certain prescriptions were issued to the pharmacy by prescribers that were either not yet licensed to prescribe in California or who had not yet entered into an established standardized procedure or protocol developed by a supervising physician.

Also, The California Board of Pharmacy issued the pharmacy (former license #PHY 56100) a citation and fine order of abatement CI 2020 89223 dated **August 25, 2021,** with the fine amount of $5,000. The pharmacy was in violation when dangerous drugs were stored in temperatures exceeding the recommended storage temperatures Truepill did not consider the manufacturer's stability data for drugs which may have been adulterated by heat.

PENDING MATTERS

The following Actions are currently pending or threatened against the Company. The below Actions are currently subject to ongoing discussions, negotiations, and developments.

California Board of Pharmacy

California CI 2024 105307: On August 9, 2024, the California State Board of Pharmacy sent notice of a pending citation along with information on contesting or appealing. Truepill is in process of requesting an informal hearing to contest the citation.

South Carolina Board of Pharmacy

South Carolina 2022-49: On May 3, 2023, Postmeds agreed in principle to a proposed consent order with the South Carolina Board of Pharmacy to resolve inaccuracies in prior ownership information provided to the Board. The agreement would be categorized as a public reprimand but would not be a public document and would not be reported to the National Practitioner Data Bank. The negotiated fine was $30,000. The South Carolina Board of Pharmacy has not finalized this consent order or initiated formal disciplinary proceedings.

STATE OF ILLINOIS
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
DIVISION OF PROFESSIONAL REGULATION

IN RE: The Application of		)	
POSTMEDS INC DBA TRUEPILL,		)	Case No. 2023-00783
054-app-4237687	APPLICANT.	)	

CONSENT ORDER

The Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation ("Department"), by its attorney Nicholas V. Gallo, and Applicant POSTMEDS INC ("Applicant"), by its attorney Marc N. Wagner, hereby agree to the following:

STIPULATIONS

On or about August 22, 2022, Applicant submitted to the Department a change of ownership application (the "application") for Illinois licensed pharmacy license no. 054.022350.

On or about June 16, 2020, the California State Board of Pharmacy issued Applicant a disciplinary modified citation and fine ("California Citation and Fine") under case no. 2017-78633 for Applicant filling prescriptions issued to Applicant by prescribers that were either not yet licensed to prescribe in California or who had not yet entered into an established standardized procedure or protocol developed by a supervising physician. The California Citation and Fine constitutes grounds for disciplinary action against Applicant on the authority of the Illinois Pharmacy Practice Act ("Act") at 225 ILCS 85/30(a)(8) as the grounds for action in the California Citation and Fine are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 225 ILCS 85/4(g).

On or about August 25, 2021, the California State Board of Pharmacy issued Applicant a disciplinary citation and fine order of abatement ("California Citation and Fine Order of Abatement") under case no. 2020-89223 for, including but not limited to, Applicant storing dangerous drugs in temperatures exceeding the recommended storage temperatures. The California Citation and Fine Order of Abatement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8)

as the grounds for action in the California Citation and Fine Order of Abatement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 225 ILCS 85/3(d)(12).

On or about March 8, 2022, Applicant and the North Carolina Board of Pharmacy entered into a Consent Order of Discipline for, including but not limited to, Applicant failing to report change of ownership in a timely manner. The North Carolina Agreement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8) as the grounds for action in the North Carolina Agreement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via the Act's Administrative Rules ("Rules") at 68 IAC 1330.780(a)(1).

On or about May 11, 2022, Applicant and the Louisiana Board of Pharmacy entered into a disciplinary Consent Agreement ("Louisiana Agreement") under case no. 21-0456 for, including but not limited to, Applicant failing to report change of ownership in a timely manner. The Louisiana Agreement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8) as the grounds for action in the Louisiana Agreement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 68 IAC 1330.780(a)(1).

On or about February 15, 2024, Applicant and the Board of Pharmacy for the State of Alaska entered into a disciplinary Consent Agreement ("Alaska Agreement") under case no. 2022-000434 for, including but not limited to, Applicant failing to disclose prior disciplines from another state within the required timeframe. The Alaska Agreement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8) as the grounds for action in the Alaska Agreement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 68 IAC 1330.40(c).

Pursuant to 68 IAC 1130.300(a) the following factor is considered in aggravation: (a) the presence of multiple adverse actions taken by other states against Applicant.

Pursuant to 68 IAC 1130.300(b) the following factors are considered in mitigation: (a) Applicant has cooperated with the Department in its investigation; and (b) Applicant has no prior disciplinary history with the Department.

At all times material to the matter set forth in this Consent Order, the Department had jurisdiction over the subject matter and the parties herein. Applicant has been advised of the right to have any allegation(s) reduced to written charges, to a hearing where the Department bears the burden to prove its allegations by clear and convincing evidence, to contest any charges brought and present mitigating evidence, and to administrative review of any order resulting from a hearing. Applicant knowingly waives each of these rights, as well as any right to administrative review of this Consent Order. Such waiver ceases if this Consent Order is rejected by the Secretary or the Secretary's designee or the Board. Applicant acknowledges that it has entered into this Consent Order freely and of Applicant's own will without threat or coercion by the Department or any person, and has not relied upon any representation made by or on behalf of the Department other than those specifically included herein. Applicant acknowledges that the Department attorney may be requested to communicate with the Board or the Secretary or the Secretary's designee in furtherance of the approval of this Consent Order. Applicant acknowledges that this Consent Order will be presented to the Secretary or the Secretary's designee. If this Consent Order is not approved, Applicant waives any right to raise any prejudice resulting from the Secretary or the Secretary's designee's consideration of this Consent Order. Applicant understands that this Consent Order is not effective unless and until it is adopted by the Secretary or the Secretary's designee. A copy of any original signature(s) affixed to this Consent Order shall be given the full force and effect of an original signature(s) affixed to this Consent Order.

Applicant and the Department agree, in order to resolve this case, that the Applicant be permitted to enter into a Consent Order with the Department providing for the terms and conditions contained herein which are fair and equitable in the circumstances and which are consistent with the best interests of the people of the State of Illinois.

CONDITIONS

Wherefore, the Department, by its attorney Nicholas V. Gallo, and Applicant, by its attorney Marc N. Wagner, agree:

A. Applicant's Illinois licensed pharmacy license no. 054.022350 shall be issued with a Reprimand.

B. Applicant shall pay a five-thousand-dollar ($5,000.00 USD) disciplinary fine within sixty (60) days of the effective date of this Consent Order.

C. All fines issued pursuant to this Consent Order are to be paid by personal check, company check, cashier's check, or personal money order. Said monetary instrument(s) shall be made payable to "Illinois Department of Financial and Professional Regulation," clearly indicate on the face of the monetary instrument the case number of 2023-00783 as well as license no. 054.022350, and be mailed to the following address:

Illinois Department of Financial and Professional Regulation
SSC – Accounts Receivable Section - Fines
P.O. Box 7086
Springfield, IL 62791-7086

D. Prior to the satisfaction of subsections B and C, above, Applicant shall not violate any state or federal law, rule, or regulation concerning controlled substances or the practice of wholesale drug distribution.

E. Applicant agrees that any violation of this Consent Order permits the Secretary or Secretary's designee to issue an Order forthwith mandating the automatic, indefinite, and immediate suspension of Applicant's license for a minimum period of twelve (12) months. This suspension shall not preclude the Department from taking any other disciplinary or other action it deems appropriate. In the event that Applicant(s) contest(s) in writing (by the filing with the Department within thirty (30) days the effective date of the suspension, a Petition complying with the Department's Rules of Practice in Administrative Hearings) the factual basis underlying said suspension, then Applicant(s) shall be afforded a hearing on the merits in accordance with the Department's Rules of Practice in Administrative Hearings, 68 Ill. Admin. Code 1110/et seq.

F. Applicant acknowledges that this Consent Order is a public disciplinary action and will be made available to the public. It will be reported to all applicable reporting databases.

G. This Consent Order is a final administrative order. This Consent Order shall become effective upon the signature of the Secretary or the Secretary's designee below unless otherwise stated herein.

Signatures on the following page

July 12, 2024
Date

Department Attorney – Nicholas V. Gallo

7/11/2024 | 1:39 PM PDT
Date

DocuSigned by:
Laura Peterson
Applicant – POSTMEDS INC
By: General Counsel, Truepill Inc. - Laura Peterson

7/11/2024 | 5:00 PM CDT
Date

DocuSigned by:
Lee Rosebush
Applicant's Attorney – Lee H. Rosebush

7/12/24
Date

Illinois State Board of Pharmacy Member

The foregoing Consent Order is approved in full.

DATED THIS 8th day of August, 2024.

ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
SECRETARY MARIO TRETO, JR.

Mario Treto, Jr. Secretary
Illinois Department of Financial and Professional Regulation

Case No. 2023-00783
Application No.: 054-app-4237687

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE BOARD OF PHARMACY

In the Matter of:)
)
Postmeds, Inc. doing business as (Dba) TRUEPILL)
Respondent)
Case No. 2022-000434

CONSENT AGREEMENT

IT IS HEREBY AGREED by the Department of Commerce, Community and Economic Development, Division of Corporations, Business and Professional Licensing (Division) and TRUEPILL (Respondent) as follows:

1) **Licensure.** Respondent is currently registered as an Out-of-State Pharmacy in the State of Alaska and holds License number #166601. This license was first issued on 08/27/2020 and will lapse unless renewed by 06/30/2024.

2) **Admission/Jurisdiction.** Respondent admits and agrees that the Board of Pharmacy has jurisdiction over the subject matter of their license in Alaska and over this Consent Agreement.

3) **Admission/Facts.** Respondent admits to the following facts:

a) On September 25, 2017, Staff Pharmacist working for TRUEPILL, Curtis Ancar, received a disciplinary order from the California Board of Pharmacy for failure to exercise corresponding responsibility and excessive furnishing of controlled substances.

b) On January 24, 2019, the California Board of Pharmacy cited former Pharmacist-in-Charge and former owner of TRUEPILL, Mohammad Umar Afridi, for failure to provide documentation substantiating completion of continuing education and knowingly making or signing a document with false information.

c) On December 16, 2019, the California Board of Pharmacy cited former Pharmacist-in-Charge and former owner of TRUEPILL, Mohammad Umar Afridi, for furnishing and dispensing dangerous drugs without a prescription and dispensing on order of nurse practitioner (or person of similar status).

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

d) On January 23, 2020, the California Board of Pharmacy issued a letter of admonishment to Respondent for shipping a prescription to the wrong address and shipping two prescriptions with the wrong return address.

e) On June 16, 2020, the California Board of Pharmacy issued a modified citation and fine CI 2019 78633 with the fine amount of $0.00 for receiving prescriptions by prescribers that were not licensed or have not entered into procedures with supervising physicians.

f) On April 08, 2022, Respondent submitted an Out-of-State Pharmacy Registration Ownership Change Application from license no. 166601 to license no. 193858 (now withdrawn) to the Division. Professional Fitness Question #1 was marked "Yes" indicating disciplinary actions had been issued against their license as listed above in sections a) through e).

g) Subsequent background investigation revealed Respondent failed to disclose the abovementioned 2017, 2019, and 2020 licensing actions from the California Board of Pharmacy on previous State of Alaska applications for TRUEPILL (formerly DBA Postmeds, Inc.) for licenses 137655 and 166601 dated June 08, 2018, August 06, 2020, and August 27, 2020.

h) Respondent admits that as a result of the above facts, grounds exist for possible suspension, revocation, or other disciplinary sanctions of their license pursuant to AS 08.01.075, AS 08.80.261(a)(1), AS 08.80.261(a)(6), AS 08.80.261(a)(9), AS 08.80.261(a)(11)(12)(14), 12 AAC 52.920(a)(13), and 52.920(a)(14)(c).

4) **Formal Hearing Process.** It is the intent of the parties to this Consent Agreement to provide for the compromise and settlement of all issues addressed in Paragraph 3 (above) that could be raised by an Accusation to revoke, suspend, or impose disciplinary sanctions against Respondent's license through a formal hearing process.

5) **Waiver of Rights.** Respondent understands they have the right to consult with an attorney of their own choosing and has a right to an administrative hearing on the facts in this case. Respondent understands and agrees that by signing this Consent Agreement, Respondent is waiving their rights to counsel and to a hearing. Further, Respondent understands and agrees that they are relieving the Division of any burden it has of proving the facts admitted above. Respondent further understands and agrees that by signing this Consent Agreement they are voluntarily and knowingly giving up their right to present oral and documentary evidence, to present rebuttal evidence, to cross-examine witnesses against Respondent, and to appeal the Board's decision to Superior Court.

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

6) **Effect of Non-Acceptance of Consent Agreement.** Respondent and the Division agree that this Consent Agreement is subject to the approval of the Board. They agree that, if the Board rejects this Consent Agreement, it will be void, and an Accusation may be filed. If this Consent Agreement is rejected by the Board, it will not constitute a waiver of Respondent's right to a hearing on the matters alleged in an Accusation and the admissions contained herein will have no effect. Respondent agrees that, if the Board rejects this Consent Agreement, the Board may decide the matter after a hearing, and its consideration of this Consent Agreement shall not alone be grounds for claiming that the Board is biased against Respondent, that it cannot fairly decide the case, or that it has received ex parte communication.

7) **Consent Agreement, Decision, and Order.** Respondent agrees that the Board has the authority to enter into this Consent Agreement and to issue the following Decision and Order.

PROPOSED DECISION AND ORDER

IT IS HEREBY ORDERED that any license issued to Respondent by the Board shall be subject to the following terms and conditions:

A. Violation of Agreement

If Respondent fails to comply with any term or condition of this Consent Agreement, the Division may enforce this agreement by immediately suspending Respondent's license, without an additional order from the Board or without a prior hearing, for a violation of this agreement. In addition, any suspended portion of the civil fine will be immediately due.

If Respondent's license is suspended under this paragraph, as provided above, they will be entitled to a hearing, on an expedited basis, regarding the issue of the suspension. If Respondent's license is suspended, they will continue to be responsible for all license requirements pursuant to AS 08.80.

Respondent shall maintain an active license for the entire duration of this Consent Agreement. If the Respondent lets their license lapse, and after receiving adequate notice from the Board fails to correct the problem, the failure to maintain active licensure will be considered a violation of this Consent Agreement.

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

B. Respondent Address

It is the responsibility of the Respondent to keep the Board's agent advised, in writing, at all times of their current mailing address, physical address, telephone number, current employment and any change in employment.

Failure to provide notice of any changes within 10 calendar days will constitute grounds for suspension of his or her license in accordance with paragraph 'B' above.

C. Compliance with Laws

Respondent shall obey all federal, state and local laws governing their license.

D. Authorization

Within 10 calendar days of a request by the Board agent, Respondent will sign all authorizations necessary for the release of information required by this Consent Agreement.

E. Good Faith

All parties agree to act in good faith in carrying out the stated intentions of this Consent Agreement.

F. Address of the Board

All required reports or other communication concerning compliance with this Consent Agreement shall be addressed to:

Attn: Holly Handley, Investigator
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
(907) 269-8124 Fax (907) 269-8195

G. Civil Fine

Respondent shall pay a fine of five thousand dollars ($5,000.00). This civil fine is due within 180 days of the adoption of this agreement and is payable to the "State of Alaska" in cash, certified check, or money order or via credit card.

All payments required by this Consent Agreement shall be addressed to:

Erika Prieksat, Chief Investigator
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

//

//

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

IT IS HEREBY FURTHER ORDERED that this Decision and Order shall take effect immediately upon its adoption by the Board of Pharmacy and is a public record of the Board of Pharmacy and the State of Alaska. The State may provide a copy of it to any person or entity, professional licensing board, federal, state, or local government, or other entity making a relevant inquiry.

The action taken by the Board of Pharmacy in this Consent Agreement will be reported to the National Association of Boards of Pharmacy (NABP) and the National Practitioner Data Bank (NPDB) other entities as required by law.

DATED this 5 day of October 2023, at Anchorage, Alaska.

JULIE SANDE, COMMISSIONER

DocuSigned by:
By: Erika Prieksat
34F98CE5F1DF40C...

Erika Prieksat, Chief Investigator for
Sylvan Robb, Director
Division of Corporations, Business and
Professional Licensing

I, TRUEPILL, have read the Consent Agreement, understand it, and agree to be bound by its terms and conditions.

DATED: 20th November 2023

Joseph Alexander Cipriani

SUBSCRIBED AND SWORN TO before me this 20th day of November, 2023, at Newport News, Virginia, Virginia.
(city) (state)

SEAL
COMMONWEALTH OF VIRGINIA · N · ELECTRONIC NOTARY PUBLIC
Winston Ndow
REGISTRATION NUMBER
8040550
COMMISSION EXPIRES
February 28, 2027

Winston Ndow

Notary Public in and for Virginia.
(state)

Winston Ndow
Notary Printed Name

Notarized online using audio-video communication

My commission expires: 02/28/2027

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE BOARD OF PHARMACY

In the Matter of:)
)
Postmeds, Inc. dba TRUEPILL)
)
Respondent)
Case No. 2022-000434

ORDER

The Board of Pharmacy for the State of Alaska, having examined the Consent Agreement and Proposed Decision and Order, Case No. 2022-000434, Respondent, license number #166601, adopts the Consent Agreement and Decision and Order in this matter.

This Consent Agreement takes effect immediately upon signature of this Order in accordance with the approval of the Board of Pharmacy.

The Division may enforce the Consent Agreement by immediately suspending Respondent's license, without an additional order from the Board or without a prior hearing, for a violation of the Consent Agreement.

DATED this 15th day of February, 2024, at Anchorage, Alaska.

Board of Pharmacy

By: Ashley Schaber
Chairperson

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania **Bureau of Professional and** **Occupational Affairs**	
vs.	**Case Nos.** **21-54-004050** **22-54-008273**
PostMeds Inc **Respondent**	

NOTICE

Formal disciplinary action has been filed against you. You may lose your license, certificate, registration or permit to practice your profession or occupation. You may be subject to civil penalties of up to $10,000 for each violation, and the imposition of costs of investigation.

If you wish to defend against the charges in the attached order to show cause or to present evidence to mitigate any penalty that may be imposed, the procedures for doing so are explained in the Order to Show Cause.

You have the right to retain an attorney. Although you may represent yourself without an attorney, you are advised to seek the help of an attorney. You also have the right to have an interpreter provided should you request one.

All proceedings are conducted under the Administrative Agency Law and the General Rules of Administrative Practice and Procedures.

You are directed to respond to the charges by filing a written answer within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause. IF YOU DO NOT FILE AN ANSWER, DISCIPLINARY ACTION MAY BE TAKEN AGAINST YOU WITHOUT A HEARING. Any answer submitted in this matter must be filed with the Prothonotary for the Department of State via one of the following methods:

By Mail:
Prothonotary
Department of State
2601 N Third St
PO Box 2649
Harrisburg, PA 17105-2649

By Facsimile:
(717)772-1892

By E-mail:
ra-prothonotary@pa.gov

You must also send or email a separate copy of your answer and any other pleadings or documents related to this case to the prosecuting attorney named in the Order to Show Cause.

Prothonotary Filed on
May 10 2023 02:10 PM
Department of State

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania **Bureau of Professional and** **Occupational Affairs**		
vs.	**Case Nos.**	**21-54-004050** **22-54-008273**
PostMeds Inc **Respondent**		

ORDER TO SHOW CAUSE

AND NOW, this 10th day of May 2023, **PostMeds Inc** ("Respondent") is hereby ORDERED TO SHOW CAUSE why the Pennsylvania State Board of Pharmacy ("Pennsylvania Board"), upon consideration of the Factual Allegations and the applicable law, should not suspend, revoke or otherwise restrict Respondent's registration, impose a civil penalty, or impose the costs of investigation. This action is brought pursuant to the Pharmacy Act, act of September 27, 1961, P.L. 1700, ("Act"), *as amended*, 63 P.S. §§ 390-1 to 390-13; and 63 Pa.C.S. Chapter 31 ("Chapter 31"); and will be conducted in accordance with the Administrative Agency Law, 2 Pa. C.S. §§ 501-508, 701-704, Chapter 31, and the General Rules of Administrative Practice and Procedure ("GRAPP"), 1 Pa. Code §§ 31.1-35.251.

IT IS FURTHER ORDERED that Respondent file an Answer to this Order to Show Cause in writing within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause, in accordance with Rule 35.37 of GRAPP, 1 Pa. Code § 35.37, *as amended.*

FACTUAL ALLEGATIONS

1. Respondent holds the following registration to practice as a nonresident pharmacy in the Commonwealth of Pennsylvania: registration no. NP000931.

DOS Prothonotary
May 10 2023

2. Respondent's registration was originally issued on July 3, 2017, and it is currently set to expire on August 31, 2023.

3. Absent further action by the Pennsylvania Board, the Respondent's registration may be renewed or reactivated upon the filing of the appropriate documentation and payment of the necessary fees.

4. At all times pertinent to the Factual Allegations, Respondent held a registration to practice as a nonresident pharmacy in the Commonwealth of Pennsylvania.

5. Respondent's last known address on file with the Board is: 3131 Diablo Ave, Hayward, CA 94545.

COUNT ONE

6. Paragraphs 1 through 5 are incorporated by reference.

7. At all relevant and material times, Respondent was authorized to practice as a nonresident pharmacy in the State of North Carolina.

8. On or about March 8, 2022, the State of North Carlina Board of Pharmacy ("North Carolina Board"), by way of Consent Order of Discipline, found Respondent to be in violation of the laws, rules, code and/or regulations of the State of North Carolina because Respondent failed to report a restructuring of ownership to the North Carolina Board.

9. In the March 8, 2022 Consent Order of Discipline, the North Carolina Board voided Respondent's permit from the time it was issued until the time the restructuring began and approved Respondent's change of ownership application as a successor permit.

10. A true and correct copy of the North Carolina Board's March 8, 2022 Consent Order of Discipline is attached as **EXHIBIT A** and is incorporated by reference.

DOS Prothonotary
May 10 2023

11. At all relevant and material times, Respondent was authorized to practice as a nonresident pharmacy in the State of Louisiana.

12. On or about May 11, 2022, the State of Louisiana Board of Pharmacy ("Louisiana Board"), by way of Consent Agreement at Louisiana Board Case Number 21-0456, found Respondent to be in violation of the laws, rules, code and/or regulations of the State of Louisiana because Respondent failed to report a restructuring of ownership to the Louisiana Board.

13. In the May 11, 2022 Consent Agreement, the Louisiana Board imposed a ten thousand dollar ($10,000.00) fine, two hundred fifty dollars ($250.00) in administrative costs, and three hundred twenty-four dollars and forty-eight cents ($324.48) in investigative costs.

14. A true and correct copy of the Louisiana Board's May 11, 2022 Consent Agreement, Louisiana Board Case Number 21-0456, is attached as **EXHIBIT B** and is incorporated by reference.

15. At all relevant and material times, Respondent was authorized to practice as a nonresident pharmacy in the State of Kansas.

16. On or about January 20, 2023, the State of Kansas Board of Pharmacy ("Kansas Board"), by way of Amended Summary Order at Kansas Board Case Number 22-183, found Respondent to be in violation of the laws, rules, code and/or regulations of the State of Kansas because Respondent failed to report a restructuring of ownership to the Kansas Board and failed to report disciplinary actions from North Carolina, Alabama, and California which also pertained to a failure to report a restructuring of ownership to each respeetive Board.

17. In the January 20, 2023 Amended Summary Order, the Kansas Board imposed a three thousand five hundred dollar ($3,500.00) fine.

DOS Prothonotary
May 10 2023

18. A true and correct copy of the Kansas Board's January 20, 2023 Amended Summary Order, Kansas Board Case Number 22-183, is attached as **EXHIBIT C** and is incorporated by reference.

19. Based upon the foregoing Factual Allegations, the Pennsylvania Board is authorized to suspend or revoke, or otherwise restrict Respondent's nonresident pharmacy registration under section 4.1(e) of the Act, 63 P.S. §§ 390-4.1(e); or impose a civil penalty under section 63 Pa.C.S. § 3108(b)(4), and/or impose the costs of investigation under 63 Pa.C.S. § 3108(b)(5), because Respondent violated the Act at section 4.1(g), 63 P.S. § 390-4.1(g), in that Respondent had a permit to conduct a pharmacy suspended or revoked or the nonresident pharmacy was otherwise disciplined by the proper licensing authority of another state.

PENALTIES

If the Pennsylvania Board finds that the Factual Allegations are true and correct, and determines that it has the authority to suspend or revoke the Respondent's registration, the Pennsylvania Board may, in its discretion, impose one or more of the following penalties:

- The revocation, suspension or other restriction of any licenses, certifications, registrations, permits or other authorizations to practice a profession held by Respondent in the Commonwealth of Pennsylvania, or the imposition of any other disciplinary or corrective action that the Act authorizes the Board to impose.
- The imposition of a civil penalty of up to ten thousand dollars ($10,000.00) for each and every violation of the Act. Where criminal proceedings are a basis for a violation of the Act, each count for which the Respondent was convicted may be considered a separate violation of the Act.

DOS Prothonotary
May 10 2023

PROCEDURES

All proceedings are conducted in accordance with the Administrative Agency Law, 2 Pa. C.S. §§ 501-508, 701-704; Chapter 31; and the General Rules of Administrative Practice and Procedure, 1 Pa. Code §§ 31.1-35.251. **RESPONDENT IS HEREBY ORDERED TO FILE A WRITTEN ANSWER TO THIS ORDER TO SHOW CAUSE WITHIN THIRTY (30) DAYS OF THE DATE ON THE MOST RECENT CERTIFICATE OF SERVICE ASSOCIATED WITH THIS ORDER TO SHOW CAUSE.** The Answer shall specifically admit or deny each of the Factual Allegations made herein, and shall set forth the facts and state concisely the matter of law upon which Respondent relies. If Respondent fails to file an Answer within the time allowed herein, the Factual Allegations may be deemed admitted, and the Pennsylvania Board will issue an Order which may impose penalties as set forth above.

If Respondent desires a formal administrative hearing, at which Respondent may defend against the allegations in the Order to Show Cause or to present evidence in mitigation of any penalty which may be imposed upon Respondent or any of Respondent's licenses, certifications, registrations, permits or other authorizations to practice a profession, a written request for hearing must be filed within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause. **IF RESPONDENT FAILS TO FILE A WRITTEN REQUEST FOR HEARING WITHIN THIRTY (30) DAYS OF THE DATE ON THE MOST RECENT CERTIFICATE OF SERVICE ASSOCIATED WITH THIS ORDER TO SHOW CAUSE, RESPONDENT WILL BE DEEMED TO HAVE WAIVED HIS OR HER RIGHT TO A HEARING AND FINAL JUDGMENT MAY BE ENTERED WITHOUT A HEARING.**

If a hearing is scheduled, Respondent will be notified of the specific time and place of the hearing. The hearing will be held before the Board or its duly designated Presiding Officer, in

DOS Prothonotary
May 10 2023

accordance with Section 35.185 of GRAPP, 1 Pa. Code § 35.185. Respondent may appear, with or without counsel, offer testimony or other evidence on his or her behalf, and confront and cross-examine the Commonwealth's witnesses.

Answers, requests for hearings, preliminary motions, protests, petitions to intervene, or any other pleading must be filed with the Prothonotary for the Department of State via one of the following methods:

By Mail:
Prothonotary
Department of State
2601 N Third St
PO Box 2649
Harrisburg, PA 17105-2649

By Facsimile:
(717)772-1892

By E-mail:
ra-prothonotary@pa.gov

Also, you must send or e-mail a separate copy of any documents submitted in this matter to the prosecuting attorney named below at:

By Mail:
Glenn P. Masser
Prosecuting Attorney
Commonwealth of Pennsylvania
Department of State
P.O. Box 69521
Harrisburg, PA 17106-9521

By E-mail:
gmasser@pa.gov

DOS Prothonotary
May 10 2023

Notices and petitions to intervene must be filed within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause, unless in extraordinary circumstances for good cause shown, a later filing is authorized by the agency.

BY ORDER:
DEPARTMENT OF STATE

/s/ Glenn P. Masser
Glenn P. Masser
Prosecuting Attorney
Commonwealth of Pennsylvania
Department of State
P.O. Box 69521
Harrisburg, PA 17106-9521
(717) 783-7200

DATE: 05.10.2023

DOS Prothonotary
May 10 2023

STATE OF NORTH CAROLINA
NORTH CAROLINA BOARD OF PHARMACY

IN THE MATTER OF	)	
	)	
POSTMEDS, INC. d/b/a Truepill,	)	**CONSENT ORDER**
	)	**OF DISCIPLINE**
Permit No. 13413 and Its Successor Permit(s).	)	

THIS MATTER came to be considered before a member of the North Carolina Board of Pharmacy (hereinafter, the "Board") pursuant to 21 N.C.A.C. 46 .2008. The Conference was scheduled for Thursday, February 24, 2022, and, after appropriate notice, was heard on that day by Board member Wallace E. Nelson. Respondent PostMeds, Inc. was informed of its right to be present at the pre-hearing conference and declined. The Board's General Counsel, Clinton R. Pinyan, represented the Board.

Respondent has agreed to waive a formal hearing in the above-referenced matter. It stipulates and agrees to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. By its consent, Respondent also stipulates that it waives its right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order as a basis for the action taken. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. On November 20, 2017, the Board issued Permit No. 13413 to Respondent PostMeds, Inc. d/b/a Truepill (Permit No. 13413) ("PostMeds").

2. On PostMeds' initial permit application, its then-pharmacist manager, Mohammad Umar Afridi, submitted an inaccurate statement that he was the sole owner and officer of PostMeds. In fact, PostMeds now acknowledges that Afridi and Siddharth

4857-7301-1472.v1

DOS Prothonotary.
May 10 2023

3648

Viswanathan each owned 47 percent of PostMeds on November 20, 2017, with others owning six percent, and that Viswanathan was also an officer of PostMeds.

3. Viswanathan and the minority owners' interests would not have raised questions about the permit application in this particular case. If PostMeds had disclosed the true ownership and officers of PostMeds, the Board still would have granted PostMeds a permit. However, it was an inaccurate statement that Afridi, as the person who submitted the application, knew was inaccurate. That statement prevented the Board from vetting Viswanathan as the owner of the pharmacy. Because of the inaccuracy of the representations, the initial permit was void ab initio.

4. In November 2019, PostMeds went through a corporate restructuring. During that restructuring, Truepill, Inc. was created as a holding company for PostMeds. At that time, Truepill, Inc. became the sole owner of PostMeds. Afridi, Viswanathan and the other former direct owners of PostMeds became indirect owners with the same ownership interests in the holding company, Truepill, Inc., that they had before the transfer of ownership.

5. This restructuring required PostMeds to submit a transfer of ownership application and have that application granted before the restructuring closed. PostMeds failed to do this. Therefore, even if the initial permit had been valid (which it was not), it would have become invalid upon the corporate restructuring.

6. Insertion of a new holding company between the ultimate owners and PostMeds would not have raised questions about the permit application in this particular case. The ownership interests of the ultimate owners did not change. If PostMeds had disclosed the new holding company, the Board still would have granted the transfer of ownership. However,

DOS Prothonotary.
May 10 2023

PostMeds failed to submit the transfer of ownership application or otherwise disclose the interests of Truepill, Inc.

7. In each of its subsequent renewals, PostMeds failed to correct the ownership information that it had inaccurately submitted on its initial application or to list Truepill, Inc., as the direct owner of the pharmacy.

8. On November 4, 2021, counsel for PostMeds informed the Board that its "current ownership information on file with the North Carolina Board of Pharmacy is out of date." Upon follow-up questioning, the next day, PostMeds disclosed that it should have submitted a transfer of ownership application in November 2019. It further was apparent from the ownership information that PostMeds provided that Afridi made inaccurate representations about ownership and officers on PostMed's initial application that had never been corrected.

9. PostMeds agreed to stop shipping any drugs, devices or medical equipment into the State of North Carolina until the matter was resolved. It further agreed to stop shipping or dispensing any drugs, devices or medical equipment from six other pharmacies under its ownership until the matter was resolved (even though those pharmacies did not receive permits until after the transfer of ownership had occurred, and so did not suffer from the same problem).

10. PostMeds submitted a transfer of ownership application promptly.

11. Although PostMed's disclosure of its inaccuracies was tardy, its remedial actions are a mitigating factor in this matter.

CONCLUSIONS OF LAW

1. Reporting of correct and complete ownership information on an initial pharmacy permit application or a renewal application is material, indeed essential, to the Board's ability to ensure that a pharmacy will provide services safely and competently to the public.

DOS Prothonotary
May 10 2023

2. PostMeds made inaccurate statements about its ownership and officers on its initial application, which it failed to correct at any point through its 2022 renewal. That initial permit was therefore void ab initio and violated G.S. § 90-85.38(b).

3. The creation of Truepill, Inc. as a holding company further triggered a requirement to report the ownership change and obtain a successor permit, and to do so before the closing of the transaction that created Truepill, Inc. The transaction "result[ed] in a different person . . . owning more than 50 percent interest in the permit holder . . . ." 21 NCAC 46.1603. Failure to apply for and obtain a successor permit prior to the transaction, and a continuing failure to disclose the ownership interest of Truepill, Inc., violated G.S. § 90-85.38(b).

IT IS THEREFORE ORDERED:

PostMeds was in violation of G.S. § 90-85.38(b) in North Carolina from November 20, 2017 until at least November 4, 2021. Respondent PostMed's Permit No. 13413 was **VOID** from the time that it was granted on November 20, 2017. G.S. § 90-85.38(c).

Respondent PostMed's change of ownership application is **APPROVED** as a successor permits to Permit No. 13413 (the "Successor Permit") with the following **CONDITIONS**:

1. PostMeds shall provide timely advance notice of any contemplated change in ownership to the current pharmacist-manager and any future pharmacist-manager(s) of the Successor Permit. PostMeds shall consult with the Successor Permit's pharmacist-manager(s) to determine whether any contemplated transaction triggers the need to obtain new permits. PostMeds shall authorize the Successor Permit's pharmacist-manager(s) to take any necessary action to update that ownership information with the Board or to apply for new permits. If a contemplated transaction triggers the need for new permits, PostMeds shall not complete that

DOS Prothonotary
May 10 2023

3651

transaction unless and until either the Board issues new permits or PostMeds ceases all practice of pharmacy at the permitted location.

2. The Successor Permit shall violate no laws governing the practice of pharmacy or the distribution of drugs.

3. The Successor Permit shall violate no rules or regulations of the Board.

4. If the Successor Permit fail to comply with any term or condition of this Order, it may be subject to additional disciplinary action by the Board.

This is the 8th day of March, 2022

NORTH CAROLINA BOARD OF PHARMACY

By: /s/ William A. Mixon
William A. Mixon
President

DOS Prothonotary:
May 10 2023

Respondent PostMeds, Inc. has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. Respondent freely, knowingly and voluntarily waives its right to such a hearing by entering into this Consent Order.

Respondent understands and agrees that by entering into this Consent Order, it certifies that it has read the foregoing Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions that may be taken concerning this matter.

Respondent further understands that should it violate the terms and conditions of this Consent Order, the Board may take additional action.

Respondent understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

Respondent understands that it has the right to have counsel of its choice review and advise them with respect to their rights and this Consent Order, and represents that it enters this Consent Order after consultation with counsel or after knowingly and voluntarily choosing not to consult with counsel. Respondent further agrees that the person who is executing this Consent Order has been duly authorized by any required corporation action to execute on behalf of Respondent.

CONSENTED TO BY:

M-1 D [signature] Date 3/7/22

Printed Name: Matt Davis-Ratner

Title: General Counsel

DOS Prothonotary:
May 10 2023

STATE OF _____

_____ COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the above-named representative of PostMeds, Inc. personally appeared before me this day, and acknowledged the due execution of the foregoing document.

Date:_____

_____
Notary Public

_____

My commission expires:_____

DOS Prothonotary:
May 10 2023

EXHIBIT B

DOS Prothonotary
May 10 2023

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

POSTMEDS, INC.

LOUISIANA PHARMACY PERMIT NO. 7761 **Case No. 21-0456**

****

CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy (hereinafter referred to as the "Board") on March 16, 2022 at the Board office, 3388 Brentwood Drive, Baton Rouge, LA 70809, in the matter of POSTMEDS, INC. (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 7761, 3121 Diablo Ave., Hayward, CA 94545-2701, with attorney Skip Philips and Postmeds Corporate Counsel Donnie Simkin appearing on behalf of Respondent.

WHEREAS, WHEREAS, on August 27, 2018, the Louisiana Board of Pharmacy issued a non-resident pharmacy permit, PHY.007761-NR, to Postmeds Inc. At that time, Postmeds Inc. was 31.5% owned by Mohammad Umar Afridi, 31.5% owned by Siddharth Viswanathan, 16.5% owned by Initialized III L.P., and 20.5% owned by others with no individual owner holding more than 4%. On December 17, 2021 the Board received an "Application for New Louisiana Pharmacy Permit for Nonresident Pharmacy" from Postmeds, Inc. d/b/a Truepill. Accompanying correspondence and organization chart detailed a 100% change in the ownership structure of Postmeds Inc., effective November 6, 2019. Postmeds Inc. went from being owned 31.5% by Mohammad Umar Afridi, 31.5% by Siddharth Viswanathan, 16.5% by Initialized III L.P., and 20.5% by others with no individual owner holding more than 4%, to being owned 100% by Truepill, Inc.

WHEREAS, the Board alleges that such actions constitute violations of the following:

La. R.S. 37:1241 (A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

La. R.S. 37:1221(B). No out-of-state pharmacy providing pharmacy services to residents of this state shall open, establish, operate, or maintain a pharmacy, located out-of-state, unless the pharmacy is issued a permit by the board.

La. R.S. 37:1222(A). A person applying for a permit to open, establish, operate, or maintain a pharmacy, within or outside of this state, shall complete an application in such form and contain such data as the board may require, and complete such other requirements as deemed necessary by the board, including but not limited to designation and identification of a pharmacist-in-charge.

DOS Prothonotary:
May 10 2023

La. R.S. 37:1222(E). A permit to operate a pharmacy shall not be transferable.

La. R.S. 37:1232(A). A pharmacy located outside this state which does business in this state within the meaning of this Chapter, shall hold a current pharmacy permit as provided in this Chapter. The pharmacy shall be designated a "nonresident pharmacy" and the permit shall be designated a "nonresident pharmacy permit."

LAC, Title 46: LIII §1101(A). Individuals, partnerships, corporations, limited liability companies, or associations desiring to operate a pharmacy in Louisiana, or outside the state where prescriptions drugs/devices are dispensed and delivered to Louisiana residents, shall execute an application for a pharmacy permit for their particular classification of pharmacy.

LAC, Title 46: LIII §1135(A)(1)(e). The holder of a pharmacy permit shall notify the board, in writing, prior to the transfer of ownership, in order for the board to complete an inspection of the pharmacy premises. A change of ownership of a pharmacy is evident under the following conditions: a 50 percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original permit or the last renewal application.

LAC, Title 46: LIII §1135(A)(2). The new owner(s) of the pharmacy shall submit a properly completed pharmacy permit application, with appropriate fee, to the board.

LAC, Title 46: LIII §1135(A)(4). Pharmacy permits are not transferable from the original holder(s) of the permit to the new owner(s).

LAC, Title 46: LIII §2305(A). The out-of-state pharmacy shall apply for a permit and annual permit renewals on forms provided by the board.

LAC, Title 46: LIII §2307(C). Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

To facilitate the submission of this Consent Agreement, Respondent does not contest the allegations and agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

DOS Prothonotary:
May 10 2023

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

POSTMEDS, INC., holder of Louisiana Pharmacy Permit No. 7761, is ordered to pay a fine of $10,000.00 and to reimburse the Board $250.00 for administrative costs, and $324.48 for investigative costs with total payment due the Board of $10,574.80, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter, waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing and to judicial review of this Consent Agreement. Moreover, at no time shall Respondent request the expungement, rescission or removal of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, Matt Davis-Ratner, authorized to act on behalf of and acting on behalf of **POSTMEDS, INC.**, understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

[Remainder of page intentionally left blank; signature page to follow.]

DOS Prothonotary:
May 10 2023

SIGNED, AGREED TO AND ENTERED ON THIS 6th DAY OF April, 2022.

POSTMEDS, INC.
Louisiana Pharmacy Permit No. 7761

Matt Davis-Ratner

BY: Matt Davis-Ratner
Authorized Representative

HARRY J. "SKIP" PHILIPS
Taylor Porter
450 Laurel St, 8th Floor
Baton Rouge, LA 70801
Attorney for Respondent

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on May 11, **2022,** the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Marty R. McKay
Hearing Officer for the Board

DOS Prothonotary.
May 10 2023

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 22-183
PostMeds, Inc dba Truepill	)	
	)	
Registration No. 22-117859	)	

AMENDED SUMMARY ORDER

NOW on this 20th day of January, 2023, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of PostMeds, Inc dba Truepill ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Amended Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 22-104228 which entitled Respondent to operate as a non-resident pharmacy in the State of Kansas.

2. On November 6, 2019, the ownership of Respondent's non-resident pharmacy changed.

3. On May 22, 2020, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 3, 2020 with an expiration date of June 30, 2021. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?"

DOS Prothonotary:
May 10 2023

Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

4. On June 1, 2021, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 21, 2021 with an expiration date of June 30, 2022. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?" Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

5. Due to staffing challenges, personnel turnover and administrative oversight resulting from its early, rapid growth and restructuring and the corresponding COVID-19 pandemic, Respondent mistakenly failed to report the 2019 ownership change and related disclosures to the Board in its May 22, 2020 and June 1, 2021 renewal applications.

6. On April 18, 2022, the Board received notification from Respondent of an ownership change and several past disciplinary actions not previously reported to the Board including: North Carolina Board of Pharmacy Consent Order of Discipline dated March 8, 2022; California State Board of Pharmacy Letter of Admonishment dated January 23, 2020; California State Board of Pharmacy Citation and Fine dated June 16, 2020; California State Board of Pharmacy Citation and Fine Order of Abatement dated August 25, 2021; Alabama State Board of Pharmacy Final Order dated October 25, 2021; California State Board of Pharmacy Citation and Fine dated January 24, 2019; and California State Board of Pharmacy Citation dated December 16, 2019.

DOS Prothonotary:
May 10 2023

7. On April 28, 2022, the Board received from Respondent a Form BA-22 Non-Resident Pharmacy Registration Application ("Respondent's Application"), notifying of the change in ownership effective November 6, 2019, and applying for a new non-resident pharmacy registration under the new ownership.

8. On May 20, 2022, the Board approved Respondent's Application and issued Respondent the new Non-Resident Pharmacy Registration No. of 22-117859 ("Respondent's Registration") under their new ownership.

9. Prior to receiving the ownership change application, registrant provided a letter notifying of the late ownership change, as well as unreported discipline. Ownership change application completed indicating discipline had occurred and providing details of discipline (5 occurrences).

10. In mitigation, Respondent states that it has invested in additional staff, engaged internal and external legal counsel and implemented training efforts to prevent any such reporting oversights in the future.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against a registration on any ground that would authorize the board to take action against the registration of a pharmacy under K.S.A. 65-1627, and amendments thereto.

3. Pursuant to K.S.A. 65-1627(e)(1), the Board may take action against the registration of a pharmacy upon a finding that such pharmacy has been operated in such manner

DOS Prothonotary:
May 10 2023

that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith.

4. Pursuant to K.S.A. 65-1627(e)(4), the Board may take action against the registration of a pharmacy upon a finding that the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country.

5. Pursuant to K.S.A. 65-1657, no nonresident pharmacy shall ship, mail, or deliver, in any manner, prescription drugs to a patient in this state unless registered with the Board as a nonresident pharmacy.

6. Pursuant to K.S.A. 65-1645(f), registrations shall not be transferable.

7. Pursuant to K.A.R. 68-2-9, each registrant shall notify the executive secretary of the Board in writing of any change in majority ownership of the operation for which the registration was issued within five days after the date the change in ownership becomes effective.

8. Pursuant to K.A.R. 68-2-23, each pharmacy owner shall notify the board in writing within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against the pharmacy or the pharmacy owner or any application, license, registration, or permit held by the pharmacy owner.

9. Respondent's registered facility changed ownership on November 6, 2019 but Respondent did not provide notification or file a new application with the Board until April 18 and 28, 2022, respectively.

10. Respondent's failure to submit the complete change of ownership to the Board until April 2022 is a violation pursuant to K.A.R. 68-2-9 and an unlawful transfer of the previous

DOS Prothonotary:
May 10 2023

registration to the new ownership. Respondent's actions are a violation pursuant to K.S.A. 65-1657 and K.S.A. 65-1627(e)(1), and a basis to take action against Respondent's Registration.

11. Respondent failed to notify the Board of the six disciplinary actions by North Carolina, California, and Alabama until April 18, 2022, nearly one to two years after they were effective, is a violation of K.A.R. 68-2-23 and a basis to take action against Respondent's Registration pursuant to K.S.A. 65-1627(e)(1) and (e)(4).

ORDER

Taking into account the mitigating and corrective actions of Respondent, the Board finds and concludes that Respondent's conduct, as described above, violates the Act and such conduct warrants the imposition of a fine pursuant to K.S.A. 65-1658, in the amount of $3,500.00. Respondent has 30 days from the date of this order to pay the fine.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

DOS Prothonotary:
May 10 2023

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS. 66612

IT IS SO ORDERED.

1/20/2023
Date

Kansas Board of Pharmacy

DOS Prothonotary:
May 10 2023

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 24th day of January, 2023, deposit in business mail a copy of the foregoing Amended Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

PostMeds, Inc dba Truepill
3121 Diablo Ave.
Hayward, CA 94545

and via email to:

Christopher C. Tillery
Seigfreid Bingham, P.C.
ctillery@sb-kc.com
Attorney for Respondent

Brenda L. Head
Disciplinary Counsel for the Kansas Board of Pharmacy

DOS Prothonotary:
May 10 2023

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania **Bureau of Professional and** **Occupational Affairs**		
vs.	**Case Nos.**	**21-54-004050** **22-54-008273**
PostMeds Inc **Respondent**		

CERTIFICATE OF SERVICE

I, Glenn P. Masser, hereby certify that I have this 11th day of May 2023 caused a true and correct copy of the foregoing Notice and Order to Show Cause to be served upon all parties of record in this proceeding in accordance with the requirements of Rule 33.31 of the General Rules of Administrative Practice and Procedure, 1 Pa. Code § 33.31 (relating to service by the agency).

CERTIFIED MAIL, ELECTRONIC RETURN RECEIPT REQUESTED AND FIRST-CLASS MAIL, POSTAGE PREPAID:

PostMeds Inc
3121 Diablo Ave
Hayward, CA 94545
9171.9690.0935.0253.8568.95

/s/ Glenn P. Masser
Glenn P. Masser
Prosecuting Attorney
Commonwealth of Pennsylvania
Department of State
P. O. Box 69521
Harrisburg, PA 17106-9521
(717) 783-7200

DOS Prothonotary
May 10 2023

DocuSign Envelope ID: 660533CB-A6C4-4E95-9C2C-6E586D48D9DF

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
POSTMEDS INC. dba TRUEPILL and/or TRUEPILL f/k/a POSTMEDS INC.	)	
	)	
Non-Resident Pharmacy Permit Number: 114861	)	**CASE NO: 22-L-0114**

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975), § 41-22-12(f), the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** has violated the provisions of law set out in the Statement.

2. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** shall pay an administrative fine in the amount of Three Thousand Dollars ($3,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** attempt to discharge the same. Payments shall be made payable to Alabama State Board of Pharmacy and mailed to 111 Village Street, Birmingham, Alabama 35242.

3. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama

DocuSign Envelope ID: 660533CB-A6C4-4E95-9C2C-6E586D48D9DF

Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), §20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** further waives any objection to the attorney for the Board preparing, drafting, or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** hereby releases the Board, its members, agents, representatives, servants, and employees from any and all liability, claims, damages, fees, or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.'s** permit, including, but not limited to revocation.

6. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** acknowledges and agrees that it has read this Consent Order and that it fully understands the terms, conditions, and contents of the same. **PostMeds Inc. dba Truepill and/or**

DocuSign Envelope ID: 660533CB-A6C4-4E95-9C2C-6E586D48D9DF

Truepill f/k/a PostMeds Inc. acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and agrees that it had the right to seek advice of counsel before executing this Consent Order.

DONE this the 6th of June, 2023.

PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.

BY: Donny Sinkin
Donny Sinkin

ITS: General Counsel, Truepill, Inc.

James Hoover
Counsel for **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.**

DONE this the 8th of JUNE, 2023.

ALABAMA STATE BOARD OF PHARMACY

By:
Robert M. Colburn, Jr., R. Ph., President

Jennifer Muro Neumann,
Attorney for the Alabama State Board of Pharmacy

OF COUNSEL:
Jennifer Muro Neumann, PC
Post Office Box 381082
Birmingham, AL 35238
(205) 451-3092

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 22-183
PostMeds, Inc dba Truepill	)	
	)	
Registration No. 22-117859	)	

AMENDED SUMMARY ORDER

NOW on this 20th day of January, 2023, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of PostMeds, Inc dba Truepill ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Amended Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 22-104228 which entitled Respondent to operate as a non-resident pharmacy in the State of Kansas.

2. On November 6, 2019, the ownership of Respondent's non-resident pharmacy changed.

3. On May 22, 2020, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 3, 2020 with an expiration date of June 30, 2021. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?"

Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

4. On June 1, 2021, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 21, 2021 with an expiration date of June 30, 2022. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?" Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

5. Due to staffing challenges, personnel turnover and administrative oversight resulting from its early, rapid growth and restructuring and the corresponding COVID-19 pandemic, Respondent mistakenly failed to report the 2019 ownership change and related disclosures to the Board in its May 22, 2020 and June 1, 2021 renewal applications.

6. On April 18, 2022, the Board received notification from Respondent of an ownership change and several past disciplinary actions not previously reported to the Board including: North Carolina Board of Pharmacy Consent Order of Discipline dated March 8, 2022; California State Board of Pharmacy Letter of Admonishment dated January 23, 2020; California State Board of Pharmacy Citation and Fine dated June 16, 2020; California State Board of Pharmacy Citation and Fine Order of Abatement dated August 25, 2021; Alabama State Board of Pharmacy Final Order dated October 25, 2021; California State Board of Pharmacy Citation and Fine dated January 24, 2019; and California State Board of Pharmacy Citation dated December 16, 2019.

7. On April 28, 2022, the Board received from Respondent a Form BA-22 Non-Resident Pharmacy Registration Application ("Respondent's Application"), notifying of the change in ownership effective November 6, 2019, and applying for a new non-resident pharmacy registration under the new ownership.

8. On May 20, 2022, the Board approved Respondent's Application and issued Respondent the new Non-Resident Pharmacy Registration No. of 22-117859 ("Respondent's Registration") under their new ownership.

9. Prior to receiving the ownership change application, registrant provided a letter notifying of the late ownership change, as well as unreported discipline. Ownership change application completed indicating discipline had occurred and providing details of discipline (5 occurrences).

10. In mitigation, Respondent states that it has invested in additional staff, engaged internal and external legal counsel and implemented training efforts to prevent any such reporting oversights in the future.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against a registration on any ground that would authorize the board to take action against the registration of a pharmacy under K.S.A. 65-1627, and amendments thereto.

3. Pursuant to K.S.A. 65-1627(e)(1), the Board may take action against the registration of a pharmacy upon a finding that such pharmacy has been operated in such manner

that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith.

4. Pursuant to K.S.A. 65-1627(e)(4), the Board may take action against the registration of a pharmacy upon a finding that the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country.

5. Pursuant to K.S.A. 65-1657, no nonresident pharmacy shall ship, mail, or deliver, in any manner, prescription drugs to a patient in this state unless registered with the Board as a nonresident pharmacy.

6. Pursuant to K.S.A. 65-1645(f), registrations shall not be transferable.

7. Pursuant to K.A.R. 68-2-9, each registrant shall notify the executive secretary of the Board in writing of any change in majority ownership of the operation for which the registration was issued within five days after the date the change in ownership becomes effective.

8. Pursuant to K.A.R. 68-2-23, each pharmacy owner shall notify the board in writing within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against the pharmacy or the pharmacy owner or any application, license, registration, or permit held by the pharmacy owner.

9. Respondent's registered facility changed ownership on November 6, 2019 but Respondent did not provide notification or file a new application with the Board until April 18 and 28, 2022, respectively.

10. Respondent's failure to submit the complete change of ownership to the Board until April 2022 is a violation pursuant to K.A.R. 68-2-9 and an unlawful transfer of the previous

registration to the new ownership. Respondent's actions are a violation pursuant to K.S.A. 65-1657 and K.S.A. 65-1627(e)(1), and a basis to take action against Respondent's Registration.

11. Respondent failed to notify the Board of the six disciplinary actions by North Carolina, California, and Alabama until April 18, 2022, nearly one to two years after they were effective, is a violation of K.A.R. 68-2-23 and a basis to take action against Respondent's Registration pursuant to K.S.A. 65-1627(e)(1) and (e)(4).

ORDER

Taking into account the mitigating and corrective actions of Respondent, the Board finds and concludes that Respondent's conduct, as described above, violates the Act and such conduct warrants the imposition of a fine pursuant to K.S.A. 65-1658, in the amount of $3,500.00. Respondent has 30 days from the date of this order to pay the fine.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

1/20/2023
Date

Alex Blasi
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 24th day of January, 2023, deposit in business mail a copy of the foregoing Amended Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

PostMeds, Inc dba Truepill
3121 Diablo Ave
Hayward, CA 94545

and via email to:

Christopher C. Tillery
Seigfreid Bingham, P.C.
ctillery@sb-kc.com
Attorney for Respondent

Brenda L. Head
Disciplinary Counsel for the Kansas Board of Pharmacy

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

POSTMEDS, INC.

LOUISIANA PHARMACY PERMIT NO. 7761 **Case No. 21-0456**

****

CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy (hereinafter referred to as the "Board") on March 16, 2022 at the Board office, 3388 Brentwood Drive, Baton Rouge, LA 70809, in the matter of POSTMEDS, INC. (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 7761, 3121 Diablo Ave., Hayward, CA 94545-2701, with attorney Skip Philips and Postmeds Corporate Counsel Donnie Simkin appearing on behalf of Respondent.

WHEREAS, WHEREAS, on August 27, 2018, the Louisiana Board of Pharmacy issued a non-resident pharmacy permit, PHY.007761-NR, to Postmeds Inc. At that time, Postmeds Inc. was 31.5% owned by Mohammad Umar Afridi, 31.5% owned by Siddharth Viswanathan, 16.5% owned by Initialized III L.P., and 20.5% owned by others with no individual owner holding more than 4%. On December 17, 2021 the Board received an "Application for New Louisiana Pharmacy Permit for Nonresident Pharmacy" from Postmeds, Inc. d/b/a Truepill. Accompanying correspondence and organization chart detailed a 100% change in the ownership structure of Postmeds Inc., effective November 6, 2019. Postmeds Inc. went from being owned 31.5% by Mohammad Umar Afridi, 31.5% by Siddharth Viswanathan, 16.5% by Initialized III L.P., and 20.5% by others with no individual owner holding more than 4%, to being owned 100% by Truepill, Inc.

WHEREAS, the Board alleges that such actions constitute violations of the following:

La. R.S. 37:1241 (A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

La. R.S. 37:1221(B). No out-of-state pharmacy providing pharmacy services to residents of this state shall open, establish, operate, or maintain a pharmacy, located out-of-state, unless the pharmacy is issued a permit by the board.

La. R.S. 37:1222(A). A person applying for a permit to open, establish, operate, or maintain a pharmacy, within or outside of this state, shall complete an application in such form and contain such data as the board may require, and complete such other requirements as deemed necessary by the board, including but not limited to designation and identification of a pharmacist-in-charge.

La. R.S. 37:1222(E). A permit to operate a pharmacy shall not be transferable.

La. R.S. 37:1232(A). A pharmacy located outside this state which does business in this state within the meaning of this Chapter, shall hold a current pharmacy permit as provided in this Chapter. The pharmacy shall be designated a "nonresident pharmacy" and the permit shall be designated a "nonresident pharmacy permit."

LAC, Title 46: LIII §1101(A). Individuals, partnerships, corporations, limited liability companies, or associations desiring to operate a pharmacy in Louisiana, or outside the state where prescriptions drugs/devices are dispensed and delivered to Louisiana residents, shall execute an application for a pharmacy permit for their particular classification of pharmacy.

LAC, Title 46: LIII §1135(A)(1)(e). The holder of a pharmacy permit shall notify the board, in writing, prior to the transfer of ownership, in order for the board to complete an inspection of the pharmacy premises. A change of ownership of a pharmacy is evident under the following conditions: a 50 percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original permit or the last renewal application.

LAC, Title 46: LIII §1135(A)(2). The new owner(s) of the pharmacy shall submit a properly completed pharmacy permit application, with appropriate fee, to the board.

LAC, Title 46: LIII §1135(A)(4). Pharmacy permits are not transferable from the original holder(s) of the permit to the new owner(s).

LAC, Title 46: LIII §2305(A). The out-of-state pharmacy shall apply for a permit and annual permit renewals on forms provided by the board.

LAC, Title 46: LIII §2307(C). Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

To facilitate the submission of this Consent Agreement, Respondent does not contest the allegations and agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

POSTMEDS, INC., holder of Louisiana Pharmacy Permit No. 7761, is ordered to pay a fine of $10,000.00 and to reimburse the Board $250.00 for administrative costs, and $324.48 for investigative costs with total payment due the Board of $10,574.80, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter, waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing and to judicial review of this Consent Agreement. Moreover, at no time shall Respondent request the expungement, rescission or removal of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, Matt Davis-Ratner, authorized to act on behalf of and acting on behalf of **POSTMEDS, INC.**, understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

[Remainder of page intentionally left blank; signature page to follow.]

SIGNED, AGREED TO AND ENTERED ON THIS 6th DAY OF April, 2022.

POSTMEDS, INC.
Louisiana Pharmacy Permit No. 7761

Matt Davis-Ratner

BY: Matt Davis-Ratner
Authorized Representative

HARRY J. "SKIP" PHILIPS
Taylor Porter
450 Laurel St, 8th Floor
Baton Rouge, LA 70801
Attorney for Respondent

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

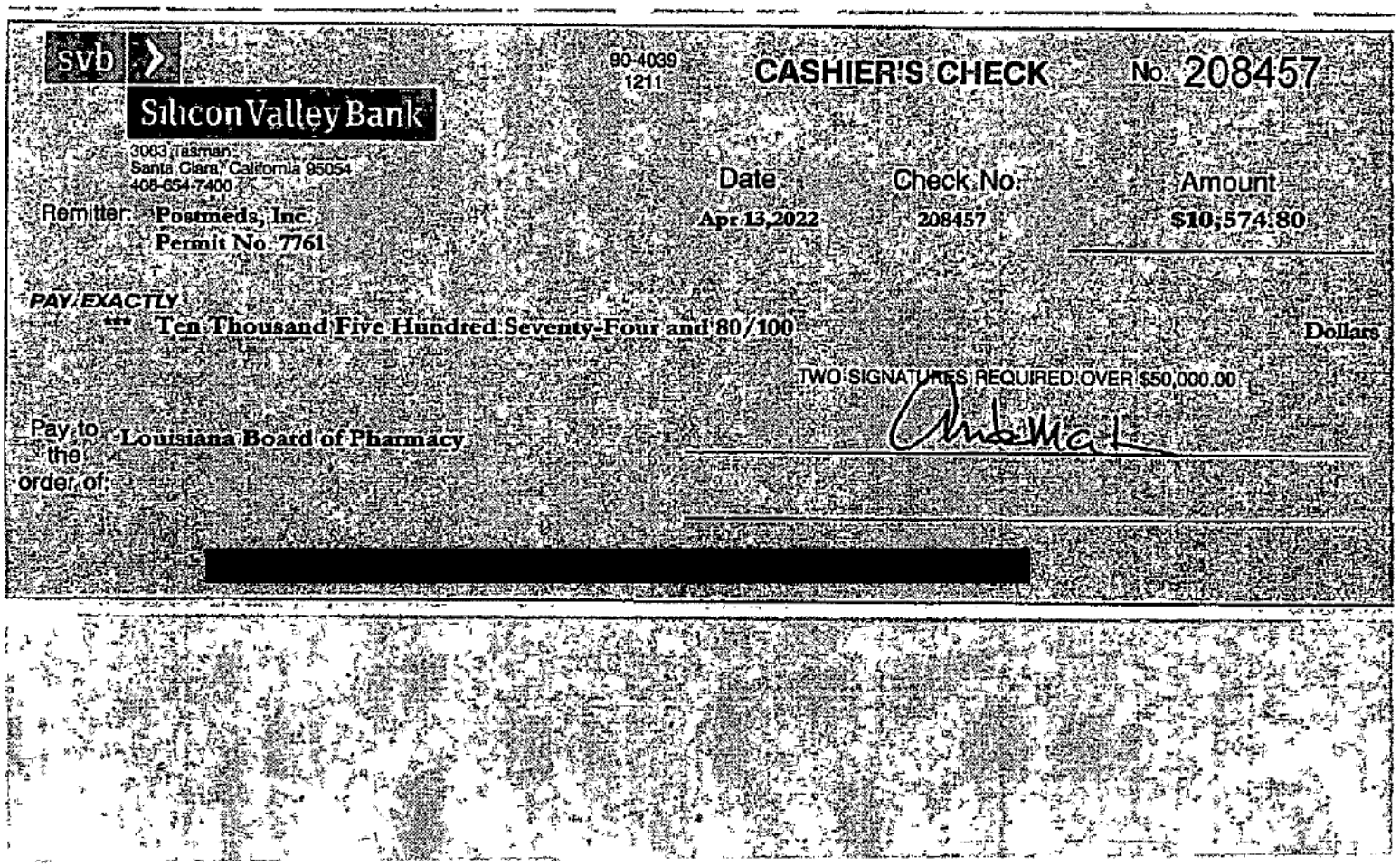
CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on May 11, **2022**, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Marty R. McKay
Hearing Officer for the Board



svb

Silicon Valley Bank

3003 Tasman
Santa Clara, California 95054
408-654-7400

90-4039
1211

CASHIER'S CHECK

No. 208457

Date	Check No.	Amount
Apr 13,2022	208457	$10,574.80

Remitter: Postmeds, Inc.
Permit No. 7761

PAY EXACTLY
*** Ten Thousand Five Hundred Seventy-Four and 80/100 Dollars

TWO SIGNATURES REQUIRED OVER $50,000.00

Pay to the order of: Louisiana Board of Pharmacy

[redacted]

STATE OF NORTH CAROLINA
NORTH CAROLINA BOARD OF PHARMACY

IN THE MATTER OF	)	
	)	
POSTMEDS, INC. d/b/a Truepill,	)	**CONSENT ORDER**
	)	**OF DISCIPLINE**
Permit No. 13413 and Its Successor Permit(s).	)	

THIS MATTER came to be considered before a member of the North Carolina Board of Pharmacy (hereinafter, the "Board") pursuant to 21 N.C.A.C. 46 .2008. The Conference was scheduled for Thursday, February 24, 2022, and, after appropriate notice, was heard on that day by Board member Wallace E. Nelson. Respondent PostMeds, Inc. was informed of its right to be present at the pre-hearing conference and declined. The Board's General Counsel, Clinton R. Pinyan, represented the Board.

Respondent has agreed to waive a formal hearing in the above-referenced matter. It stipulates and agrees to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. By its consent, Respondent also stipulates that it waives its right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order as a basis for the action taken. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. On November 20, 2017, the Board issued Permit No. 13413 to Respondent PostMeds, Inc. d/b/a Truepill (Permit No. 13413) ("PostMeds").

2. On PostMeds' initial permit application, its then-pharmacist manager, Mohammad Umar Afridi, submitted an inaccurate statement that he was the sole owner and officer of PostMeds. In fact, PostMeds now acknowledges that Afridi and Siddharth

Viswanathan each owned 47 percent of PostMeds on November 20, 2017, with others owning six percent, and that Viswanathan was also an officer of PostMeds.

3. Viswanathan and the minority owners' intcrests would not have raised questions about the permit application in this particular case. If PostMeds had disclosed the true ownership and officers of PostMeds, the Board still would have granted PostMeds a permit. However, it was an inaccurate statement that Afridi, as the person who submitted the application, knew was inaccurate. That statement prevented the Board from vetting Viswanathan as the owner of the pharmacy. Because of the inaccuracy of the representations, the initial permit was void ab initio.

4. In November 2019, PostMeds went through a corporate restructuring. During that restructuring, Truepill, Inc. was created as a holding company for PostMeds. At that time, Truepill, Inc. became the sole owner of PostMeds. Afridi, Viswanathan and the other former direct owners of PostMeds became indirect owners with the same ownership interests in the holding company, Truepill, Inc., that they had before the transfer of ownership.

5. This restructuring required PostMeds to submit a transfer of ownership application and have that application granted before the restructuring closed. PostMeds failed to do this. Therefore, even if the initial permit had been valid (which it was not), it would have become invalid upon the corporate restructuring.

6. Insertion of a new holding company between the ultimate owners and PostMeds would not have raised questions about the permit application in this particular case. The ownership interests of the ultimate owners did not change. If PostMeds had disclosed the new holding company, the Board still would have granted the transfer of ownership. However,

PostMeds failed to submit the transfer of ownership application or otherwise disclose the interests of Truepill, Inc.

7. In each of its subsequent renewals, PostMeds failed to correct the ownership information that it had inaccurately submitted on its initial application or to list Truepill, Inc., as the direct owner of the pharmacy.

8. On November 4, 2021, counsel for PostMeds informed the Board that its "current ownership information on file with the North Carolina Board of Pharmacy is out of date." Upon follow-up questioning, the next day, PostMeds disclosed that it should have submitted a transfer of ownership application in November 2019. It further was apparent from the ownership information that PostMeds provided that Afridi made inaccurate representations about ownership and officers on PostMed's initial application that had never been corrected.

9. PostMeds agreed to stop shipping any drugs, devices or medical equipment into the State of North Carolina until the matter was resolved. It further agreed to stop shipping or dispensing any drugs, devices or medical equipment from six other pharmacies under its ownership until the matter was resolved (even though those pharmacies did not receive permits until after the transfer of ownership had occurred, and so did not suffer from the same problem).

10. PostMeds submitted a transfer of ownership application promptly.

11. Although PostMed's disclosure of its inaccuracies was tardy, its remedial actions are a mitigating factor in this matter.

CONCLUSIONS OF LAW

1. Reporting of correct and complete ownership information on an initial pharmacy permit application or a renewal application is material, indeed essential, to the Board's ability to ensure that a pharmacy will provide services safely and competently to the public.

2. PostMeds made inaccurate statements about its ownership and officers on its initial application, which it failed to correct at any point through its 2022 renewal. That initial permit was therefore void ab initio and violated G.S. § 90-85.38(b).

3. The creation of Truepill, Inc. as a holding company further triggered a requirement to report the ownership change and obtain a successor permit, and to do so before the closing of the transaction that created Truepill, Inc. The transaction "result[ed] in a different person . . . owning more than 50 percent interest in the permit holder . . . ." 21 NCAC 46.1603. Failure to apply for and obtain a successor permit prior to the transaction, and a continuing failure to disclose the ownership interest of Truepill, Inc., violated G.S. § 90-85.38(b).

IT IS THEREFORE ORDERED:

PostMeds was in violation of G.S. § 90-85.38(b) in North Carolina from November 20, 2017 until at least November 4, 2021. Respondent PostMed's Permit No. 13413 was **VOID** from the time that it was granted on November 20, 2017. G.S. § 90-85.38(c).

Respondent PostMed's change of ownership application is **APPROVED** as a successor permits to Permit No. 13413 (the "Successor Permit") with the following **CONDITIONS:**

1. PostMeds shall provide timely advance notice of any contemplated change in ownership to the current pharmacist-manager and any future pharmacist-manager(s) of the Successor Permit. PostMeds shall consult with the Successor Permit's pharmacist-manager(s) to determine whether any contemplated transaction triggers the need to obtain new permits. PostMeds shall authorize the Successor Permit's pharmacist-manager(s) to take any necessary action to update that ownership information with the Board or to apply for new permits. If a contemplated transaction triggers the need for new permits, PostMeds shall not complete that

transaction unless and until either the Board issues new permits or PostMeds ceases all practice of pharmacy at the permitted location.

2. The Successor Permit shall violate no laws governing the practice of pharmacy or the distribution of drugs.

3. The Successor Permit shall violate no rules or regulations of the Board.

4. If the Successor Permit fail to comply with any term or condition of this Order, it may be subject to additional disciplinary action by the Board.

This is the 8th day of March, 2022

NORTH CAROLINA BOARD OF PHARMACY

By: /s/ William A. Mixon
William A. Mixon
President

Respondent PostMeds, Inc. has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. Respondent freely, knowingly and voluntarily waives its right to such a hearing by entering into this Consent Order.

Respondent understands and agrees that by entering into this Consent Order, it certifies that it has read the foregoing Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions that may be taken concerning this matter.

Respondent further understands that should it violate the terms and conditions of this Consent Order, the Board may take additional action.

Respondent understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

Respondent understands that it has the right to have counsel of its choice review and advise them with respect to their rights and this Consent Order, and represents that it enters this Consent Order after consultation with counsel or after knowingly and voluntarily choosing not to consult with counsel. Respondent further agrees that the person who is executing this Consent Order has been duly authorized by any required corporation action to execute on behalf of Respondent.

CONSENTED TO BY:

_____ Date 3/7/22

Printed Name: Matt Davis-Ratner

Title: General Counsel

STATE OF _____

_____ COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the above-named representative of PostMeds, Inc. personally appeared before me this day, and acknowledged the due execution of the foregoing document.

Date:_____

_____
Notary Public

_____

My commission expires:_____

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

August 25, 2021

TRUEPILL
ATTN: FRANCESCO CONSOLE, PIC
3121 DIABLO AVE
HAYWARD, CA 94545

RE: CI 2020 89223
TRUEPILL
PHY 56100

The attached Citation CI 2020 89223, has been issued to TRUEPILL, PHY 56100. A copy has been sent to the pharmacy, and a copy is being sent to the pharmacist-in-charge for informational purposes only. As pharmacist in charge it is your responsibility to insure the pharmacy's compliance with the term(s) and condition(s) of the citation by the date(s) ordered, and to ensure the pharmacy's compliance with all pharmacy laws.

The Citation references the specific statutes and regulations violated, and defines each violation charged. The Citation details the conduct that resulted in the issuance of the citation. In addition the citation may also include information regarding fine(s) assessed. If fine(s) have been assessed, the citation specifies the amount and the specific violation for which the fine was levied.

If you have any questions please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

Sincerely

Joshua Monforte
Citation and Fine Analyst

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE
ORDER OF ABATEMENT

COPY

Citation Number	Name, License No
CI 2020 89223	TRUEPILL, PHY 56100

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1714 subd. (b)	Operational Standards and Security; pharmacy responsible for pharmacy security	$5,000.00
Bus. & Prof. Code § 4169 subd. (a)(2)/Health & Safety Code § 111295	Prohibited Acts; Purchase, trade, sell, or transfer dangerous drugs to that the person knew or reasonably should have known were adulterated.../It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated	Citation without a fine

CONDUCT:

California Code of Regulations 1714, section b states, (b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy. Specifically, Truepill Pharmacy, PHY56100, located at 3121 Diablo Ave, Hayward, CA 94545 was in violation when they failed to keep dangerous drugs stored according to policy and procedure 2001.4, Oversight of Pharmacy Safety, which states: "The Pharmacy will make all attempts at maintaining a room temperature below 85F and ideally between 68-77F". Between 7/1/2020 and 9/14/2020, on numerous occasions, dangerous drug storage temperatures, summarized in Table 2, exceeded the recommended storage temperatures. The most egregious of these temperature spikes were:

a) On 8/13/2020, in the cage area of the warehouse, dangerous drugs were stored approximately 161 hours over 77 F and 47 hours over 85F.
b) On 9/6/2020, in the cage area of the warehouse, dangerous drugs were stored approximately 59 hours over 77 F and 17 hours above 85F.
c) On 8/13/2020, in the Parata Automated dispensing machine located in the warehouse, dangerous drugs were stored for approximately 163 hours above 77 F and 44 hours above 85 F.

Business and Professions Code 4169 section (a), subdivision (2) states, A person or entity shall not do any of the following: (2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code as it relates to Health and Safety Code 111295 which states, It is unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug or device that is adulterated. Specifically, Truepill Pharmacy, PHY56100, located at3121 Diablo Ave, Hayward, CA 94545 was in violation when they used the MKT calculation alone instead of in conjunction with manufactures stability data as stated in USP <1079>, which provides guidance for assessing possible adulteration to dangerous drugs stored at the pharmacy due to excessive heat. In particular, USP<1079> states, "Knowing the MKT for an excursion is useful for evaluating the potential impact on product quality. However, it is also essential to know the upper and lower temperature limits of any excursion. If these extreme temperatures are outside available stability data, it may not be possible to predict the quality impact of the excursion with any confidence regardless of the MKT. At higher temperatures the kinetics of degradation may change or new degradation reactions may occur. Truepill Pharmacy did not consider the manufacture's stability data for at least 72 dangerous drugs stored in the cage area of the warehouse which were held and offered for sale when determining if a dangerous drug was adulterated by the extreme heat, summarized in Table 3. For each one of the 72 dangerous drugs, the maximum temperature for storage was listed by the manufacturer as 77F or storage information was not listed. As there was no stability temperature for at least the 72 drugs in question and per USP<1079>, the MKT cannot be without the stability data, these drugs which were held and offered for sale were adulterated.

ORDER OF ABATEMENT

By the Abatement date/payment date submit to the Board the following:

- Either (1) full payment of the assessed fine(s) in the amount of $5,000.00; or payment in the amount of $1,000.00 and (2) provide proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within ninety (90) days.

COPY

If you choose option (2), within 90 days of this citation, you shall submit proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations. Any failure to do so shall be deemed a failure to meet the abatement requirements of this citation.

If you timely submit proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within 90 days from the date the citation was issued, this citation shall be reduced to $1,000.00 and proof of compliance of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations shall be considered satisfactory abatement of the citation.

If you fail to submit proof of compliance of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within 90 days from the date the citation was issued, the stay shall be lifted and the fine(s) in the amount of $5,000.00 shall be due and owing from you within thirty (30) days of any such failure.

CITATION ISSUED ON: August 25, 2021	TOTAL AMOUNT OF FINE(S): $5,000.00
PROOF OF ABATEMENT AND PAYMENT OF FINE(S) DUE BY: September 24, 2021	

COPY

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

January 23, 2020

VIA CERTIFIED MAIL

LETTER OF ADMONISHMENT

TRUEPILL
ATTN: MOHAMMAD UMAR AFRIDI, CEO
3121 DIABLO AVE
HAYWARD, CA 94545

RE: CI 2019 84877
TRUEPILL
PHY 56100

This LETTER OF ADMONISHMENT is being issued pursuant to Business and Professions Code section 4315 for failure to comply with the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the board's website at www.pharmacy.ca.gov, under Forms and Publications.)

The Board of Pharmacy has completed its investigation in the above referenced matter. All documentation and/or statements relating to the investigation have been accepted and included in an Investigation Report on file in this office. Facts contained in this report lead to the conclusion that the following violations of pharmacy laws or regulations have occurred:

JURISDICTION: Bus. & Prof. Code § 4315; 1764/56.10(a) - Unauthorized disclosure of prescription and medical information

Unauthorized disclosure of prescriptions: California Code of Regulations section 1764 states in pertinent part that no pharmacist shall exhibit, discuss, or reveal the contents of any prescription or any medical information furnished by the prescriber with any person other than the patient or his or her authorized representative and Civil Code section 56.10 subdivision (a) states, in pertinent part, no provider of health care shall disclose medical information regarding a patient of the provider of health care without first obtaining an authorization. Truepill Pharmacy was not in compliance with these regulations. Specifically, on 4/17/2019, Truepill Pharmacy (PHY56100) located at 3121 Diablo Avenue in Hayward, CA shipped prescription RX#1186395 to the wrong person. The prescription was intended for AR but was shipped to the address of MS in error. Also, Truepill Pharmacy shipped prescriptions to patients with a shipping label showing the return address of NuRx located at 6838 Ellicott Drive in East Syracuse, NY and from Apostrophe located at 330 2nd Street in Oakland, CA. NuRx and Apostrophe are not licensed pharmacies and prescription packages returned as undeliverable to these locations would cause the disclosure of medical information without authorization.

Shipping prescriptions to an unauthorized person violates California Code of Regulations section 1764 and Civil Code 56.10.

If you wish to contest this Letter of Admonishment, you may do so by submitting, within 30 days of the date of service of this Letter of Admonishment, namely February 22, 2020, the attached "Request for an Office Conference" form. If an office conference is not requested, compliance with the Letter of Admonishment shall not constitute an admission of the violations described in the Letter of Admonishment.

Unless it is dismissed following an office conference or you receive other instructions from the Board in writing, Pharmacy Law requires that you maintain and have readily available for inspection a copy of this Letter of Admonishment and any written corrective action plan, if any, for at least three years from the date of issuance at the top of this letter. The Letter of Admonishment will be considered a public record for purposes of disclosure for three years from issuance. The issuance of this Letter of Admonishment does not limit the board's ability to pursue other disciplinary or administrative action under Business and Professions Code section 4315, subdivision (f).

If you have any questions regarding this Letter of Admonishment, please contact Barbera Schleicher, Public Inquiry Analyst at (916) 518-3081.

Sincerely

Virginia Herold
Executive Officer
Board of Pharmacy

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

MODIFIED CITATION AND FINE

Citation Number	Name, License No
CI 2017 78633	TRUEPILL (FORMERLY POSTMEDS INC.), PHY 56100

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059 subd. (a)/Bus. & Prof. Code § 4067 subd. (a)	Furnishing dangerous drugs without a prescription/Internet; Dispensing Dangerous Drugs or Devices without Prescription; No person shall dispense or furnish, or cause to be furnished dangerous drugs...on the internet...without a prescription issued pursuant to a good faith examination	Citation without a fine
Bus. & Prof. Code § 4174	Dispensing on order of nurse practitioner or person of similar status.	Citation without a fine

CONDUCT:

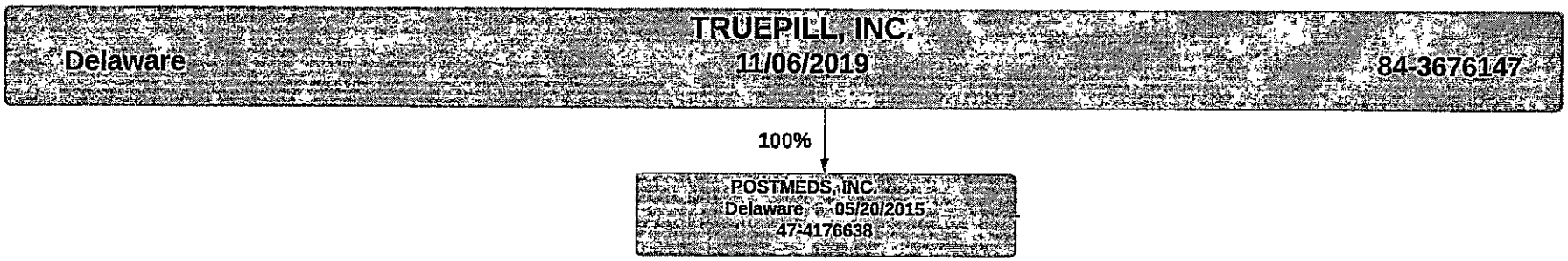
Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Business and Professions Code 4059 (a) states in pertinent part a person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. In conjunction with Business and Professions Code 4067 (a) which states no person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination of a human or animal, or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations and (f) for the purposes of this section, "good faith prior examination" includes the requirements for a physician and surgeon in Section 2242. In conjunction with Business and Professions Code 2290.5 (a) For purposes of this division, the following definitions shall apply: (3) "Health care provider" means either of the following: (A) a person who is licensed under this division. Between 4/1/2018 to 10/31/2018, Postmeds Inc. (PHY56100) located at 3121 Diablo Ave. Hayward, CA dispensed prescriptions issued by prescribers who were not licensed in California. Specifically, 2 prescriptions were issued by Nurse Practitioner Jenny Ingle; 9 prescriptions were issued by Dr. Brook Randal; 6 prescriptions were issued by Dr. Jessica Rubino and 4 prescriptions were issued by Dr. Sudhi Trye. These prescribers were not licensed in California at the time the prescriptions were initiated and shipped to a California resident. Postmeds pharmacy dispensed the prescriptions issued by unlicensed prescribers to

California residents in violation of Business and Professions Code 4059 (a) and Business and Professions Code 4067 (a).

Dispensing by Pharmacist Upon Order of Nurse Practitioner: Business and Professions Code 4174 states in pertinent part notwithstanding any other law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section 4052.1, 4052.2, 4052.3, or 4052.6. Postmeds Inc. (PHY56100) located at 3121 Diablo Ave. Hayward, CA dispensed prescriptions issued by Nurse Practitioners and Physicians Assistants who had not yet entered into an established standardized procedure or protocol developed by a supervising physician. Between 4/1/2018 and 10/31/2018, the following prescribers issued prescriptions to Postmeds without an established protocol in place: Physician's Assistant Leanne Mays issued 8 prescriptions and Physician's Assistant Susan Owen issued 6 prescriptions. Between 4/1/2018 and 10/31/2018, the following prescribers issued prescriptions to Postmeds entering into a protocol after the prescriptions were issued: Nurse Practitioner Joni Gunzburger issued 4,782 prescriptions; Nurse Practitioner Cristin Hackel issued 10,819 prescriptions and Nurse Practitioner Jessica Horwitz issued 4,711 prescriptions. Postmeds Pharmacy dispensed the prescriptions issued by Nurse Practitioners and Physicians Assistants who had not yet entered into standardized procedures or protocols as required by Business and Professions Code 4174.

CITATION ISSUED ON: June 16, 2020	TOTAL AMOUNT OF FINE(S): $0.00
PAYMENT OF FINE(S) DUE BY: July 16, 2020	

CONFIDENTIAL! DO NOT DISTRIBUTE TO THIRD PARTIES



Corporation

This organizational chart was prepared by the Legal Team & contains entity name, state of domicile, date of formation & EIN.
For additional details, please contact entities@truepill.com

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FP6189725	11-30-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	ONLINE RETAIL PHARMACY	11-29-2022

TRUEPILL
3121 DIABLO AVE
HAYWARD, CA 94545

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FP6189725	11-30-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	ONLINE RETAIL PHARMACY	11-29-2022

TRUEPILL
3121 DIABLO AVE
HAYWARD, CA 94545

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

8C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 04209	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: FT8664648 ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Truepill NY LLC

Physical Address: 850 3rd Ave., Ste. 404

City: Brooklyn State: NY Zip: 11232

Mailing Address (if different from physical address): See above

City: _____ State: _____ Zip: _____

Telephone: 518-692-3362 Toll Free # (NAC 639.708, NRS 639.23286): 855-687-8369

Fax: _____ Contact Email: compliance@truepill.com

Website: https://www.truepill.com/

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Michelle Lynne Meyer

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23766

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Michelle Lynne Meyer	NV Pharmacist Registration #: 23766
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New York

Parent Company (if any): Postmeds, Inc.

Corporation/Organization Name: Truepill NY LLC

Mailing Address: 850 3rd Ave. Ste. 404

City: Brooklyn State: NY Zip: 11232

Telephone: 518-692-3362 Email: compliance@truepill.com

Contact Person Name: Samantha Gabbard

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Co-Manager (title) for Truepill NY LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Paul Greenall

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

9/19/2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Paul Greenall hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Co-Manager (title) for Truepill NY LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

_____
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this _____ day of _____, 20_____

_____
Notary Public

California
Jurat Attatched

CALIFORNIA JURAT WITH AFFIANT STATEMENT **GOVERNMENT CODE § 8202**

☑ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], *not* Notary)

1 _____
2 _____
3 _____
4 _____
5 _____
6 _____

Signature of Document Signer No. 1 *Signature of Document Signer No. 2 (if any)*

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Marin

Subscribed and sworn to (or affirmed) before me on this 19 (Date) day of September (Month), 20 24 (Year), by
(1) Paul Greenall
(and (2) _____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

LILIA RIVAS CRESCENCIO
COMM. # 2442906
NOTARY PUBLIC-CALIFORNIA
MARIN COUNTY
My Comm. Expires APR. 27, 2027

Signature Lilia Rivas
Signature of Notary Public

Seal
Place Notary Seal Above

OPTIONAL

Though this section is optional, completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: _____ **Document Date:** _____

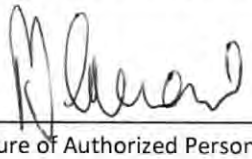
Number of Pages: _____ **Signer(s) Other Than Named Above:** _____

©2016 National Notary Association • www.NationalNotary.org • 1-800-US NOTARY (1-800-876-6827) Item #5910

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Paul Greenall

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

9/19/24

Date

Board Use Only	Date Received: _____	Amount: 500.00/ # 640884

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, WALTER T. MOSLEY, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	TRUEPILL NY LLC
DOS ID Number:	5501126
Entity Type:	DOMESTIC LIMITED LIABILITY COMPANY
Entity Status:	EXISTING
Date of Initial Filing with DOS:	02/25/2019
Statement Status:	CURRENT
Statement Due Date:	02/28/2025

I certify that the following is a list of documents on file in the Department of State for said entity:

Document Type:	ARTICLES OF ORGANIZATION
Date of Filing:	02/25/2019
Entity Name:	TRUEPILL NY LLC

Document Type:	CERTIFICATE OF PUBLICATION
Date of Filing:	07/23/2019

Document Type:	CERTIFICATE OF CHANGE
Date of Filing:	02/11/2020

Document Type:	BIENNIAL STATEMENT
Date of Filing:	02/26/2021
Effective Date:	02/01/2021

Document Type: BIENNIAL STATEMENT

Date of Filing: 02/01/2023

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on September 04, 2024 at 01:39 P.M.

WALTER T. MOSLEY
Secretary of State

Brendan C. Hughes

BRENDAN C. HUGHES
Executive Deputy Secretary of State

Authentication Number: 100006525254 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

SUPERVISING PHARMACIST
MICHELLE MEYER

2022-25

THIS IS TO CERTIFY

TRUEPILL NY LLC
850 THIRD AVE.
STE 404
BROOKLYN, NY 11232

is duly recorded as a

REGISTERED PHARMACY

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE FIRST DAY OF AUGUST, 2022.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF JULY, 2025.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER
037429

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

TRUEPILL NY LLC

X

GENERAL INFO | ENFORCEMENT ACTIONS

Type	Pharmacy
Legal Name	TRUEPILL NY LLC
Trade Name	---
Street Address	850 THIRD AVE. STE 404 BROOKLYN NY 11232
Registration No	037429
Date First Registered	August 02, 2019
Registration Begins	August 01, 2022
Registered Through	July 31, 2025
Supervisor	060799 - MEYER MICHELLE LYNNE
Establishment Status	Active
Successor	NONE

August 29, 2024 11:16 AM (ET)

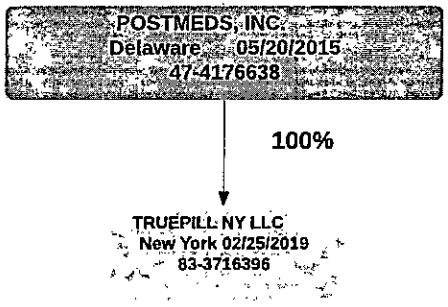
https://eservices.nysed.gov/professions/verification-search?pharmacyRegistrationNumber=037429&professionCode=020

List of Officers

Paul Greenall - [redacted] Benjamin Way, Healdsburg, CA 95448

Aaron Wurst - [redacted] Woodbury Street, Providence, RI 02906

CONFIDENTIAL! DO NOT DISTRIBUTE TO THIRD PARTIES



*No individual/entity in this group owns > = 3% of Truepill, Inc., and therefore no individul/entity in this group owns > = 5% of the Provider

**No individual owns >= 5% of Truepill, Inc., and therefore no individual/entity in this group owns > = 5% of the Provider

Corporation Limited Liability Company

This organizational chart was prepared by the Legal Team & contains entity name, state of domicile, date of formation & EIN.
For additional details, please contact entities@truepill.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Truepill NY LLC

Pharmacy/Wholesaler License # (if applicable) PH04209

Physical Address 850 3rd Ave, Ste 404

City Brooklyn State NY Zip 11232

Mailing Address (if different from physical address) same

City _____ State _____ Zip _____

Telephone 518-692-3362 Website _____

Licensing Company Email compliance@truepill.com

Section 2: Personal Information

First Michelle Middle Lynne Last Meyer

Alias(es, nicknames, name changes, etc.) Jennings

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] Jay St #16c

City Brooklyn State NY Zip 11201

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Eastchester High School		09/05-06/09	
Address	**City**	**State**	**Zip**
2 Stewart Place	Eastchester	NY	10709
Diploma/Degree obtained, if any			
High School Degree			
School Name		**From - To (MM/YY – MM/YY)**	
Northeastern University		09/09-05/15	
Address	**City**	**State**	**Zip**
360 Huntington Ave	Boston	MA	02115
Diploma/Degree obtained, if any			
PharmD			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/23-Present	[redacted]Jay St Apt 16c	Brooklyn	NY	11201
02/19-04/23	[redacted]Greenwich St TH-312A	New York	NY	10013
02/16-02/19	[redacted]W79th St Apt 3A	New York	NY	10024
05/15-02/16	[redacted]Brinsmade Ave	Bronx	NY	10465
09/14-05/15	[redacted]Lawrence St	Boston	MA	02115
09/12-08/14	[redacted]Gainsborough St	Boston	MA	02115
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Truepill NY LLC			07/20-Present	
Business Address		**City**	**State**	**Zip**
850 3rd Ave Suite 404		Brooklyn	NY	11201
Phone	**Title**		**Number of Employed Hours**	
518-692-3362	Pharmacist in Charge		8320	
Description of Duties				
Oversee pharmacists, technicians and overall operations.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/31/2016	04/21/2018	NY	Yonkers	

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
3605270	New York Board of Pharmacy

Reason/Charge
Minor & Technical Violation

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity
CVS Pharmacy

Provide explanation below:

In October 2016 the New York Board of Pharmacy imposed a $500 fine for an alleged minor and technical violation which was not contested for settlement purposes.

Original Signature (electronic, copies or stamps not accepted)

9/13/24
Date

I, Michelle Meyer, **certify that as the designated representative for**

Truepill NY LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MM I am at least 21 years of age;
3. MM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Michelle Meyer

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/13/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michelle Meyer

Print Name (First, Last)

Michelle Meyer

Original Signature (electronic, copies or stamps not accepted)

9/13/24

Date

Please have this section completed in the presence of a Notary Public.

State of NY, ss. County of KINGS

I, Michelle Meyer, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Michelle Meyer

Original Signature

9/13/24

Date

Subscribed and Sworn to before me this 13th day of September, 2024.

Notary Public Signature

TAMARA BOURDEAU
Notary Public - State of New York
No. 01BO6093396
Qualified in Kings County
My Commission Expires Sept. 29, 2027

(Seal)

THE STATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK / ALBANY, NY 12234

OFFICE OF THE PROFESSIONS
DIVISION OF PROFESSIONAL LICENSING SERVICES
Public Information Unit
Tel. (518) 474-3817 EXT: 330
Fax (518) 473-0578
E-mail: DPLSDSU@NYSED.GOV

STATE OF NEW YORK)
SS:
COUNTY OF ALBANY)

In accordance with the **Civil Practice Law and Rules Article 45**, I, Sandra Barsallo, Education Credentials Specialist 1 in the Division of Professional Licensing Services of the New York State Education Department, have caused this certificate to be prepared. I certify that I have legal custody of the official original records of the Division of Professional Licensing Services and I attest that the attached are true, complete and correct copies of the original documents in our files relating to the licensure of MICHELLE LYNNE MEYER aka MICHELLE LYNNE JENNINGS.

Witness my hand and the seal of the New York State Education Department this 9 March, 2022.

Sandra Barsallo, Education Credentials Specialist 1
Professional Licensing Services

DATED
03/09/2022

THE STATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK

OFFICE OF PROFESSIONAL DISCIPLINE, PROSECUTIONS DIVISION
ONE GATEWAY PLAZA, 3RD FLOOR, PORT CHESTER, NEW YORK 10573
Tel.: (914) 934-7554
Fax: (914) 934-7607

Re: Michelle Lynne Jennings, R.Ph. File # 3605270
License # 060799

VIOLATIONS COMMITTEE STATEMENT

TO: The New York State Office of Professional Discipline
The New York State Board of Pharmacy

I wish to settle and dispose of the misconduct allegations which are pending against me, to wit: committing unprofessional conduct (On October 31, 2016, while employed and on duty as the only pharmacist at the CVS Pharmacy, [redacted], New York, I had the assistance of four pharmacy technicians) in violation of Section 6509(9) of the Education Law and in specific violation of Section 29.7(a)(21)(ii)(a) of the Rules of the Board of Regents (8 NYCRR). For the purposes of settlement I do not contest said allegations. I understand that this settlement will be a matter of public record. My check in the sum of $500.00, payable to the order of "New York State Education Department," is enclosed.

Michelle Meyer 4/11/18
Signature Date
a/k/a MICHELLE LYNNE JENNINGS

:ds

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FT8664648	11-30-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	10-16-2022

TRUEPILL NY LLC
850 3RD AVE STE 404
BROOKLYN, NY 112321523

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FT8664648	11-30-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	10-16-2022

TRUEPILL NY LLC
850 3RD AVE STE 404
BROOKLYN, NY 112321523

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Pharmacy e-Profile ID:	1489518		Inspection Information
Legal Business Name:	TruePill NY LLC	Conference Call Date:	N/A
Doing Business As (DBA):	TruePill	Start Time: 24-hour format (13:00)	N/A
Address:	850 3rd Ave, Ste 404	End Time: 24-hour format (13:00)	N/A
City:	Brooklyn	Onsite Inspection Date:	11/19/2022
State:	NY	Start Time: 24-hour format (13:00)	9:30
Zip Code:	11232	End Time: 24-hour format (13:00)	13:45
Telephone number:	518-692-3362	Inspector Name:	Tony H. Qi, PharmD
Toll free number:	855-687-8369	Inspection Performed by (NABP, State, etc):	NABP
Fax number:	718-499-3362	Observer Name/Affiliation (if applicable):	N/A
Website:	www.truepill.com	Observer Name/Affiliation (if applicable):	N/A

Pharmacy Hours of Operation — Check if 24/7: ☐

	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	(X)
Sunday			x (Open as needed)
Monday	9:00	18:00	
Tuesday	9:00	18:00	
Wednesday	9:00	18:00	
Thursday	9:00	18:00	
Friday	9:00	18:00	
Saturday	10:00	17:00	

Key Pharmacy Personnel

	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	Mark Makhinson	mark.makhinson@truepill.com	157297
Nonsterile Compounding Supervisor	N/A	N/A	N/A
Sterile Compounding Supervisor	N/A	N/A	N/A
Hazardous Compounding Supervisor	N/A	N/A	N/A

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Dennis (He Heng) Chan	Pharmacist	Y
2	Alexia Papaderos	Pharmacist	Y
3	Lisa Yee	Pharmacist	Y
4	Raman Kaur	Pharmacist	Y
5	Shaneka Long	Pharmacy Technician	NA
6	Shadasia Hagins	Pharmacy Technician	NA
7	Alan Lazebnik	Intern	NA
8	Injee Choi	Intern	NA
9	Derek Zamora	Pharmacy Technician	NA
10	Shonelle Hurry	Support	NA

If more than 10, list the first 10 below, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present.

Business Licensure Information for State of Residence and Federal (board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	License Type/Number	Expiration Date
NY State Board of Pharmacy	TruePill NY LLC	Pharmacy/037429	7/31/2025
US Department of Justice	TruePill NY LLC	CS/FT8664648	11/30/2025

Inspector Notes: List states in which Non-Resident licenses are held: The pharmacy holds licenses in 49 states except Arkansas. Since the last VPP in November 2020, the pharmacy has expanded into additional locations in the US. Additional fulfillment centers include Hayward and Los Angeles, CA; Austin, TX; Cleveland, OH; Redmond, WA; and Miami, FL. The pharmacy is licensed as an open-setting retail pharmacy, and it is located on the 4th floor of an office complex in Brooklyn with minimal patient traffic. It receives prescription orders from Mark Cuban's Cost Plus and GoodRx Care, as well as multiple Telehealth platforms, including M, Simple, Vetcove and Wisp, etc., with deliveries via USPS, FedEx, and UPS. Packaging can vary per client request. Labeling indicates TruePill with auxiliary labels indicating client companies. Patient orders refill by contacting each respective client company, and counseling is done by this (TruePill) pharmacy. The company's Hayward, CA location has the capability to route prescription orders per geographic and client contract basis to this location. This location receives prescription orders also independently. No ReliOn insulins were observed onsite.

® National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Attachments

(NO PHI, including prescription numbers)

Attachment Name	Description

Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply	
Traditional retail	X	Telepharmacy	
Open to the Public	X	Central Fill/Processing/Shared Services	
Closed Door		Specialty Pharmacy	X
Drive-through window		Handles Medical Marijuana	
Mail/Deliver (in state)	X	Nuclear Pharmacy	
Mail/Deliver (out-of-state list below)	X	Manufacturer	
Veterinary Pharmacy	X	Wholesale Distributor	
Investigational Drugs, Clinical Trials/Research		Provide products for "Office Use"	
Institutional		Outsourcing Facility	
Long-Term Care		Nonsterile Compounding	
HMO/PBM only		Nonsterile Hazardous Drug Compounding	
Internet Pharmacy (New Rx)		Sterile Compounding	
Internet Pharmacy (Refill Rx)		Sterile Hazardous Drug Compounding	

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Facility Size in Square Feet and Number of PECs		Personnel	
Total Pharmacy size:	8000	Total Pharmacists:	13 (11 full time, 2 part time)
Nonsterile Compounding Room size:	N/A	Number of Compounding Pharmacists	0
Nonsterile Compounding powder hoods number:	0	Total Graduate Students or Residents:	0
Nonsterile Hazardous Drugs (HD) Compounding Room size:	N/A	Total Student Interns:	2
Nonsterile HD Compounding BSC/CACI hoods number:	0	Total Technicians:	29 (25 full time, 4 part time)
Sterile Compounding Ante Room size:	N/A	Number of Compounding Technicians	0
Sterile Compounding Clean/Buffer Room size:	N/A	Of technicians, how many are certified?	0
Sterile Compounding Number LAFW hoods/areas:	0	Of technicians, how many are techs-in-training?	0
Sterile Compounding Number BSC hoods:	0	Total Other Licensed Personnel:	0
Sterile Compounding Number CAI/CACI hoods:	0	Total Other Unlicensed Personnel:	7 supportive
Negative Pressure Sterile HD Room size:	N/A	Ratio #tech:#RPh present at time of inspection:	2 Tech/2 intern : 4 RPh
Sterile HD Compounding Number of BSC hoods:	0	Total Pharmacist Hours Per Week:	480
Sterile HD Compounding Number of CACI hoods:	0	Total Technician Hours Per Week:	1080

Volume Dispensed		Volume Distributed	
Total Prescriptions Dispensed/day:	1500-2000	Total Orders Distributed/day:	0
% Veterinary Prescriptions	2%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	0% (no CDS since June 2022)	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	0%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	0%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	0%	% Hazardous Drugs (HD) Orders	0%

Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific, is not labeled with the patient name at the pharmacy.

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)	357	0	month of Oct 2022
Alaska (AK)	5	0	month of Oct 2022
Arizona (AZ)	101	0	month of Oct 2022
Arkansas (AR)			
California (CA)	4435	0	month of Oct 2022
Colorado (CO)	330	0	month of Oct 2022
Connecticut (CT)	1057	0	month of Oct 2022
Delaware (DE)	118	0	month of Oct 2022
District of Columbia (DC)	24	0	month of Oct 2022
Florida (FL)	2789	0	month of Oct 2022
Georgia (GA)	1234	0	month of Oct 2022
Hawaii (HI)	23	0	month of Oct 2022
Idaho (ID)	73	0	month of Oct 2022
Illinois (IL)	1341	0	month of Oct 2022
Indiana (IN)	332	0	month of Oct 2022
Iowa (IA)	80	0	month of Oct 2022
Kansas (KS)	481	0	month of Oct 2022
Kentucky (KY)	377	0	month of Oct 2022
Louisiana (LA)	131	0	month of Oct 2022
Maine (ME)	812	0	month of Oct 2022
Maryland (MD)	2079	0	month of Oct 2022
Massachusetts (MA)	1089	0	month of Oct 2022
Michigan (MI)	1682	0	month of Oct 2022
Minnesota (MN)	971	0	month of Oct 2022
Mississippi (MS)	102	0	month of Oct 2022
Missouri (MO)	312	0	month of Oct 2022
Montana (MT)	72	0	month of Oct 2022

Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific, is not labeled with the patient name at the pharmacy.

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month): Note: if not available, request information be sent to VPP and note that information was requested in grid.			
State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)	39	0	month of Oct 2022
Nevada (NV)	36	0	month of Oct 2022
New Hampshire (NH)	151	0	month of Oct 2022
New Jersey (NJ)	957	0	month of Oct 2022
New Mexico (NM)	59	0	month of Oct 2022
New York (NY)	8261	0	month of Oct 2022
North Carolina (NC)	1184	0	month of Oct 2022
North Dakota (ND)	16	0	month of Oct 2022
Ohio (OH)	999	0	month of Oct 2022
Oklahoma (OK)	194	0	month of Oct 2022
Oregon (OR)	231	0	month of Oct 2022
Pennsylvania (PA)	3158	0	month of Oct 2022
Rhode Island (RI)	139	0	month of Oct 2022
South Carolina (SC)	1259	0	month of Oct 2022
South Dakota (SD)	26	0	month of Oct 2022
Tennessee (TN)	805	0	month of Oct 2022
Texas (TX)	3993	0	month of Oct 2022
Utah (UT)	207	0	month of Oct 2022
Vermont (VT)	76	0	month of Oct 2022
Virginia (VA)	1626	0	month of Oct 2022
Washington (WA)	631	0	month of Oct 2022
West Virginia (WV)	81	0	month of Oct 2022
Wisconsin (WI)	1343	0	month of Oct 2022
Wyoming (WY)	33	0	month of Oct 2022
Other:			

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: TruePill NY LLC dba TruePill

e-Profile ID: 1489518

Inspection Date: 11/19/2022

		Finding	Notes
General Pharmacy			
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	No	Alexia Papaderos, RPh and Dennis (He Heng) Chan, RPh mainly assisted the inspection. PIC Mark Makhinson dialed in.
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	40 hours
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	No	
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	No	
4.01	Does the pharmacy hold .pharmacy verification?	No	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	No	
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	No	
8.00	Are photographs allowed during the inspection (no PHI)?	Yes	
9.00	List of additional personnel interviewed as part of the inspection, including name and title:		Alexia Papaderos, RPh; Dennis (He Heng) Chan, RPh; Lisa Yee, RPh
Types of Practice Additional Questions	**If any part of a question is no, enter "No" and explain the observation.**		
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	No	All prescriptions are delivered to patient's residences.
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: TruePill NY LLC dba TruePill
e-Profile ID: 1489518
Inspection Date: 11/19/2022

		Finding	Notes
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
	General Operations and Licensure — If any part of a question is no, enter "No" and explain the observation.		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	Yes	
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	7/25/2019; this was the initial pharmacy inspection and the pharmacy has not had additional visits.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	No	No deficiencies were noted.
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	No	
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: TruePill NY LLC dba TruePill
e-Profile ID: 1489518
Inspection Date: 11/19/2022

		Finding	Notes
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	Yes	URAC Specialty (2/1/2020-2/1/2023); URAC Mail (2/1/2020-2/1/2023)
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	All records have been kept since the inception of 2019 and all records are kept electronically.
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	Yes	
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	They are kept electronically.
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	They are kept electronically.
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronic record-keeping and web-based dispensing software are in place to prevent accidental deletion.
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	N/A	
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	Personnel stated that it is in the P&P and being implemented and monitored by the corporate office in CA and the corporate compliance personnel in NC.

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: TruePill NY LLC dba TruePill
e-Profile ID: 1489518
Inspection Date: 11/19/2022

		Finding	Notes
Personnel	**If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	The corporate office and the corporate compliance officer keep an internal spreadsheet that lists all licensed personnel status.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	PIC and compliance officer check the NY Profession Education website and the third-party website called SureCheck USA tracks the OIG exclusion list.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	No additional services are being provided.
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	Yes	The pharmacy maintains the NY state BOP's requirement of 2 Techs to 1 RPh.
Facility and Security	**If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	The entrance and the pharmacy are equipped with cameras that record only video. Camera also faces the controlled substance safe.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	Yes	
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	The contingency plan is to utilize other sister locations to ensure patient continuity of care.
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	N/A	No destruction onsite.
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	Inmar is the reverse distributor.
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	Yes	Inmar serves monthly and by demand.

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: TruePill NY LLC dba TruePill
e-Profile ID: 1489518
Inspection Date: 11/19/2022

		Finding	Notes
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	Yes	The pharmacy has minimal patient traffic on the 4th floor. It has a waiting area at the entrance for counseling. Patients can only ring the bell and enter the pharmacy.
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	No	Out of the three smart sense readers, one was not reading, and the second had an alarming reading. The personnel reset both units. The third unit had a reading of 70F. A general temperature unit indicated 70F in the main dispensing room and 80F in the smaller drug storage room where the refrigerator and controlled substance safe are located.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	Unknown	At the time of the inspection, the personnel could not access the smart sense app to retrieve past history and current temperature readings, the two units in the main dispensing room were not able to provide the readings.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	The excursion plan was in place so the person would be notified when the excursions occur.
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	The pharmacy applies a smart sensor 24/7 wireless monitoring device for refrigerated items. The range was 2°-8°C. Excursions are notified to the PIC via text and email.
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	Yes	6.2°C
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	Two freezers are used to store only ice packs.
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	N/A	
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	The pharmacy will utilize an onsite generator.
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	Onsite generator will be utilized.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	Yes	Six Kirby Lester, one Parata Max and one Parata Mini.
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	Yes	

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: TruePill NY LLC dba TruePill
e-Profile ID: 1489518
Inspection Date: 11/19/2022

		Finding	Notes
Product Receipt and Inventory *If any part of a question is no, enter "No" and explain the observation.*			
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	Yes	The pharmacy had a documented vetting process for vendor sources at on-boarding.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	No	
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	No	
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	Yes	
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	No	Besides the list provided in the application, the personnel interviewed provided the following vendor sources: McKesson, Anda, TopRx, ParMed, KeySource, Mayne and Prasco.
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	Yes	The personnel interviewed were not familiar with the due diligence steps. PIC stated via telephone that the corporate compliance team is checking the DSCSA requirements.
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	No	
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	No	
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	The pharmacy personnel will examine the seal of totes and bottles and review the invoices for comparison.
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	N/A	The pharmacy has not had an incident since the inception of 2019.
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	No	Invoices from different vendors were filed separately in the drawer, and selected invoices were reviewed. PIC stated via telephone that the corporate compliance team is checking the DSCSA requirements.
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: TruePill NY LLC dba TruePill
e-Profile ID: 1489518
Inspection Date: 11/19/2022

		Finding	Notes
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	Yes	Personnel onsite confirmed that some pharmacy personnel still could use Form 222 to order controls but could not specify the names.
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	Yes	The assistant pharmacy director is the one that can order controlled substances using CSOS.
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	Yes	
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	Yes	
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	The pharmacy keeps a perpetual inventory for all medications electronically.
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	No incidents were detected since the inception. The pharmacy has a P&P to report incidents to the local PD and the BOP.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	Yes	
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	Yes	CII medications are counted in real-time perpetually in the electronic dispensing system.
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	Yes	3/29/2022 was the most recent CDS inventory recorded when the incoming and outgoing PIC occurred.
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	Yes	
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: TruePill NY LLC dba TruePill
e-Profile ID: 1489518
Inspection Date: 11/19/2022

		Finding	Notes
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	The pharmacy conducts outdated check monthly and it includes OTC products.
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	Selected shelves were reviewed.
60.02	How often is active-stock examined for drugs past the expiration date?		Monthly check is conducted.
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	No	
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	N/A	

Prescription Processing

If any part of a question is no, enter "No" and explain the observation.

64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	Pharmacy technicians are the ones typically conducting data entries. TPOX has the ability to integrate data received from clients directly into the system.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	Yes	It is indicated in the system with the pet name, species, and then owner's last name.
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hord copy, faxed, verbal, and electronic prescriptions.*	Yes	PioneerRX has the internal capability to check the prescriber's legitimacy by checking the NPI, DEA and NPPES.

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: TruePill NY LLC dba TruePill
e-Profile ID: 1489518
Inspection Date: 11/19/2022

		Finding	Notes
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Yes	Once a truly suspected prescription is determined, the pharmacist can directly contact the prescriber for verification.
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Unknown	The telehealth or electronic platform forwards patient information, including allergy, and complete medication lists to the pharmacy. Reviewed prescriptions revealed a different state residence between the patient and the prescriber.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	Electronic prescribing is for both controlled substances and non-controlled substances.
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	Yes	
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	PV1 (pharmacist verification step one) was reviewed at the pharmacy, and it must be done by an RPh before fulfillment.
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	DUR is being checked at PV1 and also being verified by PV2 pharmacist Lisa Yee, at the time of the inspection.
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	Yes	DUR occurs based upon information collected by the electronic platforms.
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	No	
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	The pharmacy reports PMP automatically through PioneerRX, including zero reporting.

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: TruePill NY LLC dba TruePill
e-Profile ID: 1489518
Inspection Date: 11/19/2022

		Finding	Notes
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Yes	
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	DUR overrides are being documented by a RPh during both PV1 and PV2 steps.
67.07	Is the DUR process performed electronically by the computer system? ***Identify integrated drug database used.***	Yes	Medispan is the drug database per Lisa Yee.
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	N/A	
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	No	
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	PV2 occurs after fulfillment and by a licensed RPh, and the electronic system captures the RP's initials.
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	Labels indicate TruePill is the fulfillment pharmacy with some indications per request from each client on the bottle
70.00	**Confidentiality:** Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	The pharmacy is in the transition of consolidating all filling from PioneerRx to TPOX, a recently developed filling software. The pharmacy currently still operates both software.
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	The pharmacy personnel and the application stated that there were no shared services between co-owned facilities. CA location will transfer the prescription to this location if there is a contractual, patient geographic, and/or product limitations.
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: TruePill NY LLC dba TruePill
e-Profile ID: 1489518
Inspection Date: 11/19/2022

		Finding	Notes
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
	Patient Counseling and Communication **If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all <u>new</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	No	
75.01	Is an "offer" to counsel made for all <u>new</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	Yes	Offer-To-Counsel can be provided to rare pickup patients by anyone opening the front door.
76.00	Does the pharmacist provide counseling for all <u>refilled</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	No	
76.01	Is an "offer" to counsel made for all <u>refilled</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	Yes	Offer-To-Counsel can be provided to rare pickup patients by anyone opening the front door.
77.00	Does the pharmacist provide counseling for <u>refilled</u> prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	No	
77.01	Is an "offer" to counsel made for all <u>refilled</u> prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer".*	Yes	Offer-To-Counsel can be provided to rare pickup patients by anyone opening the front door.

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: TruePill NY LLC dba TruePill
e-Profile ID: 1489518
Inspection Date: 11/19/2022

		Finding	Notes
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	N/A	There are no delivered prescriptions.
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Every prescription comes with a QR code which patients can scan and watch a video regarding how to take and the expected side effects. The pharmacy also provides a "URAC" pamphlet for every client offering 24-hour pharmacist availability for counseling.
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	Yes	PPIs are included in every mailed package. Information is provided by Lexicomp Clinical information.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	Yes	MedGuides are automatically printed for included medications.
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn).*	N/A	The pharmacy does not have REMS medications.
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	Yes	If there is actual patient counseling, it can be recorded in the PioneerRx and TPOX software.
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).*	Yes	Calls after hours can be handled by the Hayward CA locations.
85.00	Are processes in place to handle a drug recall?	No	The issue is within the Parata Max and Parata Mini. The process reviewed in details revealed that the cells were not always emptied before another medication lot being placed. So the lot number on the sticker placed outside of each cell may not necessarily reflect the true lot numbers included.
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: TruePill NY LLC dba TruePill
e-Profile ID: 1489518
Inspection Date: 11/19/2022

		Finding	Notes
Quality Assurance/Quality Improvement Program	**If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	Mainly the corporate compliance manager located in NC is responsible for data aggregation with the assistance from the site PIC.
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	Electronic
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	Electronic
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	Yes	With each event

© National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: TruePill NY LLC dba TruePill
e-Profile ID: 1489518
Inspection Date: 11/19/2022

		Finding	Notes
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	N/A	
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	Yes	Qualified incidents would be reported to the respective agencies.
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	N/A	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	No	
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	No	
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	

Acronym	Definition
ACD	Automated Compounding Device
ACOEM	American College of Occupational and Environmental Medicine
ACPH	Air Changes Per Hour
ADA	Americans with Disabilities Act
ADR	Adverse Drug Reaction
ALARA	As Low As Reasonably Achievable
API	Active Pharmaceutical Ingredient
ASHP	American Society of Health-System Pharmacists
ASTM	American Society for Testing and Materials
AU	Authorized User
BOP	Board of Pharmacy
BSC	Biological Safety Cabinet
BUD	Beyond Use Date
CACI	Compounding Aseptic Containment Isolator
CAI	Compounding Aseptic Isolator
CDC	Center for Disease Control and Prevention
CETA	Controlled Environment Testing Association
CFR	Code of Federal Regulations
CFU	Colony-forming unit
CLIA	Clinical Laboratory Improvement Amendment
COA	Certificate of Analysis
C-PEC	Containment Primary Engineering Control
CQI	Continuous Quality Improvement
CS	Controlled substance
C-SCA	Containment Segregated Compounding Area
C-SEC	Containment Secondary Engineering Control
CSOS	Controlled Substance Ordering System
CSP	Compounded Sterile Preparation
CSTD	Closed-System drug-Transfer Device
CVE	Containment Ventilated Enclosure
DBA	Doing business as
DCA	Direct Compounding Area
DEA	Drug Enforcement Administration
DME	Durable medical equipment
DOT	Department of Transportation
DUR	Drug Utilization Review

EMT	Emergency medical technician
EPA	Environmental Protection Agency
FCC	Food Chemicals Codex
FDA	Food and Drug Administration
GHS	Globally Harmonized System (of classification and labeling of chemicals)
HazMat	Hazardous Materials
HCS	Hazardous Communication Standard
HD	Hazardous Drug
HEPA	High Efficiency Particulate Air (filter)
HIPAA	Health Insurance Portability and Accountability Act
HMO	Health maintenance organization
IPA	Isopropyl Alcohol
IV	Intravenous
LAFW	Laminar Air Flow Workbench
LOD	Line of Demarcation
MSDS	Material Safety Data Sheet
MTM	Medication Therapy Management
NF	National Formulary
NIOSH	National Institute for Occupational Safety and Health
NRC	Nuclear Regulatory Commission
NSAID	Non-steroidal anti-inflammatory drug
NVLAP	National Voluntary Laboratory Accreditation Program
OIG	Office of the Inspector General
ONS	Oncology Nursing Society
OSHA	Occupational Safety and Health Administration
OTC	Over-the-Counter
P&P	Policies and Procedures
PBM	Pharmacy benefits manager
PDMP	Prescription drug monitoring program
PEC	Primary Engineering Control
PHI	Protected Health Information
PIC	Pharmacist-in-charge
PMP	Prescription Monitoring Program
PPE	Personal Protective Equipment
PPI	Patient Package Insert
QA	Quality Assurance
QI	Quality Improvement

QRE	Quality Related Event
RAM	Radioactive Material
RCRA	Resource Conservation and Recovery Act
REMS	Risk evaluation mitigation strategy
RSO	Radiation Safety Officer
Rx	Prescription
SDS	Safety Data Sheet (formerly MSDS – Material Safety Data Sheet)
SOP	Standard Operating Procedure
ULPA	Ultra Low Particulate Air (filter)
USP	United States Pharmacopeia
VAERS	Vaccine Adverse Event Reporting System
VFC	Vaccines for Children Program
WD	Wholesale distributor

Term	Definition
Dispense/dispensing	Pursuant to a patient specific prescription, labeled with patient name at the pharmacy
Distribute/distributing	Delivered/sent to a practitioner or health care facility for office use or further dispensing, no prescription, not labeled with a patient name at the pharmacy.
Type of Practice: Central Fill/Processing/ Shared Services	Where part of the prescription processing and dispensing process occurs at another location
Type of Practice: Closed Door	Such as a mail order facility, prescriptions cannot be picked up at the facility, all are sent
Type of Practice: HMO/PBM only	Limited to only the beneficiaries of the specific insurance program - no cash patients
Type of Practice: Institutional	Such as a hospital or jail
Type of Practice: Internet Pharmacy	Pharmacy advertises on the internet, patients fill/refill prescriptions and revise patient profile information on-line.
Type of Practice: Investigational Drugs, Clinical Trials or Research	Approved to handle investigational drugs
Type of Practice: Long Term Care	Nursing Home pharmacy
Type of Practice: Manufacturer	Registered with the FDA as a manufacturer
Type of Practice: Open to the Public	Patients are able to come into the pharmacy to pick up filled prescriptions and interact with a pharmacist
Type of Practice: Outsourcing Facility	Registered with the FDA as an Outsourcing Facility
Type of Practice: Provides Office Use	Distributes prescription and/or compounded preparations to providers for administration or resale. No prescription, not labeled with a patient name by the pharmacy.
Type of Practice: Specialty Pharmacy	Business is primarily with specialty drugs and works with specific disease states
Type of Practice: Telepharmacy	Pharmacy oversees a remote location staffed by a technician supervised via audio/visual system by a pharmacist at this facility.
Type of Practice: Traditional retail	Also known as Community Pharmacy.
Type of Practice: Veterinary Pharmacy	Pharmacy business is primarily or exclusively for animals.
Type of Practice: Wholesale Distributor	Pharmacy is licensed or registered as a wholesale distributor

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Truepill NY LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): NY NRP2793

Physical Address: 850 3rd Ave STE 404

City: Brooklyn State: NY Zip: 11232

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 518-692-3362 Website: n/a

Licensing Company Email: compliance@truepill.com

Section 2: Personal Information

First: Aaron Middle: Michael Last: Wurst

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Addr[redacted] Woodbury Street

City: Providence State: RI Zip: 02906

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Harvard Business School		08/13 - 05/15	
Address	**City**	**State**	**Zip**
Harvard Business School	Boston	MA	02163
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
Cornell University		09/05 - 05/07	
Address	**City**	**State**	**Zip**
Cornell University	Ithaca	NY	14850
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
United States Military Academy		06/03 - 06/05	
Address	**City**	**State**	**Zip**
606 Thayer Rd	West Point	NY	10996
Diploma/Degree obtained, if any			
no degree			

School Name		From - To (MM/YY – MM/YY)	
University of Toledo		08/02 - 05/03	
Address	**City**	**State**	**Zip**
2801 Bancroft St	Toledo	OH	43606
Diploma/Degree obtained, if any			
no degree			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/16 - current	[redacted]Woodbury Street	Providence	RI	02906
08/15 - 08/16	[redacted]Park Row West, APT 512	Providence	RI	02903
06/13 - 07/15	[redacted]Akron Street APT 418	Cambridge	MA	02138

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Postmeds Inc D/B/A Truepill			11/23 - current	
Business Address		**City**	**State**	**Zip**
3121 Diablo Ave		Hayward	CA	94545
Phone	**Title**			
650-353-5495	President			
Description of Duties				
Oversee P&L and the development and execution of our business strategy, and commercial growth.				

Business Name			From - To (MM/YY – MM/YY)	
The Carlyle Group			01/21 - 11/23	
Business Address		**City**	**State**	**Zip**
1001 Pennsylvania Ave NW		Washington	DC	20004
Phone	**Title**			
	Principal			
Description of Duties				
Lead the Healthcare team for Carlyle' s Global Portfolio Solutions (GPS) group				

Business Name			From - To (MM/YY – MM/YY)	
CVS Health			08/11 - 01/23	
Business Address		**City**	**State**	**Zip**
1 CVS Drive		Woonsocket	RI	02895
Phone	**Title**			
	Vice President			
Description of Duties				
Managed and sat on the Retail Leadership Team				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:		Yes	No
1.	Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2.	If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3.	Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4.	Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5.	Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6.	Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7.	Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8.	Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9.	Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10.	Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Aaron Wurst

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12 Sept 2024

Date

Please have this section completed in the presence of a Notary Public.

State of Rhode Island, ss. County of Providence

I, Aaron Wurst, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12 Sept 2024

Date

Subscribed and Sworn to before me this 12 day of September 2024

Notary Public Signature

Randi Stanley
Notary Public, State of Rhode Island
My Commission Expires October 13, 2024
Notary # 759760

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Truepill NY LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): NRP2793

Physical Address: 850 3rd Ave STE 404

City: Brooklyn State: NY Zip: 11232

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 518-692-3362 Website: n/a

Licensing Company Email: compliance@truepill.com

Section 2: Personal Information

First: Paul Middle: James Last: Greenall

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Benjamin Way

City: Healdsburg State: CA Zip: 95448

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Bayes Business School, University of London		10/98 - 07/02	
Address	**City**	**State**	**Zip**
106 Bunhill Row	London	UK	EC1Y 8TZ
Diploma/Degree obtained, if any			
BSC Business Management			

School Name		From - To (MM/YY – MM/YY)	
Abbotsfield School		09/91-07/98	
Address	**City**	**State**	**Zip**
Clifton Gardens	Hillingdon	UK	UB10 0EX
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/20-Date	[redacted] Benjamin Way	Healdsburg	CA	95448
09/11 - 07/20	[redacted] Church St, Apt H	San Francisco	CA	94114
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Postmeds Inc D/B/A Truepill			07/22 - Date	
Business Address		**City**	**State**	**Zip**
3121 Diablo Ave		Hayward	CA	94545
Phone	**Title**			
855-910-8606	CEO			
Description of Duties				
Managing the overall resources and operations of company, making major corporate decisions, and acting as the main point of contact between the board of directors, employees, and the public.				

Business Name			From - To (MM/YY – MM/YY)	
Prophet Brand Strategy LLC			04/19 - 06/22	
Business Address		**City**	**State**	**Zip**
150 Spear St Ste 1300		San Francisco	CA	94105
Phone	**Title**			
(415) 518-5692	Senior Partner, Chief Strategy Officer			
Description of Duties				
Primary responsibility for strategy formulation and management, including developing the corporate vision and strategy, overseeing strategic planning, and leading strategic initiatives, including M&A, transformation, partnerships, and costs				

Business Name			From - To (MM/YY – MM/YY)	
McKesson Corporation			07/09-12/18	
Business Address		**City**	**State**	**Zip**
1 Post Street		San Francisco	CA	94104
Phone	**Title**			
415-983-8300	Sr Vice President, Enterprise Strategy			
Description of Duties				
Primary responsibility for strategy formulation and management, including developing the corporate vision and strategy, overseeing strategic planning, and leading strategic initiatives, including M&A, transformation, partnerships, and costs				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?	✓	
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 & 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
06/01/2007	06/01/2007	MN	Metropolitan Airport	Hennepin
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
225001		Metropolitan Airport		
Reason/Charge				
Petty Misdemeanor - Airport Ordinance Violation				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Self			N/A	
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

Petty Misdemeanor Airport Ordinance Violation with $300 fine, expunged 9/27/2021 by State Statute. Original documentation unavailable due to fire loss.

MN Statute 609.2 - "Petty misdemeanor" a petty offense which is prohibited by ordinance or statute, which does not constitute a crime and for which a sentence of a fine of not more than $300 may be imposed.

Original Signature (electronic, copies or stamps not accepted)

9/19/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Paul Greenall

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/19/24

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

California All-Purpose
Acknowledgment Attached

(Seal)

CALIFORNIA ALL-PURPOSE ACKNOWLEDGEMENT

A Notary Public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Marin }

On September 19, 2024, before me, Lilia Rivas Crescencio, Notary Public,

personally appeared Paul Greenall

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of State of California that the foregoing paragraph is true and correct.

LILIA RIVAS CRESCENCIO
COMM. # 2442906
NOTARY PUBLIC-CALIFORNIA
MARIN COUNTY
My Comm. Expires APR. 27, 2027

WITNESS my hand and official seal.

SIGNATURE Lilia Rivas

PLACE NOTARY SEAL ABOVE

Though the information below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent removal and reattachment of this form to another document.

Description of attached document

Title or type of document: Personal History Application

Document Date: _____ Number of Pages: _____

Signer(s) Other than Named Above: _____

POSTMEDS, INC. DBA TRUEPILL DISCIPLINARY SUMMARY

California resident license PHY 58585
California old resident license PHY 56100

Illinois Board of Pharmacy

The Illinois Board issued the pharmacy (non-resident license #054.022249) a Consent Order of Discipline effective **August 8, 2024** resolving alleged violations of the Illinois Pharmacy Practice Act stemming from disciplinary actions by proper licensing authority of another state. As per the terms of the Consent Order, Pharmacy has agreed to pay a $5,000 administrative fine to the Illinois State Board of Pharmacy.

Alaska Board of Pharmacy

The Alaska Board issued the pharmacy (non resident license #166601) a Consent Order of Discipline effective **February 15, 2024** resolving alleged violations of the Alaska Pharmacy Practice Act stemming from disciplinary actions by proper licensing authority of another state. As per the terms of the Consent Order, Pharmacy has agreed to pay a $5,000 administrative fine to the Alaska State Board of Pharmacy.

Pennsylvania Board of Pharmacy

The Pennsylvania Board issued the pharmacy (non resident license #NP000931) a Consent Order of Discipline effective **November 7, 2023** resolving alleged violations of the Pennsylvania Pharmacy Practice Act stemming from disciplinary actions by proper licensing authority of another state. As per the terms of the Consent Order, Pharmacy has agreed to pay a $3,500 administrative fine to the Pennsylvania State Board of Pharmacy.

DEA Memorandum of Agreement

On December 15, 2022, the federal Drug Enforcement Agency ("DEA") issued Postmeds, Inc ("Truepill-Hayward") an administrative Order to Show Cause ("OSC") regarding revocation of its DEA registration FP6189725. **On September 28, 2023**, Truepill-Hayward and DEA reached a non-monetary resolution of the OSC proceedings through a Memorandum of Agreement ("MOA"). Under the MOA, Truepill-Hayward will maintain its active DEA registration without paying a fine and without suspension or revocation of its registration, while making certain agreed changes to its processes and procedures going forward. The MOA is specific to Truepill-Hayward and does not involve other Truepill pharmacies commonly owned by or affiliated with Truepill-Hayward.

Alabama Board of Pharmacy

The Alabama Board issued the pharmacy (non resident license #114861) a Consent Order of Discipline dated **June 6, 2023**. The Pharmacy has resolved alleged violations of the Alabama Pharmacy Practice Act through entry of a Consent Order with the Alabama State Board of Pharmacy on June 8, 2023. As per the terms of the Consent Order, Pharmacy has agreed to pay a $3,000 administrative fine to the Alabama State Board of Pharmacy.

Kansas Board of Pharmacy

The Kansas Board of Pharmacy issued the pharmacy (non resident license #22-117859) an amended Summary Order effective **February 8, 2023**. The pharmacy did not report the change of ownership in a

timely manner, and paid a fine. The Kansas Board of Pharmacy approved the change of ownership application, and issued license 22-117859 on May 20, 2022.

Louisiana Board of Pharmacy

The Louisiana Board of Pharmacy issued the pharmacy (non resident license #PHY.007761-NR) a Consent Order of Discipline dated **May 11, 2022.** The pharmacy did not report the change of ownership in a timely manner. The Louisiana Board of Pharmacy approved the change of ownership application with a new permit number PHY.008479-NR as a successor to permit number PHY.007761-NR.

North Carolina Board of Pharmacy

The North Carolina Board of Pharmacy issued the pharmacy a Consent Order of Discipline dated **March 8, 2022.** The pharmacy made inaccurate statements about its ownership and officers on its initial application in November 2017 and did not correct this until November 2021. The North Carolina Board of Pharmacy approved the change of ownership application with a new permit number 14900 as a successor to permit number 13413.

Maine Board of Pharmacy

The Maine Board of Pharmacy notified the pharmacy on **March 30, 2022** that its non-resident license (#MO40002429) was terminated effective November 6, 2019 for reporting deficiencies related to its ownership. The pharmacy submitted a change of ownership application for licensure, and has been issued a new pharmacy license (#MO40003167) on November 2, 2022.

California Board of Pharmacy

The California Board of Pharmacy issued the pharmacy (former license #PHY 56100) a letter of admonishment CI 2019 84877 dated **January 23, 2020,** concluding an investigation that found the pharmacy shipped a prescription to the wrong patient and shipped two prescriptions with the wrong return address.

The California Board of Pharmacy issued the pharmacy (former license #PHY 56100) a modified citation and fine CI 2019 78633 dated **June 16, 2020,** with the fine amount of $0.00. In 2018, certain prescriptions were issued to the pharmacy by prescribers that were either not yet licensed to prescribe in California or who had not yet entered into an established standardized procedure or protocol developed by a supervising physician.

Also, The California Board of Pharmacy issued the pharmacy (former license #PHY 56100) a citation and fine order of abatement CI 2020 89223 dated **August 25, 2021,** with the fine amount of $5,000. The pharmacy was in violation when dangerous drugs were stored in temperatures exceeding the recommended storage temperatures Truepill did not consider the manufacturer's stability data for drugs which may have been adulterated by heat.

PENDING MATTERS

The following Actions are currently pending or threatened against the Company. The below Actions are currently subject to ongoing discussions, negotiations, and developments.

California Board of Pharmacy

California CI 2024 105307: On August 9, 2024, the California State Board of Pharmacy sent notice of a pending citation along with information on contesting or appealing. Truepill is in process of requesting an informal hearing to contest the citation.

South Carolina Board of Pharmacy

South Carolina 2022-49: On May 3, 2023, Postmeds agreed in principle to a proposed consent order with the South Carolina Board of Pharmacy to resolve inaccuracies in prior ownership information provided to the Board. The agreement would be categorized as a public reprimand but would not be a public document and would not be reported to the National Practitioner Data Bank. The negotiated fine was $30,000. The South Carolina Board of Pharmacy has not finalized this consent order or initiated formal disciplinary proceedings.

STATE OF ILLINOIS
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
DIVISION OF PROFESSIONAL REGULATION

IN RE: The Application of		)	
POSTMEDS INC DBA TRUEPILL,		)	Case No. 2023-00783
054-app-4237687	APPLICANT.	)	

CONSENT ORDER

The Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation ("Department"), by its attorney Nicholas V. Gallo, and Applicant POSTMEDS INC ("Applicant"), by its attorney Marc N. Wagner, hereby agree to the following:

STIPULATIONS

On or about August 22, 2022, Applicant submitted to the Department a change of ownership application (the "application") for Illinois licensed pharmacy license no. 054.022350.

On or about June 16, 2020, the California State Board of Pharmacy issued Applicant a disciplinary modified citation and fine ("California Citation and Fine") under case no. 2017-78633 for Applicant filling prescriptions issued to Applicant by prescribers that were either not yet licensed to prescribe in California or who had not yet entered into an established standardized procedure or protocol developed by a supervising physician. The California Citation and Fine constitutes grounds for disciplinary action against Applicant on the authority of the Illinois Pharmacy Practice Act ("Act") at 225 ILCS 85/30(a)(8) as the grounds for action in the California Citation and Fine are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 225 ILCS 85/4(g).

On or about August 25, 2021, the California State Board of Pharmacy issued Applicant a disciplinary citation and fine order of abatement ("California Citation and Fine Order of Abatement") under case no. 2020-89223 for, including but not limited to, Applicant storing dangerous drugs in temperatures exceeding the recommended storage temperatures. The California Citation and Fine Order of Abatement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8)

as the grounds for action in the California Citation and Fine Order of Abatement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 225 ILCS 85/3(d)(12).

On or about March 8, 2022, Applicant and the North Carolina Board of Pharmacy entered into a Consent Order of Discipline for, including but not limited to, Applicant failing to report change of ownership in a timely manner. The North Carolina Agreement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8) as the grounds for action in the North Carolina Agreement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via the Act's Administrative Rules ("Rules") at 68 IAC 1330.780(a)(1).

On or about May 11, 2022, Applicant and the Louisiana Board of Pharmacy entered into a disciplinary Consent Agreement ("Louisiana Agreement") under case no. 21-0456 for, including but not limited to, Applicant failing to report change of ownership in a timely manner. The Louisiana Agreement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8) as the grounds for action in the Louisiana Agreement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 68 IAC 1330.780(a)(1).

On or about February 15, 2024, Applicant and the Board of Pharmacy for the State of Alaska entered into a disciplinary Consent Agreement ("Alaska Agreement") under case no. 2022-000434 for, including but not limited to, Applicant failing to disclose prior disciplines from another state within the required timeframe. The Alaska Agreement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8) as the grounds for action in the Alaska Agreement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 68 IAC 1330.40(c).

Pursuant to 68 IAC 1130.300(a) the following factor is considered in aggravation: (a) the presence of multiple adverse actions taken by other states against Applicant.

Pursuant to 68 IAC 1130.300(b) the following factors are considered in mitigation: (a) Applicant has cooperated with the Department in its investigation; and (b) Applicant has no prior disciplinary history with the Department.

At all times material to the matter set forth in this Consent Order, the Department had jurisdiction over the subject matter and the parties herein. Applicant has been advised of the right to have any allegation(s) reduced to written charges, to a hearing where the Department bears the burden to prove its allegations by clear and convincing evidence, to contest any charges brought and present mitigating evidence, and to administrative review of any order resulting from a hearing. Applicant knowingly waives each of these rights, as well as any right to administrative review of this Consent Order. Such waiver ceases if this Consent Order is rejected by the Secretary or the Secretary's designee or the Board. Applicant acknowledges that it has entered into this Consent Order freely and of Applicant's own will without threat or coercion by the Department or any person, and has not relied upon any representation made by or on behalf of the Department other than those specifically included herein. Applicant acknowledges that the Department attorney may be requested to communicate with the Board or the Secretary or the Secretary's designee in furtherance of the approval of this Consent Order. Applicant acknowledges that this Consent Order will be presented to the Secretary or the Secretary's designee. If this Consent Order is not approved, Applicant waives any right to raise any prejudice resulting from the Secretary or the Secretary's designee's consideration of this Consent Order. Applicant understands that this Consent Order is not effective unless and until it is adopted by the Secretary or the Secretary's designee. A copy of any original signature(s) affixed to this Consent Order shall be given the full force and effect of an original signature(s) affixed to this Consent Order.

Applicant and the Department agree, in order to resolve this case, that the Applicant be permitted to enter into a Consent Order with the Department providing for the terms and conditions contained herein which are fair and equitable in the circumstances and which are consistent with the best interests of the people of the State of Illinois.

CONDITIONS

Wherefore, the Department, by its attorney Nicholas V. Gallo, and Applicant, by its attorney Marc N. Wagner, agree:

A. Applicant's Illinois licensed pharmacy license no. 054.022350 shall be issued with a Reprimand.

B. Applicant shall pay a five-thousand-dollar ($5,000.00 USD) disciplinary fine within sixty (60) days of the effective date of this Consent Order.

C. All fines issued pursuant to this Consent Order are to be paid by personal check, company check, cashier's check, or personal money order. Said monetary instrument(s) shall be made payable to "Illinois Department of Financial and Professional Regulation," clearly indicate on the face of the monetary instrument the case number of 2023-00783 as well as license no. 054.022350, and be mailed to the following address:

Illinois Department of Financial and Professional Regulation
SSC – Accounts Receivable Section - Fines
P.O. Box 7086
Springfield, IL 62791-7086

D. Prior to the satisfaction of subsections B and C, above, Applicant shall not violate any state or federal law, rule, or regulation concerning controlled substances or the practice of wholesale drug distribution.

E. Applicant agrees that any violation of this Consent Order permits the Secretary or Secretary's designee to issue an Order forthwith mandating the automatic, indefinite, and immediate suspension of Applicant's license for a minimum period of twelve (12) months. This suspension shall not preclude the Department from taking any other disciplinary or other action it deems appropriate. In the event that Applicant(s) contest(s) in writing (by the filing with the Department within thirty (30) days the effective date of the suspension, a Petition complying with the Department's Rules of Practice in Administrative Hearings) the factual basis underlying said suspension, then Applicant(s) shall be afforded a hearing on the merits in accordance with the Department's Rules of Practice in Administrative Hearings, 68 Ill. Admin. Code 1110/et seq.

F. Applicant acknowledges that this Consent Order is a public disciplinary action and will be made available to the public. It will be reported to all applicable reporting databases.

G. This Consent Order is a final administrative order. This Consent Order shall become effective upon the signature of the Secretary or the Secretary's designee below unless otherwise stated herein.

Signatures on the following page

July 12, 2024
Date

Department Attorney – Nicholas V. Gallo

7/11/2024 | 1:39 PM PDT
Date

DocuSigned by:
Laura Peterson
Applicant – POSTMEDS INC
By: General Counsel, Truepill Inc. - Laura Peterson

7/11/2024 | 5:00 PM CDT
Date

DocuSigned by:
Lee Rosebush
Applicant's Attorney -- Lee H. Rosebush

7/12/24
Date

Illinois State Board of Pharmacy Member

The foregoing Consent Order is approved in full.

DATED THIS 8th day of August, 2024.

ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
SECRETARY MARIO TRETO, JR.

Mario Treto, Jr. Secretary
Illinois Department of Financial and Professional Regulation

Case No. 2023-00783
Application No.: 054-app-4237687

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE BOARD OF PHARMACY

In the Matter of:)
)
Postmeds, Inc. doing business as (Dba) TRUEPILL)
Respondent)
Case No. 2022-000434

CONSENT AGREEMENT

IT IS HEREBY AGREED by the Department of Commerce, Community and Economic Development, Division of Corporations, Business and Professional Licensing (Division) and TRUEPILL (Respondent) as follows:

1) **Licensure.** Respondent is currently registered as an Out-of-State Pharmacy in the State of Alaska and holds License number #166601. This license was first issued on 08/27/2020 and will lapse unless renewed by 06/30/2024.

2) **Admission/Jurisdiction.** Respondent admits and agrees that the Board of Pharmacy has jurisdiction over the subject matter of their license in Alaska and over this Consent Agreement.

3) **Admission/Facts.** Respondent admits to the following facts:

a) On September 25, 2017, Staff Pharmacist working for TRUEPILL, Curtis Ancar, received a disciplinary order from the California Board of Pharmacy for failure to exercise corresponding responsibility and excessive furnishing of controlled substances.

b) On January 24, 2019, the California Board of Pharmacy cited former Pharmacist-in-Charge and former owner of TRUEPILL, Mohammad Umar Afridi, for failure to provide documentation substantiating completion of continuing education and knowingly making or signing a document with false information.

c) On December 16, 2019, the California Board of Pharmacy cited former Pharmacist-in-Charge and former owner of TRUEPILL, Mohammad Umar Afridi, for furnishing and dispensing dangerous drugs without a prescription and dispensing on order of nurse practitioner (or person of similar status).

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

d) On January 23, 2020, the California Board of Pharmacy issued a letter of admonishment to Respondent for shipping a prescription to the wrong address and shipping two prescriptions with the wrong return address.

e) On June 16, 2020, the California Board of Pharmacy issued a modified citation and fine CI 2019 78633 with the fine amount of $0.00 for receiving prescriptions by prescribers that were not licensed or have not entered into procedures with supervising physicians.

f) On April 08, 2022, Respondent submitted an Out-of-State Pharmacy Registration Ownership Change Application from license no. 166601 to license no. 193858 (now withdrawn) to the Division. Professional Fitness Question #1 was marked "Yes" indicating disciplinary actions had been issued against their license as listed above in sections a) through e).

g) Subsequent background investigation revealed Respondent failed to disclose the abovementioned 2017, 2019, and 2020 licensing actions from the California Board of Pharmacy on previous State of Alaska applications for TRUEPILL (formerly DBA Postmeds, Inc.) for licenses 137655 and 166601 dated June 08, 2018, August 06, 2020, and August 27, 2020.

h) Respondent admits that as a result of the above facts, grounds exist for possible suspension, revocation, or other disciplinary sanctions of their license pursuant to AS 08.01.075, AS 08.80.261(a)(1), AS 08.80.261(a)(6), AS 08.80.261(a)(9), AS 08.80.261(a)(11)(12)(14), 12 AAC 52.920(a)(13), and 52.920(a)(14)(c).

4) **Formal Hearing Process.** It is the intent of the parties to this Consent Agreement to provide for the compromise and settlement of all issues addressed in Paragraph 3 (above) that could be raised by an Accusation to revoke, suspend, or impose disciplinary sanctions against Respondent's license through a formal hearing process.

5) **Waiver of Rights.** Respondent understands they have the right to consult with an attorney of their own choosing and has a right to an administrative hearing on the facts in this case. Respondent understands and agrees that by signing this Consent Agreement, Respondent is waiving their rights to counsel and to a hearing. Further, Respondent understands and agrees that they are relieving the Division of any burden it has of proving the facts admitted above. Respondent further understands and agrees that by signing this Consent Agreement they are voluntarily and knowingly giving up their right to present oral and documentary evidence, to present rebuttal evidence, to cross-examine witnesses against Respondent, and to appeal the Board's decision to Superior Court.

6) **Effect of Non-Acceptance of Consent Agreement.** Respondent and the Division agree that this Consent Agreement is subject to the approval of the Board. They agree that, if the Board rejects this Consent Agreement, it will be void, and an Accusation may be filed. If this Consent Agreement is rejected by the Board, it will not constitute a waiver of Respondent's right to a hearing on the matters alleged in an Accusation and the admissions contained herein will have no effect. Respondent agrees that, if the Board rejects this Consent Agreement, the Board may decide the matter after a hearing, and its consideration of this Consent Agreement shall not alone be grounds for claiming that the Board is biased against Respondent, that it cannot fairly decide the case, or that it has received ex parte communication.

7) **Consent Agreement, Decision, and Order.** Respondent agrees that the Board has the authority to enter into this Consent Agreement and to issue the following Decision and Order.

PROPOSED DECISION AND ORDER

IT IS HEREBY ORDERED that any license issued to Respondent by the Board shall be subject to the following terms and conditions:

A. Violation of Agreement

If Respondent fails to comply with any term or condition of this Consent Agreement, the Division may enforce this agreement by immediately suspending Respondent's license, without an additional order from the Board or without a prior hearing, for a violation of this agreement. In addition, any suspended portion of the civil fine will be immediately due.

If Respondent's license is suspended under this paragraph, as provided above, they will be entitled to a hearing, on an expedited basis, regarding the issue of the suspension. If Respondent's license is suspended, they will continue to be responsible for all license requirements pursuant to AS 08.80.

Respondent shall maintain an active license for the entire duration of this Consent Agreement. If the Respondent lets their license lapse, and after receiving adequate notice from the Board fails to correct the problem, the failure to maintain active licensure will be considered a violation of this Consent Agreement.

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

B. Respondent Address

It is the responsibility of the Respondent to keep the Board's agent advised, in writing, at all times of their current mailing address, physical address, telephone number, current employment and any change in employment.

Failure to provide notice of any changes within 10 calendar days will constitute grounds for suspension of his or her license in accordance with paragraph 'B' above.

C. Compliance with Laws

Respondent shall obey all federal, state and local laws governing their license.

D. Authorization

Within 10 calendar days of a request by the Board agent, Respondent will sign all authorizations necessary for the release of information required by this Consent Agreement.

E. Good Faith

All parties agree to act in good faith in carrying out the stated intentions of this Consent Agreement.

F. Address of the Board

All required reports or other communication concerning compliance with this Consent Agreement shall be addressed to:

Attn: Holly Handley, Investigator
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
(907) 269-8124 Fax (907) 269-8195

G. Civil Fine

Respondent shall pay a fine of five thousand dollars ($5,000.00). This civil fine is due within 180 days of the adoption of this agreement and is payable to the "State of Alaska" in cash, certified check, or money order or via credit card.

All payments required by this Consent Agreement shall be addressed to:

Erika Prieksat, Chief Investigator
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

//

//

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

IT IS HEREBY FURTHER ORDERED that this Decision and Order shall take effect immediately upon its adoption by the Board of Pharmacy and is a public record of the Board of Pharmacy and the State of Alaska. The State may provide a copy of it to any person or entity, professional licensing board, federal, state, or local government, or other entity making a relevant inquiry.

The action taken by the Board of Pharmacy in this Consent Agreement will be reported to the National Association of Boards of Pharmacy (NABP) and the National Practitioner Data Bank (NPDB) other entities as required by law.

DATED this 5 day of October 2023, at Anchorage, Alaska.

JULIE SANDE, COMMISSIONER

DocuSigned by:
By: Erika Prieksat
34F98CE5F1DF48C...

Erika Prieksat, Chief Investigator for
Sylvan Robb, Director
Division of Corporations, Business and
Professional Licensing

I, TRUEPILL, have read the Consent Agreement, understand it, and agree to be bound by its terms and conditions.

Joseph Alexander Cipriani

DATED: 20th November 2023

SUBSCRIBED AND SWORN TO before me this 20th day of November, 2023, at Newport News, Virginia.
(city) (state)

SEAL
COMMONWEALTH OF VIRGINIA · ELECTRONIC NOTARY PUBLIC · N
Winston Ndow
REGISTRATION NUMBER
8040550
COMMISSION EXPIRES
February 28, 2027

Winston Ndow

Notary Public in and for Virginia.
(state)

Winston Ndow
Notary Printed Name

Notarized online using audio-video communication

My commission expires: 02/28/2027

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE BOARD OF PHARMACY

In the Matter of:)
)
Postmeds, Inc. dba TRUEPILL)
)
Respondent)
Case No. 2022-000434

ORDER

The Board of Pharmacy for the State of Alaska, having examined the Consent Agreement and Proposed Decision and Order, Case No. 2022-000434, Respondent, license number #166601, adopts the Consent Agreement and Decision and Order in this matter.

This Consent Agreement takes effect immediately upon signature of this Order in accordance with the approval of the Board of Pharmacy.

The Division may enforce the Consent Agreement by immediately suspending Respondent's license, without an additional order from the Board or without a prior hearing, for a violation of the Consent Agreement.

DATED this 15th day of February, 2024, at Anchorage, Alaska.

Board of Pharmacy

By: Ashley Shaber
Chairperson

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania **Bureau of Professional and** **Occupational Affairs**		
vs.	**Case Nos.**	**21-54-004050** **22-54-008273**
PostMeds Inc **Respondent**		

NOTICE

Formal disciplinary action has been filed against you. You may lose your license, certificate, registration or permit to practice your profession or occupation. You may be subject to civil penalties of up to $10,000 for each violation, and the imposition of costs of investigation.

If you wish to defend against the charges in the attached order to show cause or to present evidence to mitigate any penalty that may be imposed, the procedures for doing so are explained in the Order to Show Cause.

You have the right to retain an attorney. Although you may represent yourself without an attorney, you are advised to seek the help of an attorney. You also have the right to have an interpreter provided should you request one.

All proceedings are conducted under the Administrative Agency Law and the General Rules of Administrative Practice and Procedures.

You are directed to respond to the charges by filing a written answer within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause. IF YOU DO NOT FILE AN ANSWER, DISCIPLINARY ACTION MAY BE TAKEN AGAINST YOU WITHOUT A HEARING. Any answer submitted in this matter must be filed with the Prothonotary for the Department of State via one of the following methods:

By Mail:
Prothonotary
Department of State
2601 N Third St
PO Box 2649
Harrisburg, PA 17105-2649

By Facsimile:
(717)772-1892

By E-mail:
ra-prothonotary@pa.gov

You must also send or email a separate copy of your answer and any other pleadings or documents related to this case to the prosecuting attorney named in the Order to Show Cause.

Prothonotary Filed On
May 10 2023 02:10 PM
Department of State

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania **Bureau of Professional and** **Occupational Affairs**		
vs.	**Case Nos.**	**21-54-004050** **22-54-008273**
PostMeds Inc **Respondent**		

ORDER TO SHOW CAUSE

AND NOW, this 10th day of May 2023, **PostMeds Inc** ("Respondent") is hereby ORDERED TO SHOW CAUSE why the Pennsylvania State Board of Pharmacy ("Pennsylvania Board"), upon consideration of the Factual Allegations and the applicable law, should not suspend, revoke or otherwise restrict Respondent's registration, impose a civil penalty, or impose the costs of investigation. This action is brought pursuant to the Pharmacy Act, act of September 27, 1961, P.L. 1700, ("Act"), *as amended*, 63 P.S. §§ 390-1 to 390-13; and 63 Pa.C.S. Chapter 31 ("Chapter 31"); and will be conducted in accordance with the Administrative Agency Law, 2 Pa. C.S. §§ 501-508, 701-704, Chapter 31, and the General Rules of Administrative Practice and Procedure ("GRAPP"), 1 Pa. Code §§ 31.1-35.251.

IT IS FURTHER ORDERED that Respondent file an Answer to this Order to Show Cause in writing within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause, in accordance with Rule 35.37 of GRAPP, 1 Pa. Code § 35.37, *as amended.*

FACTUAL ALLEGATIONS

1. Respondent holds the following registration to practice as a nonresident pharmacy in the Commonwealth of Pennsylvania: registration no. NP000931.

DOS Prothonotary
May 10 2023

2. Respondent's registration was originally issued on July 3, 2017, and it is currently set to expire on August 31, 2023.

3. Absent further action by the Pennsylvania Board, the Respondent's registration may be renewed or reactivated upon the filing of the appropriate documentation and payment of the necessary fees.

4. At all times pertinent to the Factual Allegations, Respondent held a registration to practice as a nonresident pharmacy in the Commonwealth of Pennsylvania.

5. Respondent's last known address on file with the Board is: 3131 Diablo Ave, Hayward, CA 94545.

COUNT ONE

6. Paragraphs 1 through 5 are incorporated by reference.

7. At all relevant and material times, Respondent was authorized to practice as a nonresident pharmacy in the State of North Carolina.

8. On or about March 8, 2022, the State of North Carlina Board of Pharmacy ("North Carolina Board"), by way of Consent Order of Discipline, found Respondent to be in violation of the laws, rules, code and/or regulations of the State of North Carolina because Respondent failed to report a restructuring of ownership to the North Carolina Board.

9. In the March 8, 2022 Consent Order of Discipline, the North Carolina Board voided Respondent's permit from the time it was issued until the time the restructuring began and approved Respondent's change of ownership application as a successor permit.

10. A true and correct copy of the North Carolina Board's March 8, 2022 Consent Order of Discipline is attached as **EXHIBIT A** and is incorporated by reference.

DOS Prothonotary
May 10 2023

11. At all relevant and material times, Respondent was authorized to practice as a nonresident pharmacy in the State of Louisiana.

12. On or about May 11, 2022, the State of Louisiana Board of Pharmacy ("Louisiana Board"), by way of Consent Agreement at Louisiana Board Case Number 21-0456, found Respondent to be in violation of the laws, rules, code and/or regulations of the State of Louisiana because Respondent failed to report a restructuring of ownership to the Louisiana Board.

13. In the May 11, 2022 Consent Agreement, the Louisiana Board imposed a ten thousand dollar ($10,000.00) fine, two hundred fifty dollars ($250.00) in administrative costs, and three hundred twenty-four dollars and forty-eight cents ($324.48) in investigative costs.

14. A true and correct copy of the Louisiana Board's May 11, 2022 Consent Agreement, Louisiana Board Case Number 21-0456, is attached as **EXHIBIT B** and is incorporated by reference.

15. At all relevant and material times, Respondent was authorized to practice as a nonresident pharmacy in the State of Kansas.

16. On or about January 20, 2023, the State of Kansas Board of Pharmacy ("Kansas Board"), by way of Amended Summary Order at Kansas Board Case Number 22-183, found Respondent to be in violation of the laws, rules, code and/or regulations of the State of Kansas because Respondent failed to report a restructuring of ownership to the Kansas Board and failed to report disciplinary actions from North Carolina, Alabama, and California which also pertained to a failure to report a restructuring of ownership to each respective Board.

17. In the January 20, 2023 Amended Summary Order, the Kansas Board imposed a three thousand five hundred dollar ($3,500.00) fine.

DOS Prothonotary
May 10 2023

18. A true and correct copy of the Kansas Board's January 20, 2023 Amended Summary Order, Kansas Board Case Number 22-183, is attached as **EXHIBIT C** and is incorporated by reference.

19. Based upon the foregoing Factual Allegations, the Pennsylvania Board is authorized to suspend or revoke, or otherwise restrict Respondent's nonresident pharmacy registration under section 4.1(e) of the Act, 63 P.S. §§ 390-4.1(e); or impose a civil penalty under section 63 Pa.C.S. § 3108(b)(4), and/or impose the costs of investigation under 63 Pa.C.S. § 3108(b)(5), because Respondent violated the Act at section 4.1(g), 63 P.S. § 390-4.1(g), in that Respondent had a permit to conduct a pharmacy suspended or revoked or the nonresident pharmacy was otherwise disciplined by the proper licensing authority of another state.

PENALTIES

If the Pennsylvania Board finds that the Factual Allegations are true and correct, and determines that it has the authority to suspend or revoke the Respondent's registration, the Pennsylvania Board may, in its discretion, impose one or more of the following penalties:

- The revocation, suspension or other restriction of any licenses, certifications, registrations, permits or other authorizations to practice a profession held by Respondent in the Commonwealth of Pennsylvania, or the imposition of any other disciplinary or corrective action that the Act authorizes the Board to impose.
- The imposition of a civil penalty of up to ten thousand dollars ($10,000.00) for each and every violation of the Act. Where criminal proceedings are a basis for a violation of the Act, each count for which the Respondent was convicted may be considered a separate violation of the Act.

DOS Prothonotary
May 10 2023

PROCEDURES

All proceedings are conducted in accordance with the Administrative Agency Law, 2 Pa. C.S. §§ 501-508, 701-704; Chapter 31; and the General Rules of Administrative Practice and Procedure, 1 Pa. Code §§ 31.1-35.251. **RESPONDENT IS HEREBY ORDERED TO FILE A WRITTEN ANSWER TO THIS ORDER TO SHOW CAUSE WITHIN THIRTY (30) DAYS OF THE DATE ON THE MOST RECENT CERTIFICATE OF SERVICE ASSOCIATED WITH THIS ORDER TO SHOW CAUSE.** The Answer shall specifically admit or deny each of the Factual Allegations made herein, and shall set forth the facts and state concisely the matter of law upon which Respondent relies. If Respondent fails to file an Answer within the time allowed herein, the Factual Allegations may be deemed admitted, and the Pennsylvania Board will issue an Order which may impose penalties as set forth above.

If Respondent desires a formal administrative hearing, at which Respondent may defend against the allegations in the Order to Show Cause or to present evidence in mitigation of any penalty which may be imposed upon Respondent or any of Respondent's licenses, certifications, registrations, permits or other authorizations to practice a profession, a written request for hearing must be filed within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause. **IF RESPONDENT FAILS TO FILE A WRITTEN REQUEST FOR HEARING WITHIN THIRTY (30) DAYS OF THE DATE ON THE MOST RECENT CERTIFICATE OF SERVICE ASSOCIATED WITH THIS ORDER TO SHOW CAUSE, RESPONDENT WILL BE DEEMED TO HAVE WAIVED HIS OR HER RIGHT TO A HEARING AND FINAL JUDGMENT MAY BE ENTERED WITHOUT A HEARING.**

If a hearing is scheduled, Respondent will be notified of the specific time and place of the hearing. The hearing will be held before the Board or its duly designated Presiding Officer, in

DOS Prothonotary
May 10 2023

accordance with Section 35.185 of GRAPP, 1 Pa. Code § 35.185. Respondent may appear, with or without counsel, offer testimony or other evidence on his or her behalf, and confront and cross-examine the Commonwealth's witnesses.

Answers, requests for hearings, preliminary motions, protests, petitions to intervene, or any other pleading must be filed with the Prothonotary for the Department of State via one of the following methods:

By Mail:
Prothonotary
Department of State
2601 N Third St
PO Box 2649
Harrisburg, PA 17105-2649

By Facsimile:
(717)772-1892

By E-mail:
ra-prothonotary@pa.gov

Also, you must send or e-mail a separate copy of any documents submitted in this matter to the prosecuting attorney named below at:

By Mail:
Glenn P. Masser
Prosecuting Attorney
Commonwealth of Pennsylvania
Department of State
P.O. Box 69521
Harrisburg, PA 17106-9521

By E-mail:
gmasser@pa.gov

DOS Prothonotary
May 10 2023

Notices and petitions to intervene must be filed within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause, unless in extraordinary circumstances for good cause shown, a later filing is authorized by the agency.

BY ORDER:
DEPARTMENT OF STATE

/s/ Glenn P. Masser
Glenn P. Masser
Prosecuting Attorney
Commonwealth of Pennsylvania
Department of State
P.O. Box 69521
Harrisburg, PA 17106-9521
(717) 783-7200

DATE: 05.10.2023

DOS Prothonotary
May 10 2023

STATE OF NORTH CAROLINA
NORTH CAROLINA BOARD OF PHARMACY

IN THE MATTER OF	)	
	)	
POSTMEDS, INC. d/b/a Truepill,	)	**CONSENT ORDER**
	)	**OF DISCIPLINE**
Permit No. 13413 and Its Successor Permit(s).	)	

THIS MATTER came to be considered before a member of the North Carolina Board of Pharmacy (hereinafter, the "Board") pursuant to 21 N.C.A.C. 46 .2008. The Conference was scheduled for Thursday, February 24, 2022, and, after appropriate notice, was heard on that day by Board member Wallace E. Nelson. Respondent PostMeds, Inc. was informed of its right to be present at the pre-hearing conference and declined. The Board's General Counsel, Clinton R. Pinyan, represented the Board.

Respondent has agreed to waive a formal hearing in the above-referenced matter. It stipulates and agrees to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. By its consent, Respondent also stipulates that it waives its right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order as a basis for the action taken. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. On November 20, 2017, the Board issued Permit No. 13413 to Respondent PostMeds, Inc. d/b/a Trucpill (Permit No. 13413) ("PostMeds").

2. On PostMeds' initial permit application, its then-pharmacist manager, Mohammad Umar Afridi, submitted an inaccurate statement that he was the sole owner and officer of PostMeds. In fact, PostMeds now acknowledges that Afridi and Siddharth

DOS Prothonotary.
May 10 2023

Viswanathan each owned 47 percent of PostMeds on November 20, 2017, with others owning six percent, and that Viswanathan was also an officer of PostMeds.

3. Viswanathan and the minority owners' interests would not have raised questions about the permit application in this particular case. If PostMeds had disclosed the true ownership and officers of PostMeds, the Board still would have granted PostMeds a permit. However, it was an inaccurate statement that Afridi, as the person who submitted the application, knew was inaccurate. That statement prevented the Board from vetting Viswanathan as the owner of the pharmacy. Because of the inaccuracy of the representations, the initial permit was void ab initio.

4. In November 2019, PostMeds went through a corporate restructuring. During that restructuring, Truepill, Inc. was created as a holding company for PostMeds. At that time, Truepill, Inc. became the sole owner of PostMeds. Afridi, Viswanathan and the other former direct owners of PostMeds became indirect owners with the same ownership interests in the holding company, Truepill, Inc., that they had before the transfer of ownership.

5. This restructuring required PostMeds to submit a transfer of ownership application and have that application granted before the restructuring closed. PostMeds failed to do this. Therefore, even if the initial permit had been valid (which it was not), it would have become invalid upon the corporate restructuring.

6. Insertion of a new holding company between the ultimate owners and PostMeds would not have raised questions about the permit application in this particular case. The ownership interests of the ultimate owners did not change. If PostMeds had disclosed the new holding company, the Board still would have granted the transfer of ownership. However,

DOS Prothonotary.
May 10 2023

PostMeds failed to submit the transfer of ownership application or otherwise disclose the interests of Truepill, Inc.

7. In each of its subsequent renewals, PostMeds failed to correct the ownership information that it had inaccurately submitted on its initial application or to list Truepill, Inc., as the direct owner of the pharmacy.

8. On November 4, 2021, counsel for PostMeds informed the Board that its "current ownership information on file with the North Carolina Board of Pharmacy is out of date." Upon follow-up questioning, the next day, PostMeds disclosed that it should have submitted a transfer of ownership application in November 2019. It further was apparent from the ownership information that PostMeds provided that Afridi made inaccurate representations about ownership and officers on PostMed's initial application that had never been corrected.

9. PostMeds agreed to stop shipping any drugs, devices or medical equipment into the State of North Carolina until the matter was resolved. It further agreed to stop shipping or dispensing any drugs, devices or medical equipment from six other pharmacies under its ownership until the matter was resolved (even though those pharmacies did not receive permits until after the transfer of ownership had occurred, and so did not suffer from the same problem).

10. PostMeds submitted a transfer of ownership application promptly.

11. Although PostMed's disclosure of its inaccuracies was tardy, its remedial actions are a mitigating factor in this matter.

CONCLUSIONS OF LAW

1. Reporting of correct and complete ownership information on an initial pharmacy permit application or a renewal application is material, indeed essential, to the Board's ability to ensure that a pharmacy will provide services safely and competently to the public.

DOS Prothonotary:
May 10 2023

2. PostMeds made inaccurate statements about its ownership and officers on its initial application, which it failed to correct at any point through its 2022 renewal. That initial permit was therefore void ab initio and violated G.S. § 90-85.38(b).

3. The creation of Truepill, Inc. as a holding company further triggered a requirement to report the ownership change and obtain a successor permit, and to do so before the closing of the transaction that created Truepill, Inc. The transaction "result[ed] in a different person . . . owning more than 50 pereent interest in the permit holder . . . ." 21 NCAC 46.1603. Failure to apply for and obtain a successor permit prior to the transaction, and a continuing failure to disclose the ownership interest of Truepill, Inc., violated G.S. § 90-85.38(b).

IT IS THEREFORE ORDERED:

PostMeds was in violation of G.S. § 90-85.38(b) in North Carolina from November 20, 2017 until at least November 4, 2021. Respondent PostMed's Permit No. 13413 was **VOID** from the time that it was granted on November 20, 2017. G.S. § 90-85.38(c).

Respondent PostMed's change of ownership application is **APPROVED** as a successor permits to Permit No. 13413 (the "Successor Permit") with the following **CONDITIONS:**

1. PostMeds shall provide timely advance notiee of any contemplated change in ownership to the current pharmacist-manager and any future pharmacist-manager(s) of the Successor Permit. PostMeds shall consult with the Successor Permit's pharmacist-manager(s) to determine whether any contemplated transaction triggers the need to obtain new permits. PostMeds shall authorize the Successor Permit's pharmacist-manager(s) to take any necessary action to update that ownership information with the Board or to apply for new permits. If a contemplated transaction triggers the need for new permits, PostMeds shall not complete that

DOS Prothonotary.
May 10 2023

transaction unless and until either the Board issues new permits or PostMeds ceases all practice of pharmacy at the permitted location.

2. The Successor Permit shall violate no laws governing the practice of pharmacy or the distribution of drugs.

3. The Successor Permit shall violate no rules or regulations of the Board.

4. If the Successor Permit fail to comply with any term or condition of this Order, it may be subject to additional disciplinary action by the Board.

This is the 8th day of March, 2022

NORTH CAROLINA BOARD OF PHARMACY

By: /s/ William A. Mixon
William A. Mixon
President

DOS Prothonotary.
May 10 2023

Respondent PostMeds, Inc. has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. Respondent freely, knowingly and voluntarily waives its right to such a hearing by entering into this Consent Order.

Respondent understands and agrees that by entering into this Consent Order, it certifies that it has read the foregoing Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions that may be taken concerning this matter.

Respondent further understands that should it violate the terms and conditions of this Consent Order, the Board may take additional action.

Respondent understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

Respondent understands that it has the right to have counsel of its choice review and advise them with respect to their rights and this Consent Order, and represents that it enters this Consent Order after consultation with counsel or after knowingly and voluntarily choosing not to consult with counsel. Respondent further agrees that the person who is executing this Consent Order has been duly authorized by any required corporation action to execute on behalf of Respondent.

CONSENTED TO BY:

M-D Date 3/7/22

Printed Name: Matt Davis-Ratner

Title: General Counsel

DOS Prothonotary.
May 10 2023

STATE OF _____

_____ COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the above-named representative of PostMeds, Inc. personally appeared before me this day, and acknowledged the due execution of the foregoing document.

Date:_____

_____
Notary Public

_____

My commission expires:_____

DOS Prothonotary:
May 10 2023

EXHIBIT B

DOS Prothonotary
May 10 2023

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

POSTMEDS, INC.

LOUISIANA PHARMACY PERMIT NO. 7761 **Case No. 21-0456**

****

CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy (hereinafter referred to as the "Board") on March 16, 2022 at the Board office, 3388 Brentwood Drive, Baton Rouge, LA 70809, in the matter of POSTMEDS, INC. (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 7761, 3121 Diablo Ave., Hayward, CA 94545-2701, with attorney Skip Philips and Postmeds Corporate Counsel Donnie Simkin appearing on behalf of Respondent.

WHEREAS, WHEREAS, on August 27, 2018, the Louisiana Board of Pharmacy issued a non-resident pharmacy permit, PHY.007761-NR, to Postmeds Inc. At that time, Postmeds Inc. was 31.5% owned by Mohammad Umar Afridi, 31.5% owned by Siddharth Viswanathan, 16.5% owned by Initialized III L.P., and 20.5% owned by others with no individual owner holding more than 4%. On December 17, 2021 the Board received an "Application for New Louisiana Pharmacy Permit for Nonresident Pharmacy" from Postmeds, Inc. d/b/a Truepill. Accompanying correspondence and organization chart detailed a 100% change in the ownership structure of Postmeds Inc., effective November 6, 2019. Postmeds Inc. went from being owned 31.5% by Mohammad Umar Afridi, 31.5% by Siddharth Viswanathan, 16.5% by Initialized III L.P., and 20.5% by others with no individual owner holding more than 4%, to being owned 100% by Truepill, Inc.

WHEREAS, the Board alleges that such actions constitute violations of the following:

La. R.S. 37:1241 (A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

La. R.S. 37:1221(B). No out-of-state pharmacy providing pharmacy services to residents of this state shall open, establish, operate, or maintain a pharmacy, located out-of-state, unless the pharmacy is issued a permit by the board.

La. R.S. 37:1222(A). A person applying for a permit to open, establish, operate, or maintain a pharmacy, within or outside of this state, shall complete an application in such form and contain such data as the board may require, and complete such other requirements as deemed necessary by the board, including but not limited to designation and identification of a pharmacist-in-charge.

DOS Prothonotary.
May 10 2023

La. R.S. 37:1222(E). A permit to operate a pharmacy shall not be transferable.

La. R.S. 37:1232(A). A pharmacy located outside this state which does business in this state within the meaning of this Chapter, shall hold a current pharmacy permit as provided in this Chapter. The pharmacy shall be designated a "nonresident pharmacy" and the permit shall be designated a "nonresident pharmacy permit."

LAC, Title 46: LIII §1101(A). Individuals, partnerships, corporations, limited liability companies, or associations desiring to operate a pharmacy in Louisiana, or outside the state where prescriptions drugs/devices are dispensed and delivered to Louisiana residents, shall execute an application for a pharmacy permit for their particular classification of pharmacy.

LAC, Title 46: LIII §1135(A)(1)(e). The holder of a pharmacy permit shall notify the board, in writing, prior to the transfer of ownership, in order for the board to complete an inspection of the pharmacy premises. A change of ownership of a pharmacy is evident under the following conditions: a 50 percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original permit or the last renewal application.

LAC, Title 46: LIII §1135(A)(2). The new owner(s) of the pharmacy shall submit a properly completed pharmacy permit application, with appropriate fee, to the board.

LAC, Title 46: LIII §1135(A)(4). Pharmacy permits are not transferable from the original holder(s) of the permit to the new owner(s).

LAC, Title 46: LIII §2305(A). The out-of-state pharmacy shall apply for a permit and annual permit renewals on forms provided by the board.

LAC, Title 46: LIII §2307(C). Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

To facilitate the submission of this Consent Agreement, Respondent does not contest the allegations and agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

DOS Prothonotary:
May 10 2023

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

POSTMEDS, INC., holder of Louisiana Pharmacy Permit No. 7761, is ordered to pay a fine of $10,000.00 and to reimburse the Board $250.00 for administrative costs, and $324.48 for investigative costs with total payment due the Board of $10,574.80, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter, waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing and to judicial review of this Consent Agreement. Moreover, at no time shall Respondent request the expungement, rescission or removal of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, Matt Davis-Ratner, authorized to act on behalf of and acting on behalf of **POSTMEDS, INC.**, understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

[Remainder of page intentionally left blank; signature page to follow.]

DOS Prothonotary:
May 10 2023

SIGNED, AGREED TO AND ENTERED ON THIS 6th DAY OF April, 2022.

POSTMEDS, INC.
Louisiana Pharmacy Permit No. 7761

Matt Davis-Ratner

BY: Matt Davis-Ratner
Authorized Representative

Harry J. Philips

HARRY J. "SKIP" PHILIPS
Taylor Porter
450 Laurel St, 8th Floor
Baton Rouge, LA 70801
Attorney for Respondent

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

Carlos Finalet

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on May 11, 2022, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Marty R McKay

Marty R. McKay
Hearing Officer for the Board

DOS Prothonotary.
May 10 2023

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 22-183
PostMeds, Inc dba Truepill	)	
	)	
Registration No. 22-117859	)	

AMENDED SUMMARY ORDER

NOW on this 20th day of January, 2023, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of PostMeds, Inc dba Truepill ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Amended Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 22-104228 which entitled Respondent to operate as a non-resident pharmacy in the State of Kansas.

2. On November 6, 2019, the ownership of Respondent's non-resident pharmacy changed.

3. On May 22, 2020, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 3, 2020 with an expiration date of June 30, 2021. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?"

DOS Prothonotary:
May 10 2023

Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

4. On June 1, 2021, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 21, 2021 with an expiration date of June 30, 2022. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?" Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

5. Due to staffing challenges, personnel turnover and administrative oversight resulting from its early, rapid growth and restructuring and the corresponding COVID-19 pandemic, Respondent mistakenly failed to report the 2019 ownership change and related disclosures to the Board in its May 22, 2020 and June 1, 2021 renewal applications.

6. On April 18, 2022, the Board received notification from Respondent of an ownership change and several past disciplinary actions not previously reported to the Board including: North Carolina Board of Pharmacy Consent Order of Discipline dated March 8, 2022; California State Board of Pharmacy Letter of Admonishment dated January 23, 2020; California State Board of Pharmacy Citation and Fine dated June 16, 2020; California State Board of Pharmacy Citation and Fine Order of Abatement dated August 25, 2021; Alabama State Board of Pharmacy Final Order dated October 25, 2021; California State Board of Pharmacy Citation and Fine dated January 24, 2019; and California State Board of Pharmacy Citation dated December 16, 2019.

DOS Prothonotary:
May 10 2023

3795

7. On April 28, 2022, the Board received from Respondent a Form BA-22 Non-Resident Pharmacy Registration Application ("Respondent's Application"), notifying of the change in ownership effective November 6, 2019, and applying for a new non-resident pharmacy registration under the new ownership.

8. On May 20, 2022, the Board approved Respondent's Application and issued Respondent the new Non-Resident Pharmacy Registration No. of 22-117859 ("Respondent's Registration") under their new ownership.

9. Prior to receiving the ownership change application, registrant provided a letter notifying of the late ownership change, as well as unreported discipline. Ownership change application completed indicating discipline had occurred and providing details of discipline (5 occurrences).

10. In mitigation, Respondent states that it has invested in additional staff, engaged internal and external legal counsel and implemented training efforts to prevent any such reporting oversights in the future.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against a registration on any ground that would authorize the board to take action against the registration of a pharmacy under K.S.A. 65-1627, and amendments thereto.

3. Pursuant to K.S.A. 65-1627(e)(1), the Board may take action against the registration of a pharmacy upon a finding that such pharmacy has been operated in such manner

DOS Prothonotary:
May 10 2023

that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith.

4. Pursuant to K.S.A. 65-1627(e)(4), the Board may take action against the registration of a pharmacy upon a finding that the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country.

5. Pursuant to K.S.A. 65-1657, no nonresident pharmacy shall ship, mail, or deliver, in any manner, prescription drugs to a patient in this state unless registered with the Board as a nonresident pharmacy.

6. Pursuant to K.S.A. 65-1645(f), registrations shall not be transferable.

7. Pursuant to K.A.R. 68-2-9, each registrant shall notify the executive secretary of the Board in writing of any change in majority ownership of the operation for which the registration was issued within five days after the date the change in ownership becomes effective.

8. Pursuant to K.A.R. 68-2-23, each pharmacy owner shall notify the board in writing within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against the pharmacy or the pharmacy owner or any application, license, registration, or permit held by the pharmacy owner.

9. Respondent's registered facility changed ownership on November 6, 2019 but Respondent did not provide notification or file a new application with the Board until April 18 and 28, 2022, respectively.

10. Respondent's failure to submit the complete change of ownership to the Board until April 2022 is a violation pursuant to K.A.R. 68-2-9 and an unlawful transfer of the previous

DOS Prothonotary:
May 10 2023

registration to the new ownership. Respondent's actions are a violation pursuant to K.S.A. 65-1657 and K.S.A. 65-1627(e)(1), and a basis to take action against Respondent's Registration.

11. Respondent failed to notify the Board of the six disciplinary actions by North Carolina, California, and Alabama until April 18, 2022, nearly one to two years after they were effective, is a violation of K.A.R. 68-2-23 and a basis to take action against Respondent's Registration pursuant to K.S.A. 65-1627(e)(1) and (e)(4).

ORDER

Taking into account the mitigating and corrective actions of Respondent, the Board finds and concludes that Respondent's conduct, as described above, violates the Act and such conduct warrants the imposition of a fine pursuant to K.S.A. 65-1658, in the amount of $3,500.00. Respondent has 30 days from the date of this order to pay the fine.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

DOS Prothonotary:
May 10 2023

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

1/20/2023
Date

Kansas Board of Pharmacy

DOS Prothonotary:
May 10 2023

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 24th day of January, 2023, deposit in business mail a copy of the foregoing Amended Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

PostMeds, Inc dba Truepill
3121 Diablo Ave.
Hayward, CA 94545

and via email to:

Christopher C. Tillery
Seigfreid Bingham, P.C.
ctillery@sb-kc.com
Attorney for Respondent

Brenda L. Head
Disciplinary Counsel for the Kansas Board of Pharmacy

DOS Prothonotary:
May 10 2023

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania **Bureau of Professional and** **Occupational Affairs**		
vs.	**Case Nos.**	**21-54-004050** **22-54-008273**
PostMeds Inc **Respondent**		

CERTIFICATE OF SERVICE

I, Glenn P. Masser, hereby certify that I have this 11th day of May 2023 caused a true and correct copy of the foregoing Notice and Order to Show Cause to be served upon all parties of record in this proceeding in accordance with the requirements of Rule 33.31 of the General Rules of Administrative Practice and Procedure, 1 Pa. Code § 33.31 (relating to service by the agency).

CERTIFIED MAIL, ELECTRONIC RETURN RECEIPT REQUESTED AND FIRST-CLASS MAIL, POSTAGE PREPAID:

PostMeds Inc
3121 Diablo Ave
Hayward, CA 94545
9171.9690.0935.0253.8568.95

/s/ Glenn P. Masser
Glenn P. Masser
Prosecuting Attorney
Commonwealth of Pennsylvania
Department of State
P. O. Box 69521
Harrisburg, PA 17106-9521
(717) 783-7200

DOS Prothonotary
May 10 2023

DocuSign Envelope ID: 660533CB-A6C4-4E95-9C2C-6E586D48D9DF

IN THE MATTER OF:	)	
POSTMEDS INC. dba TRUEPILL and/or TRUEPILL f/k/a POSTMEDS INC.	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
Non-Resident Pharmacy Permit Number: 114861	)	**CASE NO: 22-L-0114**

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975), § 41-22-12(f), the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** has violated the provisions of law set out in the Statement.

2. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** shall pay an administrative fine in the amount of Three Thousand Dollars ($3,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** attempt to discharge the same. Payments shall be made payable to Alabama State Board of Pharmacy and mailed to 111 Village Street, Birmingham, Alabama 35242.

3. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama

DocuSign Envelope ID: 660533CB-A6C4-4E95-9C2C-6E586D48D9DF

Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), §20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** further waives any objection to the attorney for the Board preparing, drafting, or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** hereby releases the Board, its members, agents, representatives, servants, and employees from any and all liability, claims, damages, fees, or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.'s** permit, including, but not limited to revocation.

6. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** acknowledges and agrees that it has read this Consent Order and that it fully understands the terms, conditions, and contents of the same. **PostMeds Inc. dba Truepill and/or**

DocuSign Envelope ID: 660533CB-A6C4-4E95-9C2C-6E586D48D9DF

Truepill f/k/a PostMeds Inc. acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and agrees that it had the right to seek advice of counsel before executing this Consent Order.

DONE this the 6th of June, 2023.

PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.

BY: Donny Simkin
Donny Simkin

ITS: General Counsel, Truepill, Inc.

James Hoover
Counsel for **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.**

DONE this the 8th of JUNE, 2023.

ALABAMA STATE BOARD OF PHARMACY

By: Robert M. Colburn, Jr., R. Ph., President

Jennifer Muro Neumann,
Attorney for the Alabama State Board of Pharmacy

OF COUNSEL:
Jennifer Muro Neumann, PC
Post Office Box 381082
Birmingham, AL 35238
(205) 451-3092

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 22-183
PostMeds, Inc dba Truepill	)	
	)	
Registration No. 22-117859	)	

AMENDED SUMMARY ORDER

NOW on this 20th day of January, 2023, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of PostMeds, Inc dba Truepill ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Amended Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 22-104228 which entitled Respondent to operate as a non-resident pharmacy in the State of Kansas.

2. On November 6, 2019, the ownership of Respondent's non-resident pharmacy changed.

3. On May 22, 2020, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 3, 2020 with an expiration date of June 30, 2021. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?"

Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

4. On June 1, 2021, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 21, 2021 with an expiration date of June 30, 2022. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?" Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

5. Due to staffing challenges, personnel turnover and administrative oversight resulting from its early, rapid growth and restructuring and the corresponding COVID-19 pandemic, Respondent mistakenly failed to report the 2019 ownership change and related disclosures to the Board in its May 22, 2020 and June 1, 2021 renewal applications.

6. On April 18, 2022, the Board received notification from Respondent of an ownership change and several past disciplinary actions not previously reported to the Board including: North Carolina Board of Pharmacy Consent Order of Discipline dated March 8, 2022; California State Board of Pharmacy Letter of Admonishment dated January 23, 2020; California State Board of Pharmacy Citation and Fine dated June 16, 2020; California State Board of Pharmacy Citation and Fine Order of Abatement dated August 25, 2021; Alabama State Board of Pharmacy Final Order dated October 25, 2021; California State Board of Pharmacy Citation and Fine dated January 24, 2019; and California State Board of Pharmacy Citation dated December 16, 2019.

7. On April 28, 2022, the Board received from Respondent a Form BA-22 Non-Resident Pharmacy Registration Application ("Respondent's Application"), notifying of the change in ownership effective November 6, 2019, and applying for a new non-resident pharmacy registration under the new ownership.

8. On May 20, 2022, the Board approved Respondent's Application and issued Respondent the new Non-Resident Pharmacy Registration No. of 22-117859 ("Respondent's Registration") under their new ownership.

9. Prior to receiving the ownership change application, registrant provided a letter notifying of the late ownership change, as well as unreported discipline. Ownership change application completed indicating discipline had occurred and providing details of discipline (5 occurrences).

10. In mitigation, Respondent states that it has invested in additional staff, engaged internal and external legal counsel and implemented training efforts to prevent any such reporting oversights in the future.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against a registration on any ground that would authorize the board to take action against the registration of a pharmacy under K.S.A. 65-1627, and amendments thereto.

3. Pursuant to K.S.A. 65-1627(e)(1), the Board may take action against the registration of a pharmacy upon a finding that such pharmacy has been operated in such manner

that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith.

4. Pursuant to K.S.A. 65-1627(e)(4), the Board may take action against the registration of a pharmacy upon a finding that the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country.

5. Pursuant to K.S.A. 65-1657, no nonresident pharmacy shall ship, mail, or deliver, in any manner, prescription drugs to a patient in this state unless registered with the Board as a nonresident pharmacy.

6. Pursuant to K.S.A. 65-1645(f), registrations shall not be transferable.

7. Pursuant to K.A.R. 68-2-9, each registrant shall notify the executive secretary of the Board in writing of any change in majority ownership of the operation for which the registration was issued within five days after the date the change in ownership becomes effective.

8. Pursuant to K.A.R. 68-2-23, each pharmacy owner shall notify the board in writing within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against the pharmacy or the pharmacy owner or any application, license, registration, or permit held by the pharmacy owner.

9. Respondent's registered facility changed ownership on November 6, 2019 but Respondent did not provide notification or file a new application with the Board until April 18 and 28, 2022, respectively.

10. Respondent's failure to submit the complete change of ownership to the Board until April 2022 is a violation pursuant to K.A.R. 68-2-9 and an unlawful transfer of the previous

registration to the new ownership. Respondent's actions are a violation pursuant to K.S.A. 65-1657 and K.S.A. 65-1627(e)(1), and a basis to take action against Respondent's Registration.

11. Respondent failed to notify the Board of the six disciplinary actions by North Carolina, California, and Alabama until April 18, 2022, nearly one to two years after they were effective, is a violation of K.A.R. 68-2-23 and a basis to take action against Respondent's Registration pursuant to K.S.A. 65-1627(e)(1) and (e)(4).

ORDER

Taking into account the mitigating and corrective actions of Respondent, the Board finds and concludes that Respondent's conduct, as described above, violates the Act and such conduct warrants the imposition of a fine pursuant to K.S.A. 65-1658, in the amount of $3,500.00. Respondent has 30 days from the date of this order to pay the fine.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

1/20/2023
Date

Alex Blasi
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 24th day of January, 2023, deposit in business mail a copy of the foregoing Amended Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

PostMeds, Inc dba Truepill
3121 Diablo Ave
Hayward, CA 94545

and via email to:

Christopher C. Tillery
Seigfreid Bingham, P.C.
ctillery@sb-kc.com
Attorney for Respondent

/s/ Brenda L. Head
Brenda L. Head
Disciplinary Counsel for the Kansas Board of Pharmacy

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: CONSENT ORDER

POSTMEDS, INC.

LOUISIANA PHARMACY PERMIT NO. 7761 Case No. 21-0456

****

CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy (hereinafter referred to as the "Board") on March 16, 2022 at the Board office, 3388 Brentwood Drive, Baton Rouge, LA 70809, in the matter of POSTMEDS, INC. (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 7761, 3121 Diablo Ave., Hayward, CA 94545-2701, with attorney Skip Philips and Postmeds Corporate Counsel Donnie Simkin appearing on behalf of Respondent.

WHEREAS, WHEREAS, on August 27, 2018, the Louisiana Board of Pharmacy issued a non-resident pharmacy permit, PHY.007761-NR, to Postmeds Inc. At that time, Postmeds Inc. was 31.5% owned by Mohammad Umar Afridi, 31.5% owned by Siddharth Viswanathan, 16.5% owned by Initialized III L.P., and 20.5% owned by others with no individual owner holding more than 4%. On December 17, 2021 the Board received an "Application for New Louisiana Pharmacy Permit for Nonresident Pharmacy" from Postmeds, Inc. d/b/a Truepill. Accompanying correspondence and organization chart detailed a 100% change in the ownership structure of Postmeds Inc., effective November 6, 2019. Postmeds Inc. went from being owned 31.5% by Mohammad Umar Afridi, 31.5% by Siddharth Viswanathan, 16.5% by Initialized III L.P., and 20.5% by others with no individual owner holding more than 4%, to being owned 100% by Truepill, Inc.

WHEREAS, the Board alleges that such actions constitute violations of the following:

La. R.S. 37:1241 (A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

La. R.S. 37:1221(B). No out-of-state pharmacy providing pharmacy services to residents of this state shall open, establish, operate, or maintain a pharmacy, located out-of-state, unless the pharmacy is issued a permit by the board.

La. R.S. 37:1222(A). A person applying for a permit to open, establish, operate, or maintain a pharmacy, within or outside of this state, shall complete an application in such form and contain such data as the board may require, and complete such other requirements as deemed necessary by the board, including but not limited to designation and identification of a pharmacist-in-charge.

La. R.S. 37:1222(E). A permit to operate a pharmacy shall not be transferable.

La. R.S. 37:1232(A). A pharmacy located outside this state which does business in this state within the meaning of this Chapter, shall hold a current pharmacy permit as provided in this Chapter. The pharmacy shall be designated a "nonresident pharmacy" and the permit shall be designated a "nonresident pharmacy permit."

LAC, Title 46: LIII §1101(A). Individuals, partnerships, corporations, limited liability companies, or associations desiring to operate a pharmacy in Louisiana, or outside the state where prescriptions drugs/devices are dispensed and delivered to Louisiana residents, shall execute an application for a pharmacy permit for their particular classification of pharmacy.

LAC, Title 46: LIII §1135(A)(1)(e). The holder of a pharmacy permit shall notify the board, in writing, prior to the transfer of ownership, in order for the board to complete an inspection of the pharmacy premises. A change of ownership of a pharmacy is evident under the following conditions: a 50 percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original permit or the last renewal application.

LAC, Title 46: LIII §1135(A)(2). The new owner(s) of the pharmacy shall submit a properly completed pharmacy permit application, with appropriate fee, to the board.

LAC, Title 46: LIII §1135(A)(4). Pharmacy permits are not transferable from the original holder(s) of the permit to the new owner(s).

LAC, Title 46: LIII §2305(A). The out-of-state pharmacy shall apply for a permit and annual permit renewals on forms provided by the board.

LAC, Title 46: LIII §2307(C). Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

To facilitate the submission of this Consent Agreement, Respondent does not contest the allegations and agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

POSTMEDS, INC., holder of Louisiana Pharmacy Permit No. 7761, is ordered to pay a fine of $10,000.00 and to reimburse the Board $250.00 for administrative costs, and $324.48 for investigative costs with total payment due the Board of $10,574.80, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter, waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing and to judicial review of this Consent Agreement. Moreover, at no time shall Respondent request the expungement, rescission or removal of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, Matt Davis-Ratner, authorized to act on behalf of and acting on behalf of **POSTMEDS, INC.**, understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

[Remainder of page intentionally left blank; signature page to follow.]

SIGNED, AGREED TO AND ENTERED ON THIS 6th DAY OF April, 2022.

POSTMEDS, INC.
Louisiana Pharmacy Permit No. 7761

Matt Davis-Ratner

BY: Matt Davis-Ratner
Authorized Representative

Harry J. Philips

HARRY J. "SKIP" PHILIPS
Taylor Porter
450 Laurel St, 8th Floor
Baton Rouge, LA 70801
Attorney for Respondent

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

Carlos Finalet

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

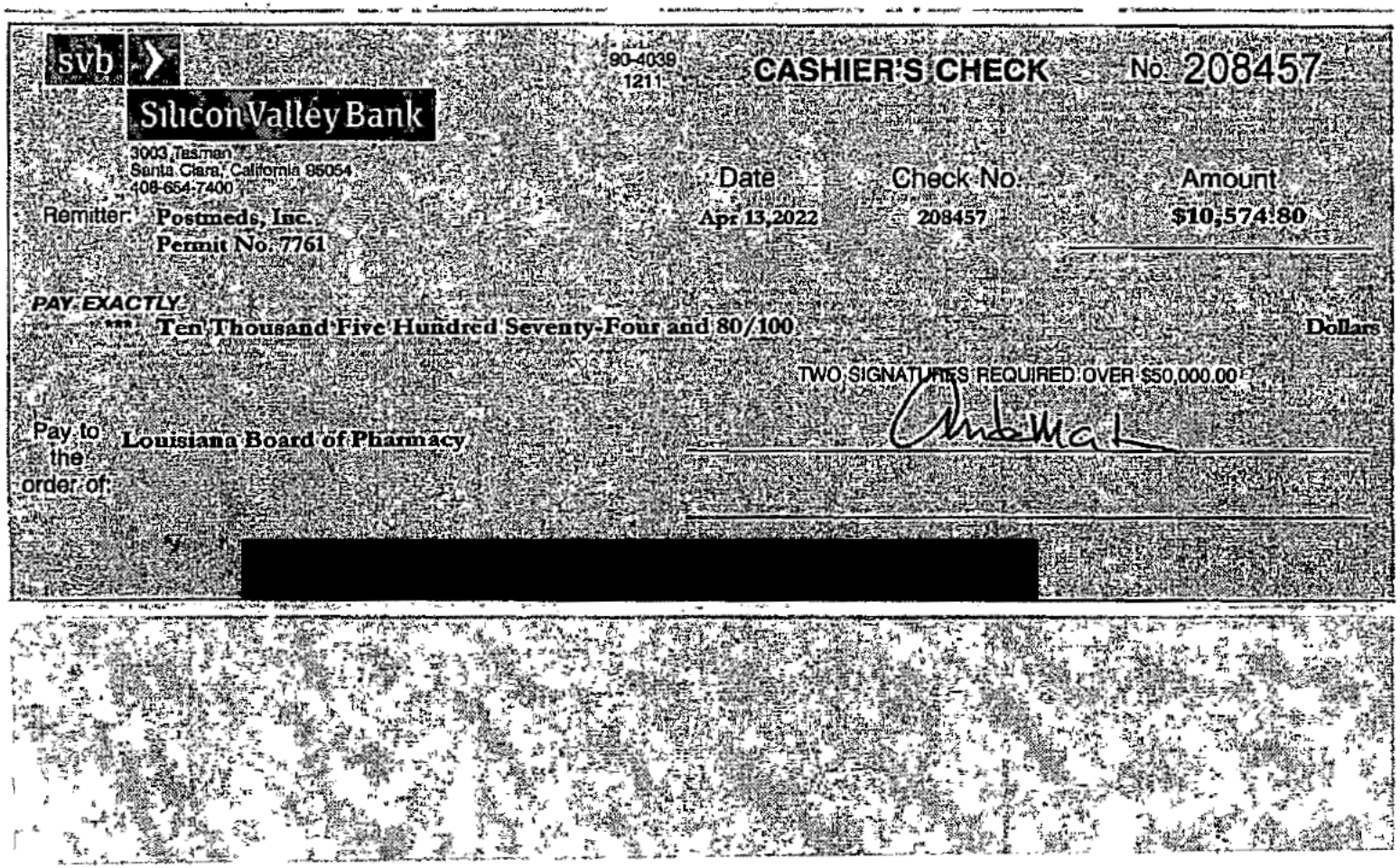
ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on May 11, **2022**, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Marty R McKay

Marty R. McKay
Hearing Officer for the Board



svb

Silicon Valley Bank

3003 Tasman
Santa Clara, California 95054
408-654-7400

90-4039
1211

CASHIER'S CHECK No. 208457

Remitter: Postmeds, Inc.
Permit No. 7761

Date	Check No.	Amount
Apr 13,2022	208457	$10,574.80

PAY EXACTLY
*** Ten Thousand Five Hundred Seventy-Four and 80/100 Dollars

TWO SIGNATURES REQUIRED OVER $50,000.00

Pay to the order of: Louisiana Board of Pharmacy

[redacted]

STATE OF NORTH CAROLINA
NORTH CAROLINA BOARD OF PHARMACY

IN THE MATTER OF	)	
	)	
POSTMEDS, INC. d/b/a Truepill,	)	**CONSENT ORDER**
	)	**OF DISCIPLINE**
Permit No. 13413 and Its Successor Permit(s).	)	

THIS MATTER came to be considered before a member of the North Carolina Board of Pharmacy (hereinafter, the "Board") pursuant to 21 N.C.A.C. 46 .2008. The Conference was scheduled for Thursday, February 24, 2022, and, after appropriate notice, was heard on that day by Board member Wallace E. Nelson. Respondent PostMeds, Inc. was informed of its right to be present at the pre-hearing conference and declined. The Board's General Counsel, Clinton R. Pinyan, represented the Board.

Respondent has agreed to waive a formal hearing in the above-referenced matter. It stipulates and agrees to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. By its consent, Respondent also stipulates that it waives its right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order as a basis for the action taken. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. On November 20, 2017, the Board issued Permit No. 13413 to Respondent PostMeds, Inc. d/b/a Truepill (Permit No. 13413) ("PostMeds").

2. On PostMeds' initial permit application, its then-pharmacist manager, Mohammad Umar Afridi, submitted an inaccurate statement that he was the sole owner and officer of PostMeds. In fact, PostMeds now acknowledges that Afridi and Siddharth

Viswanathan each owned 47 percent of PostMeds on November 20, 2017, with others owning six percent, and that Viswanathan was also an officer of PostMeds.

3. Viswanathan and the minority owners' interests would not have raised questions about the permit application in this particular case. If PostMeds had disclosed the true ownership and officers of PostMeds, the Board still would have granted PostMeds a permit. However, it was an inaccurate statement that Afridi, as the person who submitted the application, knew was inaccurate. That statement prevented the Board from vetting Viswanathan as the owner of the pharmacy. Because of the inaccuracy of the representations, the initial permit was void ab initio.

4. In November 2019, PostMeds went through a corporate restructuring. During that restructuring, Truepill, Inc. was created as a holding company for PostMeds. At that time, Truepill, Inc. became the sole owner of PostMeds. Afridi, Viswanathan and the other former direct owners of PostMeds became indirect owners with the same ownership interests in the holding company, Truepill, Inc., that they had before the transfer of ownership.

5. This restructuring required PostMeds to submit a transfer of ownership application and have that application granted before the restructuring closed. PostMeds failed to do this. Therefore, even if the initial permit had been valid (which it was not), it would have become invalid upon the corporate restructuring.

6. Insertion of a new holding company between the ultimate owners and PostMeds would not have raised questions about the permit application in this particular case. The ownership interests of the ultimate owners did not change. If PostMeds had disclosed the new holding company, the Board still would have granted the transfer of ownership. However,

PostMeds failed to submit the transfer of ownership application or otherwise disclose the interests of Truepill, Inc.

7. In each of its subsequent renewals, PostMeds failed to correct the ownership information that it had inaccurately submitted on its initial application or to list Truepill, Inc., as the direct owner of the pharmacy.

8. On November 4, 2021, counsel for PostMeds informed the Board that its "current ownership information on file with the North Carolina Board of Pharmacy is out of date." Upon follow-up questioning, the next day, PostMeds disclosed that it should have submitted a transfer of ownership application in November 2019. It further was apparent from the ownership information that PostMeds provided that Afridi made inaccurate representations about ownership and officers on PostMed's initial application that had never been corrected.

9. PostMeds agreed to stop shipping any drugs, devices or medical equipment into the State of North Carolina until the matter was resolved. It further agreed to stop shipping or dispensing any drugs, devices or medical equipment from six other pharmacies under its ownership until the matter was resolved (even though those pharmacies did not receive permits until after the transfer of ownership had occurred, and so did not suffer from the same problem).

10. PostMeds submitted a transfer of ownership application promptly.

11. Although PostMed's disclosure of its inaccuracies was tardy, its remedial actions are a mitigating factor in this matter.

CONCLUSIONS OF LAW

1. Reporting of correct and complete ownership information on an initial pharmacy permit application or a renewal application is material, indeed essential, to the Board's ability to ensure that a pharmacy will provide services safely and competently to the public.

2. PostMeds made inaccurate statements about its ownership and officers on its initial application, which it failed to correct at any point through its 2022 renewal. That initial permit was therefore void ab initio and violated G.S. § 90-85.38(b).

3. The creation of Truepill, Inc. as a holding company further triggered a requirement to report the ownership change and obtain a successor permit, and to do so before the closing of the transaction that created Truepill, Inc. The transaction "result[ed] in a different person . . . owning more than 50 percent interest in the permit holder . . . ." 21 NCAC 46.1603. Failure to apply for and obtain a successor permit prior to the transaction, and a continuing failure to disclose the ownership interest of Truepill, Inc., violated G.S. § 90-85.38(b).

IT IS THEREFORE ORDERED:

PostMeds was in violation of G.S. § 90-85.38(b) in North Carolina from November 20, 2017 until at least November 4, 2021. Respondent PostMed's Permit No. 13413 was **VOID** from the time that it was granted on November 20, 2017. G.S. § 90-85.38(c).

Respondent PostMed's change of ownership application is **APPROVED** as a successor permits to Permit No. 13413 (the "Successor Permit") with the following **CONDITIONS:**

1. PostMeds shall provide timely advance notice of any contemplated change in ownership to the current pharmacist-manager and any future pharmacist-manager(s) of the Successor Permit. PostMeds shall consult with the Successor Permit's pharmacist-manager(s) to determine whether any contemplated transaction triggers the need to obtain new permits. PostMeds shall authorize the Successor Permit's pharmacist-manager(s) to take any necessary action to update that ownership information with the Board or to apply for new permits. If a contemplated transaction triggers the need for new permits, PostMeds shall not complete that

transaction unless and until either the Board issues new permits or PostMeds ceases all practice of pharmacy at the permitted location.

2. The Successor Permit shall violate no laws governing the practice of pharmacy or the distribution of drugs.

3. The Successor Permit shall violate no rules or regulations of the Board.

4. If the Successor Permit fail to comply with any term or condition of this Order, it may be subject to additional disciplinary action by the Board.

This is the 8th day of March, 2022

NORTH CAROLINA BOARD OF PHARMACY

By: /s/ William A. Mixon
William A. Mixon
President

Respondent PostMeds, Inc. has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. Respondent freely, knowingly and voluntarily waives its right to such a hearing by entering into this Consent Order.

Respondent understands and agrees that by entering into this Consent Order, it certifies that it has read the foregoing Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions that may be taken concerning this matter.

Respondent further understands that should it violate the terms and conditions of this Consent Order, the Board may take additional action.

Respondent understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

Respondent understands that it has the right to have counsel of its choice review and advise them with respect to their rights and this Consent Order, and represents that it enters this Consent Order after consultation with counsel or after knowingly and voluntarily choosing not to consult with counsel. Respondent further agrees that the person who is executing this Consent Order has been duly authorized by any required corporation action to execute on behalf of Respondent.

CONSENTED TO BY:



Date 3/7/22

Printed Name: Matt Davis-Ratner

Title: General Counsel

STATE OF _____

_____ COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the above-named representative of PostMeds, Inc. personally appeared before me this day, and acknowledged the due execution of the foregoing document.

Date: _____

_____
Notary Public

_____

My commission expires: _____

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

August 25, 2021

TRUEPILL
ATTN: FRANCESCO CONSOLE, PIC
3121 DIABLO AVE
HAYWARD, CA 94545

RE: CI 2020 89223
TRUEPILL
PHY 56100

The attached Citation CI 2020 89223, has been issued to TRUEPILL, PHY 56100. A copy has been sent to the pharmacy, and a copy is being sent to the pharmacist-in-charge for informational purposes only. As pharmacist in charge it is your responsibility to insure the pharmacy's compliance with the term(s) and condition(s) of the citation by the date(s) ordered, and to ensure the pharmacy's compliance with all pharmacy laws.

The Citation references the specific statutes and regulations violated, and defines each violation charged. The Citation details the conduct that resulted in the issuance of the citation. In addition the citation may also include information regarding fine(s) assessed. If fine(s) have been assessed, the citation specifies the amount and the specific violation for which the fine was levied.

If you have any questions please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

Sincerely

Joshua Monforte
Citation and Fine Analyst

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE
ORDER OF ABATEMENT

COPY

Citation Number	Name, License No
CI 2020 89223	TRUEPILL, PHY 56100

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1714 subd. (b)	Operational Standards and Security; pharmacy responsible for pharmacy security	$5,000.00
Bus. & Prof. Code § 4169 subd. (a)(2)/Health & Safety Code § 111295	Prohibited Acts; Purchase, trade, sell, or transfer dangerous drugs to that the person knew or reasonably should have known were adulterated.../It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated	Citation without a fine

CONDUCT:

California Code of Regulations 1714, section b states, (b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy. Specifically, Truepill Pharmacy, PHY56100, located at 3121 Diablo Ave, Hayward, CA 94545 was in violation when they failed to keep dangerous drugs stored according to policy and procedure 2001.4, Oversight of Pharmacy Safety, which states: "The Pharmacy will make all attempts at maintaining a room temperature below 85F and ideally between 68-77F". Between 7/1/2020 and 9/14/2020, on numerous occasions, dangerous drug storage temperatures, summarized in Table 2, exceeded the recommended storage temperatures. The most egregious of these temperature spikes were:

a)On 8/13/2020, in the cage area of the warehouse, dangerous drugs were stored approximately 161 hours over 77 F and 47 hours over 85F.
b)On 9/6/2020, in the cage area of the warehouse, dangerous drugs were stored approximately 59 hours over 77 F and 17 hours above 85F.
c)On 8/13/2020, in the Parata Automated dispensing machine located in the warehouse, dangerous drugs were stored for approximately 163 hours above 77 F and 44 hours above 85 F.

Business and Professions Code 4169 section (a), subdivision (2) states, A person or entity shall not do any of the following: (2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code as it relates to Health and Safety Code 111295 which states, It is unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug or device that is adulterated. Specifically, Truepill Pharmacy, PHY56100, located at3121 Diablo Ave, Hayward, CA 94545 was in violation when they used the MKT calculation alone instead of in conjunction with manufactures stability data as stated in USP <1079>, which provides guidance for assessing possible adulteration to dangerous drugs stored at the pharmacy due to excessive heat. In particular, USP<1079> states, "Knowing the MKT for an excursion is useful for evaluating the potential impact on product quality. However, it is also essential to know the upper and lower temperature limits of any excursion. If these extreme temperatures are outside available stability data, it may not be possible to predict the quality impact of the excursion with any confidence regardless of the MKT. At higher temperatures the kinetics of degradation may change or new degradation reactions may occur. Truepill Pharmacy did not consider the manufacture's stability data for at least 72 dangerous drugs stored in the cage area of the warehouse which were held and offered for sale when determining if a dangerous drug was adulterated by the extreme heat, summarized in Table 3. For each one of the 72 dangerous drugs, the maximum temperature for storage was listed by the manufacturer as 77F or storage information was not listed. As there was no stability temperature for at least the 72 drugs in question and per USP<1079>, the MKT cannot be without the stability data, these drugs which were held and offered for sale were adulterated.

ORDER OF ABATEMENT

By the Abatement date/payment date submit to the Board the following:

- Either (1) full payment of the assessed fine(s) in the amount of $5,000.00; or payment in the amount of $1,000.00 and (2) provide proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within ninety (90) days.

COPY

If you choose option (2), within 90 days of this citation, you shall submit proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations. Any failure to do so shall be deemed a failure to meet the abatement requirements of this citation.

If you timely submit proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within 90 days from the date the citation was issued, this citation shall be reduced to $1,000.00 and proof of compliance of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations shall be considered satisfactory abatement of the citation.

If you fail to submit proof of compliance of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within 90 days from the date the citation was issued, the stay shall be lifted and the fine(s) in the amount of $5,000.00 shall be due and owing from you within thirty (30) days of any such failure.

CITATION ISSUED ON: August 25, 2021	TOTAL AMOUNT OF FINE(S): $5,000.00
PROOF OF ABATEMENT AND PAYMENT OF FINE(S) DUE BY: September 24, 2021	

COPY

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

January 23, 2020

VIA CERTIFIED MAIL

LETTER OF ADMONISHMENT

TRUEPILL
ATTN: MOHAMMAD UMAR AFRIDI, CEO
3121 DIABLO AVE
HAYWARD, CA 94545

RE: CI 2019 84877
TRUEPILL
PHY 56100

This LETTER OF ADMONISHMENT is being issued pursuant to Business and Professions Code section 4315 for failure to comply with the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the board's website at www.pharmacy.ca.gov, under Forms and Publications.)

The Board of Pharmacy has completed its investigation in the above referenced matter. All documentation and/or statements relating to the investigation have been accepted and included in an Investigation Report on file in this office. Facts contained in this report lead to the conclusion that the following violations of pharmacy laws or regulations have occurred:

JURISDICTION: Bus. & Prof. Code § 4315; 1764/56.10(a) - Unauthorized disclosure of prescription and medical information

Unauthorized disclosure of prescriptions: California Code of Regulations section 1764 states in pertinent part that no pharmacist shall exhibit, discuss, or reveal the contents of any prescription or any medical information furnished by the prescriber with any person other than the patient or his or her authorized representative and Civil Code section 56.10 subdivision (a) states, in pertinent part, no provider of health care shall disclose medical information regarding a patient of the provider of health care without first obtaining an authorization. Truepill Pharmacy was not in compliance with these regulations. Specifically, on 4/17/2019, Truepill Pharmacy (PHY56100) located at 3121 Diablo Avenue in Hayward, CA shipped prescription RX#1186395 to the wrong person. The prescription was intended for AR but was shipped to the address of MS in error. Also, Truepill Pharmacy shipped prescriptions to patients with a shipping label showing the return address of NuRx located at 6838 Ellicott Drive in East Syracuse, NY and from Apostrophe located at 330 2nd Street in Oakland, CA. NuRx and Apostrophe are not licensed pharmacies and prescription packages returned as undeliverable to these locations would cause the disclosure of medical information without authorization.

Shipping prescriptions to an unauthorized person violates California Code of Regulations section 1764 and Civil Code 56.10.

If you wish to contest this Letter of Admonishment, you may do so by submitting, within 30 days of the date of service of this Letter of Admonishment, namely February 22, 2020, the attached "Request for an Office Conference" form. If an office conference is not requested, compliance with the Letter of Admonishment shall not constitute an admission of the violations described in the Letter of Admonishment.

Unless it is dismissed following an office conference or you receive other instructions from the Board in writing, Pharmacy Law requires that you maintain and have readily available for inspection a copy of this Letter of Admonishment and any written corrective action plan, if any, for at least three years from the date of issuance at the top of this letter. The Letter of Admonishment will be considered a public record for purposes of disclosure for three years from issuance. The issuance of this Letter of Admonishment does not limit the board's ability to pursue other disciplinary or administrative action under Business and Professions Code section 4315, subdivision (f).

If you have any questions regarding this Letter of Admonishment, please contact Barbera Schleicher, Public Inquiry Analyst at (916) 518-3081.

Sincerely

Virginia Herold

Virginia Herold
Executive Officer
Board of Pharmacy

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

MODIFIED CITATION AND FINE

Citation Number	Name, License No
CI 2017 78633	TRUEPILL (FORMERLY POSTMEDS INC.), PHY 56100

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059 subd. (a)/Bus. & Prof. Code § 4067 subd. (a)	**Furnishing dangerous drugs without a prescription/Internet; Dispensing Dangerous Drugs or Devices without Prescription; No person shall dispense or furnish, or cause to be furnished dangerous drugs...on the internet...without a prescription issued pursuant to a good faith examination**	**Citation without a fine**
Bus. & Prof. Code § 4174	**Dispensing on order of nurse practitioner or person of similar status.**	**Citation without a fine**

CONDUCT:

Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Business and Professions Code 4059 (a) states in pertinent part a person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. In conjunction with Business and Professions Code 4067 (a) which states no person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination of a human or animal, or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations and (f) for the purposes of this section, "good faith prior examination" includes the requirements for a physician and surgeon in Section 2242. In conjunction with Business and Professions Code 2290.5 (a) For purposes of this division, the following definitions shall apply: (3) "Health care provider" means either of the following: (A) a person who is licensed under this division. Between 4/1/2018 to 10/31/2018, Postmeds Inc. (PHY56100) located at 3121 Diablo Ave. Hayward, CA dispensed prescriptions issued by prescribers who were not licensed in California. Specifically, 2 prescriptions were issued by Nurse Practitioner Jenny Ingle; 9 prescriptions were issued by Dr. Brook Randal; 6 prescriptions were issued by Dr. Jessica Rubino and 4 prescriptions were issued by Dr. Sudhi Trye. These prescribers were not licensed in California at the time the prescriptions were initiated and shipped to a California resident. Postmeds pharmacy dispensed the prescriptions issued by unlicensed prescribers to

California residents in violation of Business and Professions Code 4059 (a) and Business and Professions Code 4067 (a).

Dispensing by Pharmacist Upon Order of Nurse Practitioner: Business and Professions Code 4174 states in pertinent part notwithstanding any other law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section 4052.1, 4052.2, 4052.3, or 4052.6. Postmeds Inc. (PHY56100) located at 3121 Diablo Ave. Hayward, CA dispensed prescriptions issued by Nurse Practitioners and Physicians Assistants who had not yet entered into an established standardized procedure or protocol developed by a supervising physician. Between 4/1/2018 and 10/31/2018, the following prescribers issued prescriptions to Postmeds without an established protocol in place: Physician's Assistant Leanne Mays issued 8 prescriptions and Physician's Assistant Susan Owen issued 6 prescriptions. Between 4/1/2018 and 10/31/2018, the following prescribers issued prescriptions to Postmeds entering into a protocol after the prescriptions were issued: Nurse Practitioner Joni Gunzburger issued 4,782 prescriptions; Nurse Practitioner Cristin Hackel issued 10,819 prescriptions and Nurse Practitioner Jessica Horwitz issued 4,711 prescriptions. Postmeds Pharmacy dispensed the prescriptions issued by Nurse Practitioners and Physicians Assistants who had not yet entered into standardized procedures or protocols as required by Business and Professions Code 4174.

CITATION ISSUED ON: June 16, 2020	TOTAL AMOUNT OF FINE(S): $0.00
PAYMENT OF FINE(S) DUE BY: July 16, 2020	

BakerHostetler

September 20, 2024

Baker&Hostetler LLP

Marc N. Wagner
direct dial: 202.861.1557
mwagner@bakerlaw.com

CONFIDENTIAL AND PROPRIETARY
FOIA EXEMPT

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

Re: Notice of Indirect Change of Ownership—TRUEPILL NY LLC —License No. PH04209

Dear Sir or Madam:

Truepill NY LLC, a New York limited liability company, operates the pharmacy located at 850 3rd Ave, STE 404, Brooklyn, NY 11232 (the "Licensee"). Licensee holds the above referenced license. This letter serves as notice to the Board of a corporate merger at the grandparent level for the Licensee (the "Transaction"). Pursuant to this indirect change of ownership, Truepill NY LLC is submitting a change of ownership application.

In connection with the Transaction, scheduled to close on or around September 26, 2024 and pursuant to an Agreement and Plan of Merger entered into on July 28, 2024, Paulus Holdings Limited, an Irish private limited company will acquire 100% of outstanding capital stock of Truepill, Inc., the indirect owner of the Truepill NY LLC. A simplified organizational chart showing the ownership structure of the Licensee pre- and post-closing is included with the application.

This grandparent level change will not result in any change of name, location, or other material change to the current business activities of Licensee. Additionally, the Licensee's tax identification number and National Provider Identifier will not change as a result of the Transaction. Mr. Paul Greenall and Mr. Aaron Wurst will remain as Co-Managers of the Licensee. However, Licensee reserves the right to review such matters at a later date, and subject to application requirements under state laws, to make any changes that may be appropriate in light of such review and further developments.

If the Board requires any additional documentation to assist in its review and processing of the enclosed applications, please let us know as soon as possible. Please contact me at 202.861.1557 or at mwagner@bakerlaw.com with any questions or additional information requests. Thank you for your assistance.

Sincerely,

Marc N. Wagner
Associate

Enclosures

8D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FS1293884
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH_____ _____		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Seven Hills Pharmacy LLC

Physical Address: 2722 E. Kemper Rd.

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: _____ State: _____ Zip: _____

Telephone: 517-771-0367 Toll Free # (NAC 639.708, NRS 639.23286): 844-643-0169

Fax: 513-771-0369 Contact Email: compliance@truepill.com

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Christopher Spitzer

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21780

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Christopher Spitzer	NV Pharmacist Registration #: 21780
Name: Christopher Gibson	NV Pharmacist Registration #: 22645
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NR5.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Postmeds, Inc.

Corporation/Organization Name: Seven Hills Pharmacy LLC

Mailing Address: 2722 E. Kemper Rd.

City: Sharonville State: OH Zip: 45241

Telephone: 650-353-5495 Email: compliance@truepill.com

Contact Person Name: Quynh Do

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Co-Manager (title) for Seven Hills Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Paul Greenall

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

9/19/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Paul Greenall hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Co-Manager (title) for Seven Hills Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

_____
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this _____ day of _____, 20_____

_____
Notary Public

California
Jurat Attatched

CALIFORNIA JURAT WITH AFFIANT STATEMENT GOVERNMENT CODE § 8202

☑ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], *not* Notary)

1 _____
2 _____
3 _____
4 _____
5 _____

_____ _____
Signature of Document Signer No. 1 *Signature of Document Signer No. 2 (if any)*

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Marin

Subscribed and sworn to (or affirmed) before me on this 19 day of September, 2024,
Date *Month* *Year*
by
(1) Paul Greenall

(and (2) _____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature Lilia Rivas
Signature of Notary Public

TCI1 LILIA RIVAS CRESCENCIO COMM. # 2442906 NOTARY PUBLIC-CALIFORNIA MARIN COUNTY My Comm. Expires APR. 27, 2027 TCI1

Seal
Place Notary Seal Above

OPTIONAL

Though this section is optional, completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: _____ Document Date: _____

Number of Pages: _____ Signer(s) Other Than Named Above: _____

©2016 National Notary Association • www.NationalNotary.org • 1-800-US NOTARY (1-800-876-6827) Item #5910

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Paul Greenall

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

9/19/24

Date

Board Use Only	Date Received: _____	Amount: 500.00/V# 647144

UNITED STATES OF AMERICA
STATE OF OHIO
OFFICE OF THE SECRETARY OF STATE

I, Frank LaRose, do hereby certify that I am the duly elected, qualified and present acting Secretary of State for the State of Ohio, and as such have custody of the records of Ohio and Foreign business entities; that said records show SEVEN HILLS PHARMACY LLC, a Delaware Limited Liability Company, Registration Number 4684707, was registered in the State of Ohio on May 24, 2021, is currently authorized to transact business in this state.



Witness my hand and the seal of the Secretary of State at Columbus, Ohio this 11th day of October, A.D. 2022.

Ohio Secretary of State

Validation Number: 202228404922

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836 | http://www.pharmacy.ohio.gov

License 0232000312

Seven Hills Pharmacy Llc

2722 E Kemper Rd
Sharonville, OH 45241-1818
Hamilton County

Terminal - Pharmacy - Category 3

TDDD Inspection Updated 7/8/24

August 7, 2024

License 0232000312 - Seven Hills Pharmacy Llc

Full

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836
http://www.pharmacy.ohio.gov

Completed by Elizabeth Bond
Start 8/7/2024 10:07 AM
End 8/7/2024 1:04 PM

Organization

Name
Seven Hills Pharmacy Llc

License Type
Terminal - Pharmacy - Category 3

Category

License Number
0232000312

Business Type
II - Independent Community Retail (1 Outlet)

DEA Number

Responsible Person
Christopher Spitzer, R.Ph.

Hours of Operation
M-F:9AM-5PM; SaSu: Closed

Contact

Address
2722 E Kemper Rd
Sharonville, OH 45241-1818
Hamilton County

Primary Number
(727) 421-8504

Fax Number
(513) 771-0369

Website

Personnel

Name	Initials	Position	I.D. No.	Phone	Email
Christopher Gibson, RPH		Pharmacist	03236967	(513) 771-0369	christopher.gibson@truepill.com
Christopher Spitzer, R.Ph.		Pharmacist	03236754	(513) 771-0367	christopher.spitzer@truepill.com

1) *Initial Inspection Information

1) Personnel conducting inspection

Observation
Compliance Specialist Elizabeth Bond, RPh

2) Were multiple inspection guides used during this inspection?

No

3) Facility Description

Observation
Facility is a retail pharmacy servicing the patients of various online prescriber entities. Pharmacy has the ability to serve the community (walk-in patient). Pharmacy does not accept insurance. Pharmacy has limited drug stock and focuses on veterinary medicine, women's health, non-controlled weight loss and Zepbound. Pharmacy processes approximately 2,000 prescriptions per day. Pharmacy employs 12 pharmacists, 9 pharmacy technicians and 17 delivery/support personnel. Pharmacy ships prescriptions to patients in Ohio and 48 other states using USPS, UPS, and FedEx. The site doesn't currently house any controlled substances.

4) Have there been any changes in the TDDD's ownership, business name or trade name, category, or address without submitting a new application to the Board?

No

5) *Does the TDDD have a valid registration issued by the Drug Enforcement Administration?

Yes

Observation
FS1293884 EXP: 2/28/2025

6) Is the Responsible Person present during the inspection?

Yes

Observation
RP: Christopher Spitzer, RPh

7) How often is the Responsible Person at the TDDD?

Observation
40 hours per week

8) Does the TDDD distribute dangerous drugs outside of Ohio?

Yes

Observation
The pharmacy is licensed in 48 states in addition to Ohio.

9) Does the TDDD ensure all individuals are acting within their scope of practice?

Yes

12) Additional Observations

Observation
This routine inspection was conducted at the request of the licensee for out of state license renewals. No issues noted.

17.1) Disposal of controlled substances (OAC 4729:5-3-01)

1) Does the facility dispose of controlled substances?

No

Primarily utilizes reverse distributor

Observation

Pharmacy has not disposed of any controlled substances to date but would utilize Inmar (reverse distributor) for destruction.

2) REMINDER: Facility is required to dispose of controlled substance dangerous drugs in accordance with 21 C.F.R. 1317.

Observation

Facility is required to dispose of controlled substance dangerous drugs in accordance with 21 C.F.R. 1317.

The method of destruction must render the controlled substances to a state of non-retrievable. Records of controlled substance destruction that are required pursuant to 21 C.F.R. 1304 (9/25/2023) shall be maintained for a minimum of three years and made readily retrievable.

Non-retrievable means, for the purpose of destruction, the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A controlled substance is considered "non-retrievable" when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes.

3) Does the method of destruction render the controlled substances to a state of non-retrievable?

Yes

4) Are records of controlled substance destruction maintained for a minimum of three years?

No

Observation

For Information:
Rule 4729:5-3-01 | Disposal of controlled substances. Effective 7/1/24
(B) A terminal distributor of dangerous drugs shall dispose of controlled substance dangerous drugs in accordance with 21 C.F.R. 1317 (9/25/2023). The method of destruction must render the controlled substances to a state of non-retrievable. Records of controlled substance destruction that are required pursuant to 21 C.F.R. 1304 (9/25/2023) shall be maintained for a minimum of three years and made readily retrievable.

21 CFR 1304 is extensive. Form 41 is required for destruction.
1304.21 General requirements of continuing records
(e) Record of destruction. In addition to any other recordkeeping requirements, any registered person that destroys a controlled substance pursuant to § 1317.95(d), or causes the destruction of a controlled substance pursuant to § 1317.95(c), shall maintain a record of destruction on a DEA Form 41. The records shall be complete and accurate, and include the name and signature of the two employees who witnessed the destruction. Except, destruction of a controlled substance dispensed by a practitioner for immediate administration at the practitioner's registered location, when the substance is not fully exhausted (e.g., some of the substance remains in a vial, tube, or syringe after administration but cannot or may not be further utilized), shall be properly recorded in accordance with § 1304.22(c), and such record need not be maintained on a DEA Form 41.

17.2) *Report theft/significant loss: dangerous drug, controlled substance, drug document(OAC 4729:5-3-02)

1) *REMINDER: Theft or significant loss of dangerous drugs and drug documents

Observation
A terminal distributor of dangerous drugs shall notify the following upon discovery of the theft or significant loss of any dangerous drug or controlled substance, including drugs in transit that were either shipped from or to the licensed location: (1) The state board of pharmacy, by telephone or other method determined by the board, immediately upon discovery of the theft or significant loss; (2) If a controlled substance, the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1301.76 (9/9/2014); (3) Law enforcement authorities pursuant to section 2921.22 of the Revised Code.

A terminal distributor of dangerous drugs shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, and law enforcement authorities of any theft or loss of uncompleted prescription blank(s) used for writing a prescription, written prescription order(s) not yet dispensed and original prescription order(s) that have been dispensed.

A terminal distributor of dangerous drugs shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, law enforcement authorities and the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1305.16 (9/9/2014) of the theft or loss of any DEA form 222.

For more information on reporting, visit: www.pharmacy.ohio.gov/theft

2) *Has the TDDD experienced any theft or significant loss of any dangerous drugs in the past twenty-four months?

No

3) Controlled Substances: Was the theft or significant loss of controlled substances reported using the federal DEA report?

Not Applicable

4) Non-Controls: Was the theft or significant loss of non-controlled dangerous drugs reported to the board?

Not Applicable

5) Has the TDDD experienced any theft or loss of uncompleted prescription blank(s), written prescription order (s) not yet dispensed, or original prescription order(s) that have been dispensed in the past twenty-four months?

No.

6) Has the TDDD reported any theft or loss of any DEA form 222 in the past twenty-four months?

No. No losses have occurred.

8) Reporting Theft or Loss Guidance Document

Observation
The guidance document "Reporting Theft or Loss of Dangerous Drugs and Drug Documents" can be found here: www.pharmacy.ohio.gov/theft

17.4) Verification of licensure prior to sale or purchase (OAC 4729:5-3-04)

1) What drug distributors does the TDDD purchase from?

Observation
Wholesalers:

- McKesson
- TopRx
- Keysource
- Anda
- Drug Manufacturers (Merck Vet Health, BI, and Zoetis)

2) Purchase: Has the TDDD completed an annual query of the board's online roster prior to purchase of dangerous drugs at wholesale?

Yes

17.6) Storage of adulterated drugs (OAC 4729:5-3-06)

1) Does the facility have expired/adulterated drugs on site?

No

Observation
Randomly audited stock and no expired medications were identified.

17.7) Controlled substances inventory requirements (OAC 4729:5-3-07)

1) Are controlled substance inventory records maintained as required by rule?

Yes: Initial inventory completed

Yes: Annual inventory is completed

Yes: Inventory records are maintained for three years and are readily retrievable

Observation

Observed inventories dated September 6, 2022, January 10, 2023, and January 24, 2024

For Information:

CFR Requirements as of 3/2/22:

-The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

-If no initial inventory- record zero balance

-DEA biennial inventory may be done on date within two years of previous biennial inventory

-If drug becomes scheduled that previously was not: every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand.

-Inventories of dispensers: In determining the number of units of each finished form of a controlled substance in a commercial container that has been opened, the dispenser shall do as follows:

(i) Schedules I or II: make an exact count or measure of contents; or

(ii) Schedule III, IV, or V, make an estimated count or measure of contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.

Rule 4729:5-3-07 | Controlled substances inventory requirements. Effective 3/1/19

(A) Unless otherwise stated in this division of the Administrative Code, all category III terminal distributor licensees shall complete a controlled substances inventory in accordance with 21 CFR 1304.11 (9/9/2014).

(B) All controlled substance inventories performed in accordance with this rule shall be conducted on an annual basis. The annual inventory may be taken on any date which is within thirteen months of the previous inventory date.

(C) The terminal distributor's responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a terminal distributor of dangerous drugs.

(D) All inventory records shall be maintained for a period of three years from the completion date of the inventory and made readily retrievable.

(E) When a drug or compound is added to the schedule of controlled substances by state or federal law, rule or regulation, a terminal distributor shall complete an inventory pursuant to this rule of all stocks of such drug or compound no later than ten days of the drug or compound being added to the schedule.

(F) In the event a terminal distributor of dangerous drugs commences business with no controlled substances on hand, this fact shall be recorded as the initial inventory.

17.14) General security requirements (OAC 4729:5-3-14)

1) Does the TDDD provide effective controls and procedures to deter and detect the theft and diversion of dangerous drugs?

Yes

2) Observations of Overall Security System

Observation

The pharmacy is located in a single story building of solid construction and is the sole occupant of the space. Pharmacy has ten exterior entry doors. All doors have turn key locks. All doors are electronically alarmed. Two of the back doors have lock plates. Walls and floors are solid and all walls go deck to ceiling. Pharmacy space has non-opening windows. Pharmacy has one metal roll down bay-style door that is secured by the alarm system. The keys are under the control of licensed pharmacists only. Once unlocking the door, a pharmacist has to badge tap to disarm the alarm. Only pharmacist badges are programmed to disarm the alarm. Pharmacy is equipped with cameras throughout on the interior and exterior of the building. Motion sensors are located throughout. Each section of windows is equipped with a glass break. Pharmacy alarm system alerts the responsible person when the alarm is triggered or has not been set. Pharmacy barricade is adequate with no issues noted.

18.2.1) Minimum Standards (OAC 4729:5-5-02)

1) Does the TDDD ensure sufficient personnel are scheduled to work at all times?

Yes

2) Does the TDDD provide sufficient tools and equipment in updated and good repair?

Yes

3) Does the TDDD provide pharmacy personnel access to the required references?

Yes: Internet access to the board's website

Yes: Internet access Ohio laws and administrative rules (https://codes.ohio.gov)

Yes: Internet access to the code of laws of the United States of America (variously abbreviated to Code of Laws of the United States, United States Code, U.S. Code, U.S.C., or USC)

Yes: Internet access to the code of federal regulations

Yes: Access to hard copy or internet access to appropriate pharmacy reference materials

Yes: Access of telephone number of a poison control center

Observation

Micromedex and Plums

4) Does the TDDD ensure pharmacy personnel are sufficiently trained to safely and adequately perform their assigned duties?

Yes

5) Does the TDDD maintain a stock of drugs sufficient to compound and prepare the types of prescriptions offered by the pharmacy?

Yes

6) Does the TDDD maintain stock of prescription containers necessary to dispense drugs in accordance with federal and state laws?

Yes

7) *Does the TDDD ensure all areas where drugs and devices are stored and prepared are dry, welllit, well-ventilated, and maintained in a clean, sanitary, and orderly condition?

Yes

Observation

Current controlled room temperature was 69.2 degrees F and humidity was 54%.

8) *Are hours of operation of the pharmacy department posted?

Yes

9) *Are all employees of the pharmacy identified by a name tag?

Yes: Name tag includes job title

10) Does the TDDD provide adequate security for all dangerous drugs?

Yes

11) Does the TDDD provide sufficient time for pharmacists to complete professional duties and responsibilities?

Yes

18.8) *Prospective drug utilization review (OAC 4729:5-5-08)

1) Do pharmacists review the patient profile prior to dispensing a prescription?

Yes: Reviews over-utilization or under-utilization
Yes: Reviews therapeutic duplication
Yes: Reviews drug-disease state contraindications
Yes: Reviews drug-drug interactions
Yes: Reviews incorrect drug dosage
Yes: Reviews drug-allergy interactions
Yes: Reviews abuse/misuse
Yes: Reviews inappropriate duration of drug treatment
Yes: Reviews food-nutritional supplements-drug interactions

2) Do pharmacists take appropriate steps to avoid or resolve the potential problem identified during prospective drug utilization review?

Yes: Requests and reviews an OARRS report or another state's prescription drug monitoring report
Yes: Consults with the prescriber
Yes: Counsels the patient

4) Do pharmacists request and review an OARRS report covering at least one year time period prior to dispensing an outpatient prescription in specific circumstances?

Other

Observation
The site does not dispense controlled substances or reportable drugs. The site would follow applicable regulations if doing so.

5) REMINDER: Professional Judgment regarding OARRS

Observation
In the event an OARRS report is not immediately available, the pharmacist shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to reviewing a report

6) *Do any of the pharmacists use delegates to request OARRS reports?

No

7) *REMINDER: A pharmacist shall not dispense a prescription of doubtful, questionable, or suspicious origin.

Observation
Based upon information obtained during a prospective drug utilization review, a pharmacist shall use professional judgment when making a determination about the legitimacy of a prescription. A pharmacist shall not dispense a prescription of doubtful, questionable, or suspicious origin.

8) *REMINDER: OARRS reports cannot be provided directly to a patients or other health care professionals.

Observation
REMINDER: OARRS reports may be reviewed with the patient or another health care provider, however a copy may not be provided to the patient. Patients requesting a copy of their OARRS report must submit a notarized request to the Board of Pharmacy in person or by mail, and the report must be received in person at the Board office during normal business hours. Proof of identity is required to obtain an OARRS report.

18.9) Patient counseling (OAC 4729:5-5-09)

1) Do Pharmacists or pharmacists designee verbally offer to provide the service of counseling for any prescription, new or refills, dispensed?

Yes

Observation
The company has a call center located at in CA and remote services to provide verbal counseling via telephone to all patients.

3) Does the Pharmacist or Pharmacy Intern counsel the patient or caregiver when requested?

Yes

4) Are other forms of information used to supplement counseling by the Pharmacist or Intern?

Yes

Observation
Drug information sheets and/or MedGuides if applicable are sent to the patient with each dispensing.

18.14) Prescription pick-up station (OAC 4729:5-5-14)

1) PHARMACY: Does the pharmacy act as a "pick-up" station or intermediary for the purpose of having prescriptions filled?

No

2) PHARMACY: Does the pharmacy dispense dangerous drugs to a PHARMACY which offers, in any manner, its services as a "pick-up station" or intermediary for the purpose of having prescriptions filled or delivered?

No

18.17) Drugs repackaged or relabeled by a pharmacy

1) Does the pharmacy repackage dangerous drugs?

No

18.18) Dispensing customized patient medication packages by an outpatient pharmacy (OAC 4729:5-5-18)

1) Does the pharmacy dispense customized patient medication packages?

No

18.23) *Security, control and storage of dangerous drugs in an outpatient pharmacy (OAC 4729:5-5-23)

1) *Does a pharmacist provide supervision of the dangerous drugs, hypodermics, D.E.A. controlled substance order forms, and all records relating to the distribution of dangerous drugs?

Yes

2) Is the pharmacy separated from the merchandising or public areas?

Yes

Observation

In the event a patient was in-house, the patient would remain in the OTC area of the pharmacy and would be supervised by pharmacy personnel at all times. The pharmacy distribution area is separated from the OTC area by double doors.

3) Is the pharmacist on duty responsible for the security of the pharmacy and supervision of pharmacy personnel?

Yes: Pharmacist is physically present at TDDD

5) Is a pharmacist present at all times a person enters the pharmacy?

Yes

6) *Are all schedule II controlled substance dangerous drugs stored in a securely locked, substantially constructed cabinet or safe?

Not Applicable

Observation

The site does not house controlled substances. The site obtained a DEA Registration for contractual reasons and to allow for possible future growth.

7) *How is the pharmacy secured when a pharmacist cannot be present and responsible for security?

A physical barrier with suitable locks

An alarm system approved by the board

Observation

Kastle is the alarm monitoring company.
Suitable locks are approved by the board. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board of any installation or modification to a physical barrier prior to implementation.

Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board of any installation or modification to an alarm system prior to implementation. This notification requirement does not apply if a pharmacy also utilizes an approved physical barrier

8) Does the alarm system and testing meet the requirements of the rule?

Yes: It is monitored by a central station for control and can detect unauthorized access to the pharmacy

Yes: The alarm system is tested on a biannual basis.

Yes: Testing records are maintained for three years

Observation

Kastle is the alarm monitoring company. The alarm is tested on an annual basis.

9) Does the pharmacy contain all dangerous drugs, hypodermics, and D.E.A. controlled substance order forms and every other item or product that requires the supervision or sale by a pharmacist?

Yes

10) *Does only a licensed pharmacist have access to keys or other methods of gaining access to the pharmacy?

Yes

12) Are records relating to the distribution of dangerous drugs only maintained in the pharmacy?

Yes

14) Does only a pharmacist have access to the pharmacy or stock of dangerous drugs or assume responsibility for the security of dangerous drugs, hypodermics, and any other item or product that requires the supervision or sale by a pharmacist?

Yes

18) *Does the pharmacy provide services by means of a drive-through facility that can be secured?

No: No drive-thru facilities

19) *Do refrigerators and freezers used for the storage of dangerous drugs monitor the temperature?

Yes: Uses temperature monitoring system capable of detecting and alerting staff of a temperature excursion

Observation
Pharmacy uses SmartSense by Digi (TempAlert) to monitor the temperatures of the refrigerators. The current refrigerated temperature was 39.7 degrees F.

20) *Does the TDDD have policies and procedures to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs in the refrigerator(s) and freezer(s)?

Yes

21) *Does the TDDD have a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store dangerous drugs?

Yes

18.24) *Drug inventory records and other record keeping provisions (OAC 4729:5-5-24)

9) *Are all records readily retrievable and uniformly maintained for a period of three years?

Yes

10) Are all records within the past 3 years maintained on site?

Yes

Observation
The site was licensed in March of 2022 and has all applicable records on-site since license issuance.

11) *Are all records maintained under appropriate supervision and control to restrict unauthorized access?

Yes

Observation
All records are under the supervision of a licensed pharmacist.

49) Substance Abuse and Mental Health Resources for Healthcare Professionals

1) Substance Abuse and Mental Health Resources for Healthcare Professionals

Observation
The healthcare profession is not immune to substance use disorder and mental health conditions. Such medical conditions impair a healthcare professional's competency, ability, and judgment. Substance use disorder and/or mental health conditions that are left untreated may not only cause a healthcare professional to risk their career, but may also endanger the life of a patient. These medical conditions can be effectively treated, and it is possible for healthcare professionals that are in treatment or recovery to return to practice.

The State of Ohio Board of Pharmacy encourages all healthcare professionals who may be struggling with substance use disorder or mental health condition to seek help. The following are resources that can assist healthcare professionals in getting help: (The resources listed here are for informational purposes only and do not constitute an endorsement by the State of Ohio Board of Pharmacy. They do not represent a complete list of the resources available)

Ohio Careline 1-800-720-9616, emotional support, with referral to other resources if needed.
Crisis text line, text "4hope" to 741 741 to speak with a crisis counselor.
Treatment Bridge 1-877-275-6364, for addiction and mental health services.
National Suicide prevention dial 988, or call 1-800-273-8255.
Ohio Domestic Violence Network 1-800-934-9840
Pharmacist Rehabilitation Organization (www.ohiopro.org) for pharmacists and pharmacy interns.
Ohio Physicians Health Program (www.ophp.org)

50) Inspection Affirmation

1) Inspection Affirmation

Observation

As the person in charge at the time of this inspection, I affirm that I have reviewed this inspection report with the Specialist/Agent/Inspector, and understand its content.

If this inspection report requires a written response, I understand, per OAC 4729:5-3-03, that either of the following must be submitted to the State of Ohio Board of Pharmacy within 30 days of this inspection:
(1) The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or
(2) An explanation disputing the observed violations.

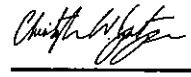
I understand that if I am not the responsible person documented on this site's Ohio terminal distributor of dangerous drugs license, I will ensure the responsible person is provided a complete copy of this inspection report in a timely manner.

I further acknowledge that a written response does not release the licensee listed in this inspection report from potential disciplinary action.

Responses must be either emailed (with a copy of the inspection report) to WRITTENRESPONSE@PHARMACY.OHIO.GOV or mailed to 77 South High Street, 17th Floor, Columbus, Ohio 43215.

Summary

No Issue Found

Reviewed by Christopher Spitzer, R.Ph. 

(signature)

License Look Up

9/16/2024 12:04 PM

Seven Hills Pharmacy LLC

License Number	0232000312
Status	Active
Sub-Status	
Board	Board of Pharmacy
License Type	Terminal - Pharmacy - Category 3
License Issue Date	03/22/2022
License Expiration Date	03/31/2025
License Effective Date	04/01/2023
Street Address	2722 E Kemper Rd
City	Sharonville
State	OH
Zipcode	45241-1818
Country	United States
Board Action	No

Supervised By:

Supervisor Name	Supervisor License	Status	Start Date	End Date
CHRISTOPHER SPITZER	03236754	Active	Mon Jan 03 00:00:00 GMT 2022	

Current date & time: **9/16/2024 12:04 PM**

STATE OF OHIO
BOARD OF PHARMACY

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until March 31, 2025.

Seven Hills Pharmacy LLC

2722 E Kemper Rd

Sharonville, OH 45241-1818

License Number: 0232000312

Terminal - Pharmacy - Category 3

Expiration Date: March 31, 2025

CLASS: Terminal - Pharmacy - Category 3
BUSINESS TYPE: II – Independent Community Retail (1 Outlet)

Responsible Person – Print, sign and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person
Christopher W. Spitzer	

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request on your Ohio eLicense Dashboard - https://elicense.ohio.gov/oh_homepage.

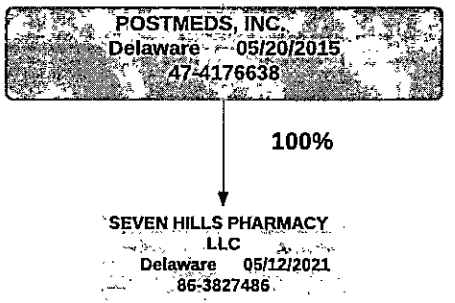
State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

List of Officers

Paul Greenall - [redacted] Benjamin Way, Healdsburg, CA 95448

Aaron Wurst - [redacted] Woodbury Street, Providence, RI 02906

CONFIDENTIAL! DO NOT DISTRIBUTE TO THIRD PARTIES



*No individual/entity in this group owns > = 3% of Truepill, Inc., and therefore no individul/entity in this group owns > = 5% of the Provider

**No individual owns >= 5% of Truepill, Inc., and therefore no individual/entity in this group owns > = 5% of the Provider

Corporation

Limited Liability Company

This organizational chart was prepared by the Legal Team & contains entity name, state of domicile, date of formation & EIN.
For additional details, please contact entities@truepill.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Seven Hills Pharmacy LLC

Pharmacy/Wholesaler License # (if applicable): OH 0232000312

Physical Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 513-771-0367 Website:

Licensing Company Email: compliance@truepill.com

Section 2: Personal Information

First: Christopher Middle: William Last: Spitzer

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Gardenside Lane

City: Loveland State: OH Zip: 45140

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Massachusetts, Dartmouth		09/16 - 05/18	
Address	**City**	**State**	**Zip**
285 Old Westport Rd	North Dartmouth	MA	02747
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
Massachusetts College of Pharmacy and Health Sciences		09/04 - 05/10	
Address	**City**	**State**	**Zip**
179 Longwood Ave	Boston	MA	02115
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Gateway Regional High School		09/00 - 06/04	
Address	**City**	**State**	**Zip**
12 Littleville Rd	Huntington	MA	01050
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/18 - present	[redacted] Gardenside Ln	Loveland	OH	45140
10/17 - 03/18	[redacted] Sanctuary Ln	Maineville	OH	45039
09/13 - 09/17	[redacted] Winchester St	Brookline	MA	02446
09/10 - 08/13	[redacted] sland Hill Ave	Malden	MA	02148
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Seven Hills Pharamacy			09/21 - present	
Business Address	**City**		**State**	**Zip**
2722 E. Kemper Rd	Sharonville		OH	45241
Phone	**Title**		**Number of Employed Hours**	
(513) 771-0367	Pharmacist in Charge		2,200	
Description of Duties				
Managing all pharmacy operations, hiring pharmacy/warehouse personnel, filling/shipping prescriptions, inventory management				

Business Name			From - To (MM/YY – MM/YY)	
CVS Health			1/18 - 8/21	
Business Address	**City**		**State**	**Zip**
13 Mary St	Cincinnati		OH	45216
Phone	**Title**		**Number of Employed Hours**	
(800) 746-7287	District Leader, Pharmacy Supervisor, Pharmacy Manager		7,040	
Description of Duties				
Responsible for the overall retail store operations in assigned district (28 stores), P&L manager, operating COVID clinics, inventory management				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Christopher Spitzer, **certify that as the designated representative for**

Seven Hills Pharmacy, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CS I am at least 21 years of age;
3. CS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christopher Spitzer

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/9/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Spitzer

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/9/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Hamilton

I, Christopher W. Spitzer, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/9/2024

Date

Subscribed and Sworn to before me this 9th day of September. 2024

Notary Public Signature

HAYLEY ABNEY - NOTARY PUBLIC
COMM EXP: AUG 4, 2025
STATE OF OHIO

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Seven Hills Pharmacy LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): OH 0232000312

Physical Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 513-771-0367 Website: n/a

Licensing Company Email: compliance@truepill.com

Section 2: Personal Information

First: Aaron Middle: Michael Last: Wurst

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Woodbury Street

City: Providence State: RI Zip: 02906

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Harvard Business School			08/13 - 05/15	
Address		**City**	**State**	**Zip**
Harvard Business School		Boston	MA	02163
Diploma/Degree obtained, if any				
MBA				
School Name			**From - To (MM/YY – MM/YY)**	
Cornell University			09/05 - 05/07	
Address		**City**	**State**	**Zip**
Cornell University		Ithaca	NY	14850
Diploma/Degree obtained, if any				
School Name			**From - To (MM/YY – MM/YY)**	
United States Military Academy			06/03 - 06/05	
Address		**City**	**State**	**Zip**
606 Thayer Rd		West Point	NY	10996
Diploma/Degree obtained, if any				
no degree				
School Name			**From - To (MM/YY – MM/YY)**	
University of Toledo			08/02 - 05/03	
Address		**City**	**State**	**Zip**
2801 Bancroft St		Toledo	OH	43606
Diploma/Degree obtained, if any				
no degree				
School Name			**From - To (MM/YY – MM/YY)**	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/16 - current	[redacted] Woodbury Street	Providence	RI	02906
08/15 - 08/16	[redacted] Park Row West, APT 512	Providence	RI	02903
06/13 - 07/15	[redacted] Akron Street APT 418	Cambridge	MA	02138
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Postmeds Inc D/B/A Truepill			11/23 - current	
Business Address		**City**	**State**	**Zip**
3121 Diablo Ave		Hayward	CA	94545
Phone	**Title**			
650-353-5495	President			
Description of Duties				
Oversee P&L and the development and execution of our business strategy, and commercial growth.				

Business Name			From - To (MM/YY – MM/YY)	
The Carlyle Group			01/21 - 11/23	
Business Address		**City**	**State**	**Zip**
1001 Pennsylvania Ave NW		Washington	DC	20004
Phone	**Title**			
	Principal			
Description of Duties				
Lead the Healthcare team for Carlyle' s Global Portfolio Solutions (GPS) group				

Business Name			From - To (MM/YY – MM/YY)	
CVS Health			08/11 - 01/23	
Business Address		**City**	**State**	**Zip**
1 CVS Drive		Woonsocket	RI	02895
Phone	**Title**			
	Vice President			
Description of Duties				
Managed and sat on the Retail Leadership Team				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:		Yes	No
1.	Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2.	If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3.	Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4.	Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5.	Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6.	Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7.	Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8.	Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9.	Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10.	Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Aaron Wurst

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12 Sept 2024

Date

Please have this section completed in the presence of a Notary Public.

State of Rhode Island, ss. County of Providence

I, Aaron Wurst, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12 Sept 2024

Date

Subscribed and Sworn to before me this 12 day of September 2024

Notary Public Signature

Randi Stanley
Notary Public, State of Rhode Island
My Commission Expires October 13, 2024
Notary # 759760

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Seven Hills Pharmacy, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): OH 0232000312

Physical Address: 2722 EE. Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: Sharonville State: _____ Zip: _____

Telephone: 513-771-0367 Website: n/a

Licensing Company Email: compliance@truepill.com

Section 2: Personal Information

First: Paul Middle: James Last: Greenall

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] Benjamin Way

City: Healdsburg State: CA Zip: 95448

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Bayes Business School, University of London			10/98 - 07/02	
Address		City	State	Zip
106 Bunhill Row		London	UK	EC1Y 8TZ
Diploma/Degree obtained, if any				
BSC Business Management				
School Name			From - To (MM/YY – MM/YY)	
Abbotsfield School			09/91-07/98	
Address		City	State	Zip
Clifton Gardens		Hillingdon	UK	UB10 0EX
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/20-Date	[redacted] Benjamin Way	Healdsburg	CA	95448
09/11 - 07/20	[redacted] Church St, Apt H	San Francisco	CA	94114
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Postmeds Inc D/B/A Truepill			07/22 - Date
Business Address	**City**	**State**	**Zip**
3121 Diablo Ave	Hayward	CA	94545
Phone	**Title**		
855-910-8606	CEO		

Description of Duties
Managing the overall resources and operations of company, making major corporate decisions, and acting as the main point of contact between the board of directors, employees, and the public.

Business Name			From - To (MM/YY – MM/YY)
Prophet Brand Strategy LLC			04/19 - 06/22
Business Address	**City**	**State**	**Zip**
150 Spear St Ste 1300	San Francisco	CA	94105
Phone	**Title**		
(415) 518-5692	Senior Partner, Chief Strategy Officer		

Description of Duties
Primary responsibility for strategy formulation and management, including developing the corporate vision and strategy, overseeing strategic planning, and leading strategic initiatives, including M&A, transformation, partnerships, and costs

Business Name			From - To (MM/YY – MM/YY)
McKesson Corporation			07/09-12/18
Business Address	**City**	**State**	**Zip**
1 Post Street	San Francisco	CA	94104
Phone	**Title**		
415-983-8300	Sr Vice President, Enterprise Strategy		

Description of Duties
Primary responsibility for strategy formulation and management, including developing the corporate vision and strategy, overseeing strategic planning, and leading strategic initiatives, including M&A, transformation, partnerships, and costs

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations		Yes	No
1.	Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2.	If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3.	Have you ever had a civil or criminal record expunged or sealed by a court order?	✓	
4.	Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5.	Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6.	Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7.	Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8.	Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9.	Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10.	Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 & 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
06/01/2007	06/01/2007	MN	Metropolitan Airport	Hennepin
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
225001		Metropolitan Airport		
Reason/Charge				
Petty Misdemeanor - Airport Ordinance Violation				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Self			N/A	
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

Petty Misdemeanor Airport Ordinance Violation with $300 fine, expunged 9/27/2021 by State Statute. Original documentation unavailable due to fire loss.

MN Statute 609.2 - "Petty misdemeanor" a petty offense which is prohibited by ordinance or statute, which does not constitute a crime and for which a sentence of a fine of not more than $300 may be imposed.

Original Signature (electronic, copies or stamps not accepted)

9/19/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Paul Greenall

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/19/24

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

California All-Purpose
Acknowledgment Attached

(Seal)

CALIFORNIA ALL-PURPOSE ACKNOWLEDGEMENT

A Notary Public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Marin

On September 19, 2024, before me, Lilia Rivas Crescencio, Notary Public,
personally appeared Paul Greenall

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of State of California that the foregoing paragraph is true and correct.

LILIA RIVAS CRESCENCIO
COMM. # 2442906
NOTARY PUBLIC-CALIFORNIA
MARIN COUNTY
My Comm Expires APR. 27, 2027

PLACE NOTARY SEAL ABOVE

WITNESS my hand and official seal.

SIGNATURE Lilia Rivas

Though the information below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent removal and reattachment of this form to another document.

Description of attached document

Title or type of document: Personal History Application

Document Date: _____ Number of Pages: _____

Signer(s) Other than Named Above: _____

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FS1293884	02-28-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	03-23-2022

SEVEN HILLS PHARMACY LLC
2722 E. KEMPER RD
SHARONVILLE, OH 45241

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FS1293884	02-28-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	03-23-2022

SEVEN HILLS PHARMACY LLC
2722 E. KEMPER RD
SHARONVILLE, OH 45241

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

POSTMEDS, INC. DBA TRUEPILL DISCIPLINARY SUMMARY

California resident license PHY 58585
California old resident license PHY 56100

Illinois Board of Pharmacy

The Illinois Board issued the pharmacy (non-resident license #054.022249) a Consent Order of Discipline effective **August 8, 2024** resolving alleged violations of the Illinois Pharmacy Practice Act stemming from disciplinary actions by proper licensing authority of another state. As per the terms of the Consent Order, Pharmacy has agreed to pay a $5,000 administrative fine to the Illinois State Board of Pharmacy.

Alaska Board of Pharmacy

The Alaska Board issued the pharmacy (non resident license #166601) a Consent Order of Discipline effective **February 15, 2024** resolving alleged violations of the Alaska Pharmacy Practice Act stemming from disciplinary actions by proper licensing authority of another state. As per the terms of the Consent Order, Pharmacy has agreed to pay a $5,000 administrative fine to the Alaska State Board of Pharmacy.

Pennsylvania Board of Pharmacy

The Pennsylvania Board issued the pharmacy (non resident license #NP000931) a Consent Order of Discipline effective **November 7, 2023** resolving alleged violations of the Pennsylvania Pharmacy Practice Act stemming from disciplinary actions by proper licensing authority of another state. As per the terms of the Consent Order, Pharmacy has agreed to pay a $3,500 administrative fine to the Pennsylvania State Board of Pharmacy.

DEA Memorandum of Agreement

On December 15, 2022, the federal Drug Enforcement Agency ("DEA") issued Postmeds, Inc ("Truepill-Hayward") an administrative Order to Show Cause ("OSC") regarding revocation of its DEA registration FP6189725. **On September 28, 2023,** Truepill-Hayward and DEA reached a non-monetary resolution of the OSC proceedings through a Memorandum of Agreement ("MOA"). Under the MOA, Truepill-Hayward will maintain its active DEA registration without paying a fine and without suspension or revocation of its registration, while making certain agreed changes to its processes and procedures going forward. The MOA is specific to Truepill-Hayward and does not involve other Truepill pharmacies commonly owned by or affiliated with Truepill-Hayward.

Alabama Board of Pharmacy

The Alabama Board issued the pharmacy (non resident license #114861) a Consent Order of Discipline dated **June 6, 2023**. The Pharmacy has resolved alleged violations of the Alabama Pharmacy Practice Act through entry of a Consent Order with the Alabama State Board of Pharmacy on June 8, 2023. As per the terms of the Consent Order, Pharmacy has agreed to pay a $3,000 administrative fine to the Alabama State Board of Pharmacy.

Kansas Board of Pharmacy

The Kansas Board of Pharmacy issued the pharmacy (non resident license #22-117859) an amended Summary Order effective **February 8, 2023**. The pharmacy did not report the change of ownership in a

timely manner, and paid a fine. The Kansas Board of Pharmacy approved the change of ownership application, and issued license 22-117859 on May 20, 2022.

Louisiana Board of Pharmacy

The Louisiana Board of Pharmacy issued the pharmacy (non resident license #PHY.007761-NR) a Consent Order of Discipline dated **May 11, 2022**. The pharmacy did not report the change of ownership in a timely manner. The Louisiana Board of Pharmacy approved the change of ownership application with a new permit number PHY.008479-NR as a successor to permit number PHY.007761-NR.

North Carolina Board of Pharmacy

The North Carolina Board of Pharmacy issued the pharmacy a Consent Order of Discipline dated **March 8, 2022**. The pharmacy made inaccurate statements about its ownership and officers on its initial application in November 2017 and did not correct this until November 2021. The North Carolina Board of Pharmacy approved the change of ownership application with a new permit number 14900 as a successor to permit number 13413.

Maine Board of Pharmacy

The Maine Board of Pharmacy notified the pharmacy on **March 30, 2022** that its non-resident license (#MO40002429) was terminated effective November 6, 2019 for reporting deficiencies related to its ownership. The pharmacy submitted a change of ownership application for licensure, and has been issued a new pharmacy license (#MO40003167) on November 2, 2022.

California Board of Pharmacy

The California Board of Pharmacy issued the pharmacy (former license #PHY 56100) a letter of admonishment CI 2019 84877 dated **January 23, 2020**, concluding an investigation that found the pharmacy shipped a prescription to the wrong patient and shipped two prescriptions with the wrong return address.

The California Board of Pharmacy issued the pharmacy (former license #PHY 56100) a modified citation and fine CI 2019 78633 dated **June 16, 2020**, with the fine amount of $0.00. In 2018, certain prescriptions were issued to the pharmacy by prescribers that were either not yet licensed to prescribe in California or who had not yet entered into an established standardized procedure or protocol developed by a supervising physician.

Also, The California Board of Pharmacy issued the pharmacy (former license #PHY 56100) a citation and fine order of abatement CI 2020 89223 dated **August 25, 2021**, with the fine amount of $5,000. The pharmacy was in violation when dangerous drugs were stored in temperatures exceeding the recommended storage temperatures Truepill did not consider the manufacturer's stability data for drugs which may have been adulterated by heat.

PENDING MATTERS

The following Actions are currently pending or threatened against the Company. The below Actions are currently subject to ongoing discussions, negotiations, and developments.

California Board of Pharmacy

California CI 2024 105307: On August 9, 2024, the California State Board of Pharmacy sent notice of a pending citation along with information on contesting or appealing. Truepill is in process of requesting an informal hearing to contest the citation.

South Carolina Board of Pharmacy

South Carolina 2022-49: On May 3, 2023, Postmeds agreed in principle to a proposed consent order with the South Carolina Board of Pharmacy to resolve inaccuracies in prior ownership information provided to the Board. The agreement would be categorized as a public reprimand but would not be a public document and would not be reported to the National Practitioner Data Bank. The negotiated fine was $30,000. The South Carolina Board of Pharmacy has not finalized this consent order or initiated formal disciplinary proceedings.

STATE OF ILLINOIS
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
DIVISION OF PROFESSIONAL REGULATION

IN RE: The Application of POSTMEDS INC DBA TRUEPILL, 054-app-4237687	APPLICANT.	)))	Case No. 2023-00783

CONSENT ORDER

The Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation ("Department"), by its attorney Nicholas V. Gallo, and Applicant POSTMEDS INC ("Applicant"), by its attorney Marc N. Wagner, hereby agree to the following:

STIPULATIONS

On or about August 22, 2022, Applicant submitted to the Department a change of ownership application (the "application") for Illinois licensed pharmacy license no. 054.022350.

On or about June 16, 2020, the California State Board of Pharmacy issued Applicant a disciplinary modified citation and fine ("California Citation and Fine") under case no. 2017-78633 for Applicant filling prescriptions issued to Applicant by prescribers that were either not yet licensed to prescribe in California or who had not yet entered into an established standardized procedure or protocol developed by a supervising physician. The California Citation and Fine constitutes grounds for disciplinary action against Applicant on the authority of the Illinois Pharmacy Practice Act ("Act") at 225 ILCS 85/30(a)(8) as the grounds for action in the California Citation and Fine are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 225 ILCS 85/4(g).

On or about August 25, 2021, the California State Board of Pharmacy issued Applicant a disciplinary citation and fine order of abatement ("California Citation and Fine Order of Abatement") under case no. 2020-89223 for, including but not limited to, Applicant storing dangerous drugs in temperatures exceeding the recommended storage temperatures. The California Citation and Fine Order of Abatement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8)

as the grounds for action in the California Citation and Fine Order of Abatement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 225 ILCS 85/3(d)(12).

On or about March 8, 2022, Applicant and the North Carolina Board of Pharmacy entered into a Consent Order of Discipline for, including but not limited to, Applicant failing to report change of ownership in a timely manner. The North Carolina Agreement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8) as the grounds for action in the North Carolina Agreement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via the Act's Administrative Rules ("Rules") at 68 IAC 1330.780(a)(1).

On or about May 11, 2022, Applicant and the Louisiana Board of Pharmacy entered into a disciplinary Consent Agreement ("Louisiana Agreement") under case no. 21-0456 for, including but not limited to, Applicant failing to report change of ownership in a timely manner. The Louisiana Agreement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8) as the grounds for action in the Louisiana Agreement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 68 IAC 1330.780(a)(1).

On or about February 15, 2024, Applicant and the Board of Pharmacy for the State of Alaska entered into a disciplinary Consent Agreement ("Alaska Agreement") under case no. 2022-000434 for, including but not limited to, Applicant failing to disclose prior disciplines from another state within the required timeframe. The Alaska Agreement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8) as the grounds for action in the Alaska Agreement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 68 IAC 1330.40(c).

Pursuant to 68 IAC 1130.300(a) the following factor is considered in aggravation: (a) the presence of multiple adverse actions taken by other states against Applicant.

Pursuant to 68 IAC 1130.300(b) the following factors are considered in mitigation: (a) Applicant has cooperated with the Department in its investigation; and (b) Applicant has no prior disciplinary history with the Department.

At all times material to the matter set forth in this Consent Order, the Department had jurisdiction over the subject matter and the parties herein. Applicant has been advised of the right to have any allegation(s) reduced to written charges, to a hearing where the Department bears the burden to prove its allegations by clear and convincing evidence, to contest any charges brought and present mitigating evidence, and to administrative review of any order resulting from a hearing. Applicant knowingly waives each of these rights, as well as any right to administrative review of this Consent Order. Such waiver ceases if this Consent Order is rejected by the Secretary or the Secretary's designee or the Board. Applicant acknowledges that it has entered into this Consent Order freely and of Applicant's own will without threat or coercion by the Department or any person, and has not relied upon any representation made by or on behalf of the Department other than those specifically included herein. Applicant acknowledges that the Department attorney may be requested to communicate with the Board or the Secretary or the Secretary's designee in furtherance of the approval of this Consent Order. Applicant acknowledges that this Consent Order will be presented to the Secretary or the Secretary's designee. If this Consent Order is not approved, Applicant waives any right to raise any prejudice resulting from the Secretary or the Secretary's designee's consideration of this Consent Order. Applicant understands that this Consent Order is not effective unless and until it is adopted by the Secretary or the Secretary's designee. A copy of any original signature(s) affixed to this Consent Order shall be given the full force and effect of an original signature(s) affixed to this Consent Order.

Applicant and the Department agree, in order to resolve this case, that the Applicant be permitted to enter into a Consent Order with the Department providing for the terms and conditions contained herein which are fair and equitable in the circumstances and which are consistent with the best interests of the people of the State of Illinois.

CONDITIONS

Wherefore, the Department, by its attorney Nicholas V. Gallo, and Applicant, by its attorney Marc N. Wagner, agree:

A. Applicant's Illinois licensed pharmacy license no. 054.022350 shall be issued with a Reprimand.

B. Applicant shall pay a five-thousand-dollar ($5,000.00 USD) disciplinary fine within sixty (60) days of the effective date of this Consent Order.

C. All fines issued pursuant to this Consent Order are to be paid by personal check, company check, cashier's check, or personal money order. Said monetary instrument(s) shall be made payable to "Illinois Department of Financial and Professional Regulation," clearly indicate on the face of the monetary instrument the case number of 2023-00783 as well as license no. 054.022350, and be mailed to the following address:

Illinois Department of Financial and Professional Regulation
SSC – Accounts Receivable Section - Fines
P.O. Box 7086
Springfield, IL 62791-7086

D. Prior to the satisfaction of subsections B and C, above, Applicant shall not violate any state or federal law, rule, or regulation concerning controlled substances or the practice of wholesale drug distribution.

E. Applicant agrees that any violation of this Consent Order permits the Secretary or Secretary's designee to issue an Order forthwith mandating the automatic, indefinite, and immediate suspension of Applicant's license for a minimum period of twelve (12) months. This suspension shall not preclude the Department from taking any other disciplinary or other action it deems appropriate. In the event that Applicant(s) contest(s) in writing (by the filing with the Department within thirty (30) days the effective date of the suspension, a Petition complying with the Department's Rules of Practice in Administrative Hearings) the factual basis underlying said suspension, then Applicant(s) shall be afforded a hearing on the merits in accordance with the Department's Rules of Practice in Administrative Hearings, 68 Ill. Admin. Code 1110/et seq.

F. Applicant acknowledges that this Consent Order is a public disciplinary action and will be made available to the public. It will be reported to all applicable reporting databases.

G. This Consent Order is a final administrative order. This Consent Order shall become effective upon the signature of the Secretary or the Secretary's designee below unless otherwise stated herein.

Signatures on the following page

July 12, 2024
Date

Department Attorney – Nicholas V. Gallo

7/11/2024 | 1:39 PM PDT
Date

DocuSigned by:
Laura Peterson
Applicant – POSTMEDS INC
By: General Counsel, Truepill Inc. - Laura Peterson

7/11/2024 | 5:00 PM CDT
Date

DocuSigned by:
Lee Rosebush
Applicant's Attorney – Lee H. Rosebush

7/12/24
Date

Illinois State Board of Pharmacy Member

The foregoing Consent Order is approved in full.

DATED THIS 8th day of August, 2024.

ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
SECRETARY MARIO TRETO, JR.

Mario Treto, Jr. Secretary
Illinois Department of Financial and Professional Regulation

Case No. 2023-00783
Application No.: 054-app-4237687

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE BOARD OF PHARMACY

In the Matter of:)
)
Postmeds, Inc. doing business as (Dba) TRUEPILL)
Respondent)
Case No. 2022-000434

CONSENT AGREEMENT

IT IS HEREBY AGREED by the Department of Commerce, Community and Economic Development, Division of Corporations, Business and Professional Licensing (Division) and TRUEPILL (Respondent) as follows:

1) **Licensure.** Respondent is currently registered as an Out-of-State Pharmacy in the State of Alaska and holds License number #166601. This license was first issued on 08/27/2020 and will lapse unless renewed by 06/30/2024.

2) **Admission/Jurisdiction.** Respondent admits and agrees that the Board of Pharmacy has jurisdiction over the subject matter of their license in Alaska and over this Consent Agreement.

3) **Admission/Facts.** Respondent admits to the following facts:

a) On September 25, 2017, Staff Pharmacist working for TRUEPILL, Curtis Ancar, received a disciplinary order from the California Board of Pharmacy for failure to exercise corresponding responsibility and excessive furnishing of controlled substances.

b) On January 24, 2019, the California Board of Pharmacy cited former Pharmacist-in-Charge and former owner of TRUEPILL, Mohammad Umar Afridi, for failure to provide documentation substantiating completion of continuing education and knowingly making or signing a document with false information.

c) On December 16, 2019, the California Board of Pharmacy cited former Pharmacist-in-Charge and former owner of TRUEPILL, Mohammad Umar Afridi, for furnishing and dispensing dangerous drugs without a prescription and dispensing on order of nurse practitioner (or person of similar status).

d) On January 23, 2020, the California Board of Pharmacy issued a letter of admonishment to Respondent for shipping a prescription to the wrong address and shipping two prescriptions with the wrong return address.

e) On June 16, 2020, the California Board of Pharmacy issued a modified citation and fine CI 2019 78633 with the fine amount of $0.00 for receiving prescriptions by prescribers that were not licensed or have not entered into procedures with supervising physicians.

f) On April 08, 2022, Respondent submitted an Out-of-State Pharmacy Registration Ownership Change Application from license no. 166601 to license no. 193858 (now withdrawn) to the Division. Professional Fitness Question #1 was marked "Yes" indicating disciplinary actions had been issued against their license as listed above in sections a) through e).

g) Subsequent background investigation revealed Respondent failed to disclose the abovementioned 2017, 2019, and 2020 licensing actions from the California Board of Pharmacy on previous State of Alaska applications for TRUEPILL (formerly DBA Postmeds, Inc.) for licenses 137655 and 166601 dated June 08, 2018, August 06, 2020, and August 27, 2020.

h) Respondent admits that as a result of the above facts, grounds exist for possible suspension, revocation, or other disciplinary sanctions of their license pursuant to AS 08.01.075, AS 08.80.261(a)(1), AS 08.80.261(a)(6), AS 08.80.261(a)(9), AS 08.80.261(a)(11)(12)(14), 12 AAC 52.920(a)(13), and 52.920(a)(14)(c).

4) **Formal Hearing Process.** It is the intent of the parties to this Consent Agreement to provide for the compromise and settlement of all issues addressed in Paragraph 3 (above) that could be raised by an Accusation to revoke, suspend, or impose disciplinary sanctions against Respondent's license through a formal hearing process.

5) **Waiver of Rights.** Respondent understands they have the right to consult with an attorney of their own choosing and has a right to an administrative hearing on the facts in this case. Respondent understands and agrees that by signing this Consent Agreement, Respondent is waiving their rights to counsel and to a hearing. Further, Respondent understands and agrees that they are relieving the Division of any burden it has of proving the facts admitted above. Respondent further understands and agrees that by signing this Consent Agreement they are voluntarily and knowingly giving up their right to present oral and documentary evidence, to present rebuttal evidence, to cross-examine witnesses against Respondent, and to appeal the Board's decision to Superior Court.

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

6) **Effect of Non-Acceptance of Consent Agreement.** Respondent and the Division agree that this Consent Agreement is subject to the approval of the Board. They agree that, if the Board rejects this Consent Agreement, it will be void, and an Accusation may be filed. If this Consent Agreement is rejected by the Board, it will not constitute a waiver of Respondent's right to a hearing on the matters alleged in an Accusation and the admissions contained herein will have no effect. Respondent agrees that, if the Board rejects this Consent Agreement, the Board may decide the matter after a hearing, and its consideration of this Consent Agreement shall not alone be grounds for claiming that the Board is biased against Respondent, that it cannot fairly decide the case, or that it has received ex parte communication.

7) **Consent Agreement, Decision, and Order.** Respondent agrees that the Board has the authority to enter into this Consent Agreement and to issue the following Decision and Order.

PROPOSED DECISION AND ORDER

IT IS HEREBY ORDERED that any license issued to Respondent by the Board shall be subject to the following terms and conditions:

A. **Violation of Agreement**

If Respondent fails to comply with any term or condition of this Consent Agreement, the Division may enforce this agreement by immediately suspending Respondent's license, without an additional order from the Board or without a prior hearing, for a violation of this agreement. In addition, any suspended portion of the civil fine will be immediately due.

If Respondent's license is suspended under this paragraph, as provided above, they will be entitled to a hearing, on an expedited basis, regarding the issue of the suspension. If Respondent's license is suspended, they will continue to be responsible for all license requirements pursuant to AS 08.80.

Respondent shall maintain an active license for the entire duration of this Consent Agreement. If the Respondent lets their license lapse, and after receiving adequate notice from the Board fails to correct the problem, the failure to maintain active licensure will be considered a violation of this Consent Agreement.

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

B. Respondent Address

It is the responsibility of the Respondent to keep the Board's agent advised, in writing, at all times of their current mailing address, physical address, telephone number, current employment and any change in employment.

Failure to provide notice of any changes within 10 calendar days will constitute grounds for suspension of his or her license in accordance with paragraph 'B' above.

C. Compliance with Laws

Respondent shall obey all federal, state and local laws governing their license.

D. Authorization

Within 10 calendar days of a request by the Board agent, Respondent will sign all authorizations necessary for the release of information required by this Consent Agreement.

E. Good Faith

All parties agree to act in good faith in carrying out the stated intentions of this Consent Agreement.

F. Address of the Board

All required reports or other communication concerning compliance with this Consent Agreement shall be addressed to:

Attn: Holly Handley, Investigator
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
(907) 269-8124 Fax (907) 269-8195

G. Civil Fine

Respondent shall pay a fine of five thousand dollars ($5,000.00). This civil fine is due within 180 days of the adoption of this agreement and is payable to the "State of Alaska" in cash, certified check, or money order or via credit card.

All payments required by this Consent Agreement shall be addressed to:

Erika Prieksat, Chief Investigator
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

//

//

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

IT IS HEREBY FURTHER ORDERED that this Decision and Order shall take effect immediately upon its adoption by the Board of Pharmacy and is a public record of the Board of Pharmacy and the State of Alaska. The State may provide a copy of it to any person or entity, professional licensing board, federal, state, or local government, or other entity making a relevant inquiry.

The action taken by the Board of Pharmacy in this Consent Agreement will be reported to the National Association of Boards of Pharmacy (NABP) and the National Practitioner Data Bank (NPDB) other entities as required by law.

DATED this 5 day of October 2023, at Anchorage, Alaska.

JULIE SANDE, COMMISSIONER

DocuSigned by:
By: Erika Prieksat
34F98CE5F1DF40C...

Erika Prieksat, Chief Investigator for
Sylvan Robb, Director
Division of Corporations, Business and
Professional Licensing

I, TRUEPILL, have read the Consent Agreement, understand it, and agree to be bound by its terms and conditions.

DATED: 20th November 2023

Joseph Alexander Cipriani

SUBSCRIBED AND SWORN TO before me this 20th day of November, 2023, at Newport News, Virginia, Virginia.
(city) (state)

SEAL
COMMONWEALTH OF VIRGINIA
N
ELECTRONIC NOTARY PUBLIC
Winston Ndow
REGISTRATION NUMBER
8040550
COMMISSION EXPIRES
February 28, 2027

Winston Ndow

Notary Public in and for Virginia.
(state)

Winston Ndow
Notary Printed Name

Notarized online using audio-video communication

My commission expires: 02/28/2027

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE BOARD OF PHARMACY

In the Matter of:

Postmeds, Inc. dba TRUEPILL

Respondent

Case No. 2022-000434

ORDER

The Board of Pharmacy for the State of Alaska, having examined the Consent Agreement and Proposed Decision and Order, Case No. 2022-000434, Respondent, license number #166601, adopts the Consent Agreement and Decision and Order in this matter.

This Consent Agreement takes effect immediately upon signature of this Order in accordance with the approval of the Board of Pharmacy.

The Division may enforce the Consent Agreement by immediately suspending Respondent's license, without an additional order from the Board or without a prior hearing, for a violation of the Consent Agreement.

DATED this 15th day of February, 2024, at Anchorage, Alaska.

Board of Pharmacy

By: Ashley Schaber
Chairperson

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania **Bureau of Professional and** **Occupational Affairs**	
vs.	**Case Nos.** **21-54-004050** **22-54-008273**
PostMeds Inc **Respondent**	

NOTICE

Formal disciplinary action has been filed against you. You may lose your license, certificate, registration or permit to practice your profession or occupation. You may be subject to civil penalties of up to $10,000 for each violation, and the imposition of costs of investigation.

If you wish to defend against the charges in the attached order to show cause or to present evidence to mitigate any penalty that may be imposed, the procedures for doing so are explained in the Order to Show Cause.

You have the right to retain an attorney. Although you may represent yourself without an attorney, you are advised to seek the help of an attorney. You also have the right to have an interpreter provided should you request one.

All proceedings are conducted under the Administrative Agency Law and the General Rules of Administrative Practice and Procedures.

You are directed to respond to the charges by filing a written answer within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause. IF YOU DO NOT FILE AN ANSWER, DISCIPLINARY ACTION MAY BE TAKEN AGAINST YOU WITHOUT A HEARING. Any answer submitted in this matter must be filed with the Prothonotary for the Department of State via one of the following methods:

By Mail:
Prothonotary
Department of State
2601 N Third St
PO Box 2649
Harrisburg, PA 17105-2649

By Facsimile:
(717)772-1892

By E-mail:
ra-prothonotary@pa.gov

You must also send or email a separate copy of your answer and any other pleadings or documents related to this case to the prosecuting attorney named in the Order to Show Cause.

Prothonotary Filed On
May 10 2023 02:10 PM
Department of State

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania Bureau of Professional and Occupational Affairs		
vs.	**Case Nos.**	**21-54-004050** **22-54-008273**
PostMeds Inc **Respondent**		

ORDER TO SHOW CAUSE

AND NOW, this 10th day of May 2023, **PostMeds Inc** ("Respondent") is hereby ORDERED TO SHOW CAUSE why the Pennsylvania State Board of Pharmacy ("Pennsylvania Board"), upon consideration of the Factual Allegations and the applicable law, should not suspend, revoke or otherwise restrict Respondent's registration, impose a civil penalty, or impose the costs of investigation. This action is brought pursuant to the Pharmacy Act, act of September 27, 1961, P.L. 1700, ("Act"), *as amended*, 63 P.S. §§ 390-1 to 390-13; and 63 Pa.C.S. Chapter 31 ("Chapter 31"); and will be conducted in accordance with the Administrative Agency Law, 2 Pa. C.S. §§ 501-508, 701-704, Chapter 31, and the General Rules of Administrative Practice and Procedure ("GRAPP"), 1 Pa. Code §§ 31.1-35.251.

IT IS FURTHER ORDERED that Respondent file an Answer to this Order to Show Cause in writing within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause, in accordance with Rule 35.37 of GRAPP, 1 Pa. Code § 35.37, *as amended.*

FACTUAL ALLEGATIONS

1. Respondent holds the following registration to practice as a nonresident pharmacy in the Commonwealth of Pennsylvania: registration no. NP000931.

DOS Prothonotary
May 10 2023

2. Respondent's registration was originally issued on July 3, 2017, and it is currently set to expire on August 31, 2023.

3. Absent further action by the Pennsylvania Board, the Respondent's registration may be renewed or reactivated upon the filing of the appropriate documentation and payment of the necessary fees.

4. At all times pertinent to the Factual Allegations, Respondent held a registration to practice as a nonresident pharmacy in the Commonwealth of Pennsylvania.

5. Respondent's last known address on file with the Board is: 3131 Diablo Ave, Hayward, CA 94545.

COUNT ONE

6. Paragraphs 1 through 5 are incorporated by reference.

7. At all relevant and material times, Respondent was authorized to practice as a nonresident pharmacy in the State of North Carolina.

8. On or about March 8, 2022, the State of North Carlina Board of Pharmacy ("North Carolina Board"), by way of Consent Order of Discipline, found Respondent to be in violation of the laws, rules, code and/or regulations of the State of North Carolina because Respondent failed to report a restructuring of ownership to the North Carolina Board.

9. In the March 8, 2022 Consent Order of Discipline, the North Carolina Board voided Respondent's permit from the time it was issued until the time the restructuring began and approved Respondent's change of ownership application as a successor permit.

10. A true and correct copy of the North Carolina Board's March 8, 2022 Consent Order of Discipline is attached as **EXHIBIT A** and is incorporated by reference.

DOS Prothonotary
May 10 2023

11. At all relevant and material times, Respondent was authorized to practice as a nonresident pharmacy in the State of Louisiana.

12. On or about May 11, 2022, the State of Louisiana Board of Pharmacy ("Louisiana Board"), by way of Consent Agreement at Louisiana Board Case Number 21-0456, found Respondent to be in violation of the laws, rules, code and/or regulations of the State of Louisiana because Respondent failed to report a restructuring of ownership to the Louisiana Board.

13. In the May 11, 2022 Consent Agreement, the Louisiana Board imposed a ten thousand dollar ($10,000.00) fine, two hundred fifty dollars ($250.00) in administrative costs, and three hundred twenty-four dollars and forty-eight cents ($324.48) in investigative costs.

14. A true and correct copy of the Louisiana Board's May 11, 2022 Consent Agreement, Louisiana Board Case Number 21-0456, is attached as **EXHIBIT B** and is incorporated by reference.

15. At all relevant and material times, Respondent was authorized to practice as a nonresident pharmacy in the State of Kansas.

16. On or about January 20, 2023, the State of Kansas Board of Pharmacy ("Kansas Board"), by way of Amended Summary Order at Kansas Board Case Number 22-183, found Respondent to be in violation of the laws, rules, code and/or regulations of the State of Kansas because Respondent failed to report a restructuring of ownership to the Kansas Board and failed to report disciplinary actions from North Carolina, Alabama, and California which also pertained to a failure to report a restructuring of ownership to each respective Board.

17. In the January 20, 2023 Amended Summary Order, the Kansas Board imposed a three thousand five hundred dollar ($3,500.00) fine.

DOS Prothonotary
May 10 2023

18. A true and correct copy of the Kansas Board's January 20, 2023 Amended Summary Order, Kansas Board Case Number 22-183, is attached as **EXHIBIT** C and is incorporated by reference.

19. Based upon the foregoing Factual Allegations, the Pennsylvania Board is authorized to suspend or revoke, or otherwise restrict Respondent's nonresident pharmacy registration under section 4.1(e) of the Act, 63 P.S. §§ 390-4.1(e); or impose a civil penalty under section 63 Pa.C.S. § 3108(b)(4), and/or impose the costs of investigation under 63 Pa.C.S. § 3108(b)(5), because Respondent violated the Act at section 4.1(g), 63 P.S. § 390-4.1(g), in that Respondent had a permit to conduct a pharmacy suspended or revoked or the nonresident pharmacy was otherwise disciplined by the proper licensing authority of another state.

PENALTIES

If the Pennsylvania Board finds that the Factual Allegations are true and correct, and determines that it has the authority to suspend or revoke the Respondent's registration, the Pennsylvania Board may, in its discretion, impose one or more of the following penalties:

- The revocation, suspension or other restriction of any licenses, certifications, registrations, permits or other authorizations to practice a profession held by Respondent in the Commonwealth of Pennsylvania, or the imposition of any other disciplinary or corrective action that the Act authorizes the Board to impose.
- The imposition of a civil penalty of up to ten thousand dollars ($10,000.00) for each and every violation of the Act. Where criminal proceedings are a basis for a violation of the Act, each count for which the Respondent was convicted may be considered a separate violation of the Act.

DOS Prothonotary
May 10 2023

PROCEDURES

All proceedings are conducted in accordance with the Administrative Agency Law, 2 Pa. C.S. §§ 501-508, 701-704; Chapter 31; and the General Rules of Administrative Practice and Procedure, 1 Pa. Code §§ 31.1-35.251. **RESPONDENT IS HEREBY ORDERED TO FILE A WRITTEN ANSWER TO THIS ORDER TO SHOW CAUSE WITHIN THIRTY (30) DAYS OF THE DATE ON THE MOST RECENT CERTIFICATE OF SERVICE ASSOCIATED WITH THIS ORDER TO SHOW CAUSE.** The Answer shall specifically admit or deny each of the Factual Allegations made herein, and shall set forth the facts and state concisely the matter of law upon which Respondent relies. If Respondent fails to file an Answer within the time allowed herein, the Factual Allegations may be deemed admitted, and the Pennsylvania Board will issue an Order which may impose penalties as set forth above.

If Respondent desires a formal administrative hearing, at which Respondent may defend against the allegations in the Order to Show Cause or to present evidence in mitigation of any penalty which may be imposed upon Respondent or any of Respondent's licenses, certifications, registrations, permits or other authorizations to practice a profession, a written request for hearing must be filed within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause. **IF RESPONDENT FAILS TO FILE A WRITTEN REQUEST FOR HEARING WITHIN THIRTY (30) DAYS OF THE DATE ON THE MOST RECENT CERTIFICATE OF SERVICE ASSOCIATED WITH THIS ORDER TO SHOW CAUSE, RESPONDENT WILL BE DEEMED TO HAVE WAIVED HIS OR HER RIGHT TO A HEARING AND FINAL JUDGMENT MAY BE ENTERED WITHOUT A HEARING.**

If a hearing is scheduled, Respondent will be notified of the specific time and place of the hearing. The hearing will be held before the Board or its duly designated Presiding Officer, in

DOS Prothonotary
May 10 2023

accordance with Section 35.185 of GRAPP, 1 Pa. Code § 35.185. Respondent may appear, with or without counsel, offer testimony or other evidence on his or her behalf, and confront and cross-examine the Commonwealth's witnesses.

Answers, requests for hearings, preliminary motions, protests, petitions to intervene, or any other pleading must be filed with the Prothonotary for the Department of State via one of the following methods:

By Mail:
Prothonotary
Department of State
2601 N Third St
PO Box 2649
Harrisburg, PA 17105-2649

By Facsimile:
(717)772-1892

By E-mail:
ra-prothonotary@pa.gov

Also, you must send or e-mail a separate copy of any documents submitted in this matter to the prosecuting attorney named below at:

By Mail:
Glenn P. Masser
Prosecuting Attorney
Commonwealth of Pennsylvania
Department of State
P.O. Box 69521
Harrisburg, PA 17106-9521

By E-mail:
gmasser@pa.gov

DOS Prothonotary
May 10 2023

Notices and petitions to intervene must be filed within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause, unless in extraordinary circumstances for good cause shown, a later filing is authorized by the agency.

BY ORDER:
DEPARTMENT OF STATE

/s/ Glenn P. Masser
Glenn P. Masser
Prosecuting Attorney
Commonwealth of Pennsylvania
Department of State
P.O. Box 69521
Harrisburg, PA 17106-9521
(717) 783-7200

DATE: 05.10.2023

DOS Prothonotary
May 10 2023

STATE OF NORTH CAROLINA
NORTH CAROLINA BOARD OF PHARMACY

IN THE MATTER OF	)	
	)	
POSTMEDS, INC. d/b/a Truepill,	)	**CONSENT ORDER**
	)	**OF DISCIPLINE**
Permit No. 13413 and Its Successor Permit(s).	)	

THIS MATTER came to be considered before a member of the North Carolina Board of Pharmacy (hereinafter, the "Board") pursuant to 21 N.C.A.C. 46 .2008. The Conference was scheduled for Thursday, February 24, 2022, and, after appropriate notice, was heard on that day by Board member Wallace E. Nelson. Respondent PostMeds, Inc. was informed of its right to be present at the pre-hearing conference and declined. The Board's General Counsel, Clinton R. Pinyan, represented the Board.

Respondent has agreed to waive a formal hearing in the above-referenced matter. It stipulates and agrees to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. By its consent, Respondent also stipulates that it waives its right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order as a basis for the action taken. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. On November 20, 2017, the Board issued Permit No. 13413 to Respondent PostMeds, Inc. d/b/a Truepill (Permit No. 13413) ("PostMeds").

2. On PostMeds' initial permit application, its then-pharmacist manager, Mohammad Umar Afridi, submitted an inaccurate statement that he was the sole owner and officer of PostMeds. In fact, PostMeds now acknowledges that Afridi and Siddharth

DOS Prothonotary
May 10 2023

Viswanathan each owned 47 percent of PostMeds on November 20, 2017, with others owning six percent, and that Viswanathan was also an officer of PostMeds.

3. Viswanathan and the minority owners' interests would not have raised questions about the permit application in this particular case. If PostMeds had disclosed the true ownership and officers of PostMeds, the Board still would have granted PostMeds a permit. However, it was an inaccurate statement that Afridi, as the person who submitted the application, knew was inaccurate. That statement prevented the Board from vetting Viswanathan as the owner of the pharmacy. Because of the inaccuracy of the representations, the initial permit was void ab initio.

4. In November 2019, PostMeds went through a corporate restructuring. During that restructuring, Truepill, Inc. was created as a holding company for PostMeds. At that time, Truepill, Inc. became the sole owner of PostMeds. Afridi, Viswanathan and the other former direct owners of PostMeds became indirect owners with the same ownership interests in the holding company, Truepill, Inc., that they had before the transfer of ownership.

5. This restructuring required PostMeds to submit a transfer of ownership application and have that application granted before the restructuring closed. PostMeds failed to do this. Therefore, even if the initial permit had been valid (which it was not), it would have become invalid upon the corporate restructuring.

6. Insertion of a new holding company between the ultimate owners and PostMeds would not have raised questions about the permit application in this particular case. The ownership interests of the ultimate owners did not change. If PostMeds had disclosed the new holding company, the Board still would have granted the transfer of ownership. However,

DOS Prothonotary.
May 10 2023

PostMeds failed to submit the transfer of ownership application or otherwise disclose the interests of Truepill, Inc.

7. In each of its subsequent renewals, PostMeds failed to correct the ownership information that it had inaccurately submitted on its initial application or to list Truepill, Inc., as the direct owner of the pharmacy.

8. On November 4, 2021, counsel for PostMeds informed the Board that its "current ownership information on file with the North Carolina Board of Pharmacy is out of date." Upon follow-up questioning, the next day, PostMeds disclosed that it should have submitted a transfer of ownership application in November 2019. It further was apparent from the ownership information that PostMeds provided that Afridi made inaccurate representations about ownership and officers on PostMed's initial application that had never been corrected.

9. PostMeds agreed to stop shipping any drugs, devices or medical equipment into the State of North Carolina until the matter was resolved. It further agreed to stop shipping or dispensing any drugs, devices or medical equipment from six other pharmacies under its ownership until the matter was resolved (even though those pharmacies did not receive permits until after the transfer of ownership had occurred, and so did not suffer from the same problem).

10. PostMeds submitted a transfer of ownership application promptly.

11. Although PostMed's disclosure of its inaccuracies was tardy, its remedial actions are a mitigating factor in this matter.

CONCLUSIONS OF LAW

1. Reporting of correct and complete ownership information on an initial pharmacy permit application or a renewal application is material, indeed essential, to the Board's ability to ensure that a pharmacy will provide services safely and competently to the public.

DOS Prothonotary.
May 10 2023

2. PostMeds made inaccurate statements about its ownership and officers on its initial application, which it failed to correct at any point through its 2022 renewal. That initial permit was therefore void ab initio and violated G.S. § 90-85.38(b).

3. The creation of Truepill, Inc. as a holding company further triggered a requirement to report the ownership change and obtain a successor permit, and to do so before the closing of the transaction that created Truepill, Inc. The transaction "result[ed] in a different person . . . owning more than 50 percent interest in the permit holder . . . ." 21 NCAC 46.1603. Failure to apply for and obtain a successor permit prior to the transaction, and a continuing failure to disclose the ownership interest of Truepill, Inc., violated G.S. § 90-85.38(b).

IT IS THEREFORE ORDERED:

PostMeds was in violation of G.S. § 90-85.38(b) in North Carolina from November 20, 2017 until at least November 4, 2021. Respondent PostMed's Permit No. 13413 was **VOID** from the time that it was granted on November 20, 2017. G.S. § 90-85.38(c).

Respondent PostMed's change of ownership application is **APPROVED** as a successor permits to Permit No. 13413 (the "Successor Permit") with the following **CONDITIONS:**

1. PostMeds shall provide timely advance notice of any contemplated change in ownership to the current pharmacist-manager and any future pharmacist-manager(s) of the Successor Permit. PostMeds shall consult with the Successor Permit's pharmacist-manager(s) to determine whether any contemplated transaction triggers the need to obtain new permits. PostMeds shall authorize the Successor Permit's pharmacist-manager(s) to take any necessary action to update that ownership information with the Board or to apply for new permits. If a contemplated transaction triggers the need for new permits, PostMeds shall not complete that

DOS Prothonotary:
May 10 2023

transaction unless and until either the Board issues new permits or PostMeds ceases all practice of pharmacy at the permitted location.

2. The Successor Permit shall violate no laws governing the practice of pharmacy or the distribution of drugs.

3. The Successor Permit shall violate no rules or regulations of the Board.

4. If the Successor Permit fail to comply with any term or condition of this Order, it may be subject to additional disciplinary action by the Board.

This is the 8th day of March, 2022

NORTH CAROLINA BOARD OF PHARMACY

By: /s/ William A. Mixon
William A. Mixon
President

DOS Prothonotary:
May 10 2023

Respondent PostMeds, Inc. has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. Respondent freely, knowingly and voluntarily waives its right to such a hearing by entering into this Consent Order.

Respondent understands and agrees that by entering into this Consent Order, it certifies that it has read the foregoing Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions that may be taken concerning this matter.

Respondent further understands that should it violate the terms and conditions of this Consent Order, the Board may take additional action.

Respondent understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

Respondent understands that it has the right to have counsel of its choice review and advise them with respect to their rights and this Consent Order, and represents that it enters this Consent Order after consultation with counsel or after knowingly and voluntarily choosing not to consult with counsel. Respondent further agrees that the person who is executing this Consent Order has been duly authorized by any required corporation action to execute on behalf of Respondent.

CONSENTED TO BY:

M-1 _____ Date 3/7/22

Printed Name: Matt Davis-Ratner

Title: General Counsel

DOS Prothonotary.
May 10 2023

STATE OF _____

_____ COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the above-named representative of PostMeds, Inc. personally appeared before me this day, and acknowledged the due execution of the foregoing document.

Date:_____

_____
Notary Public

_____

My commission expires:_____

DOS Prothonotary:
May 10 2023

EXHIBIT B

DOS Prothonotary
May 10 2023

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

POSTMEDS, INC.

LOUISIANA PHARMACY PERMIT NO. 7761 **Case No. 21-0456**

****

CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy (hereinafter referred to as the "Board") on March 16, 2022 at the Board office, 3388 Brentwood Drive, Baton Rouge, LA 70809, in the matter of POSTMEDS, INC. (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 7761, 3121 Diablo Ave., Hayward, CA 94545-2701, with attorney Skip Philips and Postmeds Corporate Counsel Donnie Simkin appearing on behalf of Respondent.

WHEREAS, WHEREAS, on August 27, 2018, the Louisiana Board of Pharmacy issued a non-resident pharmacy permit, PHY.007761-NR, to Postmeds Inc. At that time, Postmeds Inc. was 31.5% owned by Mohammad Umar Afridi, 31.5% owned by Siddharth Viswanathan, 16.5% owned by Initialized III L.P., and 20.5% owned by others with no individual owner holding more than 4%. On December 17, 2021 the Board received an "Application for New Louisiana Pharmacy Permit for Nonresident Pharmacy" from Postmeds, Inc. d/b/a Truepill. Accompanying correspondence and organization chart detailed a 100% change in the ownership structure of Postmeds Inc., effective November 6, 2019. Postmeds Inc. went from being owned 31.5% by Mohammad Umar Afridi, 31.5% by Siddharth Viswanathan, 16.5% by Initialized III L.P., and 20.5% by others with no individual owner holding more than 4%, to being owned 100% by Truepill, Inc.

WHEREAS, the Board alleges that such actions constitute violations of the following:

La. R.S. 37:1241 (A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

La. R.S. 37:1221(B). No out-of-state pharmacy providing pharmacy services to residents of this state shall open, establish, operate, or maintain a pharmacy, located out-of-state, unless the pharmacy is issued a permit by the board.

La. R.S. 37:1222(A). A person applying for a permit to open, establish, operate, or maintain a pharmacy, within or outside of this state, shall complete an application in such form and contain such data as the board may require, and complete such other requirements as deemed necessary by the board, including but not limited to designation and identification of a pharmacist-in-charge.

DOS Prothonotary.
May 10 2023

La. R.S. 37:1222(E). A permit to operate a pharmacy shall not be transferable.

La. R.S. 37:1232(A). A pharmacy located outside this state which does business in this state within the meaning of this Chapter, shall hold a current pharmacy permit as provided in this Chapter. The pharmacy shall be designated a "nonresident pharmacy" and the permit shall be designated a "nonresident pharmacy permit."

LAC, Title 46: LIII §1101(A). Individuals, partnerships, corporations, limited liability companies, or associations desiring to operate a pharmacy in Louisiana, or outside the state where prescriptions drugs/devices are dispensed and delivered to Louisiana residents, shall execute an application for a pharmacy permit for their particular classification of pharmacy.

LAC, Title 46: LIII §1135(A)(I)(e). The holder of a pharmacy permit shall notify the board, in writing, prior to the transfer of ownership, in order for the board to complete an inspection of the pharmacy premises. A change of ownership of a pharmacy is evident under the following conditions: a 50 percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original permit or the last renewal application.

LAC, Title 46: LIII §1135(A)(2). The new owner(s) of the pharmacy shall submit a properly completed pharmacy permit application, with appropriate fee, to the board.

LAC, Title 46: LIII §1135(A)(4). Pharmacy permits are not transferable from the original holder(s) of the permit to the new owner(s).

LAC, Title 46: LIII §2305(A). The out-of-state pharmacy shall apply for a permit and annual permit renewals on forms provided by the board.

LAC, Title 46: LIII §2307(C). Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

To facilitate the submission of this Consent Agreement, Respondent does not contest the allegations and agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

DOS Prothonotary.
May 10 2023

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

POSTMEDS, INC., holder of Louisiana Pharmacy Permit No. 7761, is ordered to pay a fine of $10,000.00 and to reimburse the Board $250.00 for administrative costs, and $324.48 for investigative costs with total payment due the Board of $10,574.80, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter, waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing and to judicial review of this Consent Agreement. Moreover, at no time shall Respondent request the expungement, rescission or removal of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, Matt Davis-Ratner, authorized to act on behalf of and acting on behalf of **POSTMEDS, INC.**, understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

[Remainder of page intentionally left blank; signature page to follow.]

DOS Prothonotary:
May 10 2023

SIGNED, AGREED TO AND ENTERED ON THIS 6th DAY OF April, 2022.

POSTMEDS, INC.
Louisiana Pharmacy Permit No. 7761

Matt Davis-Ratner

BY: Matt Davis-Ratner
Authorized Representative

Harry J. Philips

HARRY J. "SKIP" PHILIPS
Taylor Porter
450 Laurel St, 8th Floor
Baton Rouge, LA 70801
Attorney for Respondent

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

Carlos Finalet

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on May 11, **2022**, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Marty R McKay

Marty R. McKay
Hearing Officer for the Board

DOS Prothonotary.
May 10 2023

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 22-183
PostMeds, Inc dba Truepill	)	
	)	
Registration No. 22-117859	)	

AMENDED SUMMARY ORDER

NOW on this 20th day of January, 2023, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of PostMeds, Inc dba Truepill ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Amended Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 22-104228 which entitled Respondent to operate as a non-resident pharmacy in the State of Kansas.

2. On November 6, 2019, the ownership of Respondent's non-resident pharmacy changed.

3. On May 22, 2020, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 3, 2020 with an expiration date of June 30, 2021. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?"

DOS Prothonotary:
May 10 2023

Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

4. On June 1, 2021, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 21, 2021 with an expiration date of June 30, 2022. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?" Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

5. Due to staffing challenges, personnel turnover and administrative oversight resulting from its early, rapid growth and restructuring and the corresponding COVID-19 pandemic, Respondent mistakenly failed to report the 2019 ownership change and related disclosures to the Board in its May 22, 2020 and June 1, 2021 renewal applications.

6. On April 18, 2022, the Board received notification from Respondent of an ownership change and several past disciplinary actions not previously reported to the Board including: North Carolina Board of Pharmacy Consent Order of Discipline dated March 8, 2022; California State Board of Pharmacy Letter of Admonishment dated January 23, 2020; California State Board of Pharmacy Citation and Fine dated June 16, 2020; California State Board of Pharmacy Citation and Fine Order of Abatement dated August 25, 2021; Alabama State Board of Pharmacy Final Order dated October 25, 2021; California State Board of Pharmacy Citation and Fine dated January 24, 2019; and California State Board of Pharmacy Citation dated December 16, 2019.

DOS Prothonotary:
May 10 2023

3912

7. On April 28, 2022, the Board received from Respondent a Form BA-22 Non-Resident Pharmacy Registration Application ("Respondent's Application"), notifying of the change in ownership effective November 6, 2019, and applying for a new non-resident pharmacy registration under the new ownership.

8. On May 20, 2022, the Board approved Respondent's Application and issued Respondent the new Non-Resident Pharmacy Registration No. of 22-117859 ("Respondent's Registration") under their new ownership.

9. Prior to receiving the ownership change application, registrant provided a letter notifying of the late ownership change, as well as unreported discipline. Ownership change application completed indicating discipline had occurred and providing details of discipline (5 occurrences).

10. In mitigation, Respondent states that it has invested in additional staff, engaged internal and external legal counsel and implemented training efforts to prevent any such reporting oversights in the future.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against a registration on any ground that would authorize the board to take action against the registration of a pharmacy under K.S.A. 65-1627, and amendments thereto.

3. Pursuant to K.S.A. 65-1627(e)(1), the Board may take action against the registration of a pharmacy upon a finding that such pharmacy has been operated in such manner

DOS Prothonotary.
May 10 2023

that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith.

4. Pursuant to K.S.A. 65-1627(e)(4), the Board may take action against the registration of a pharmacy upon a finding that the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country.

5. Pursuant to K.S.A. 65-1657, no nonresident pharmacy shall ship, mail, or deliver, in any manner, prescription drugs to a patient in this state unless registered with the Board as a nonresident pharmacy.

6. Pursuant to K.S.A. 65-1645(f), registrations shall not be transferable.

7. Pursuant to K.A.R. 68-2-9, each registrant shall notify the executive secretary of the Board in writing of any change in majority ownership of the operation for which the registration was issued within five days after the date the change in ownership becomes effective.

8. Pursuant to K.A.R. 68-2-23, each pharmacy owner shall notify the board in writing within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against the pharmacy or the pharmacy owner or any application, license, registration, or permit held by the pharmacy owner.

9. Respondent's registered facility changed ownership on November 6, 2019 but Respondent did not provide notification or file a new application with the Board until April 18 and 28, 2022, respectively.

10. Respondent's failure to submit the complete change of ownership to the Board until April 2022 is a violation pursuant to K.A.R. 68-2-9 and an unlawful transfer of the previous

DOS Prothonotary:
May 10 2023

registration to the new ownership. Respondent's actions are a violation pursuant to K.S.A. 65-1657 and K.S.A. 65-1627(e)(1), and a basis to take action against Respondent's Registration.

11. Respondent failed to notify the Board of the six disciplinary actions by North Carolina, California, and Alabama until April 18, 2022, nearly one to two years after they were effective, is a violation of K.A.R. 68-2-23 and a basis to take action against Respondent's Registration pursuant to K.S.A. 65-1627(e)(1) and (e)(4).

ORDER

Taking into account the mitigating and corrective actions of Respondent, the Board finds and concludes that Respondent's conduct, as described above, violates the Act and such conduct warrants the imposition of a fine pursuant to K.S.A. 65-1658, in the amount of $3,500.00. Respondent has 30 days from the date of this order to pay the fine.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

DOS Prothonotary:
May 10 2023

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

1/20/2023
Date

Alex Blasi
Kansas Board of Pharmacy

DOS Prothonotary:
May 10 2023

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 24th day of January, 2023, deposit in business mail a copy of the foregoing Amended Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

PostMeds, Inc dba Truepill
3121 Diablo Ave.
Hayward, CA 94545

and via email to:

Christopher C. Tillery
Seigfreid Bingham, P.C.
ctillery@sb-kc.com
Attorney for Respondent

Brenda L. Head
Disciplinary Counsel for the Kansas Board of Pharmacy

DOS Prothonotary:
May 10 2023

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania **Bureau of Professional and** **Occupational Affairs**		
vs.	**Case Nos.**	**21-54-004050** **22-54-008273**
PostMeds Inc **Respondent**		

CERTIFICATE OF SERVICE

I, Glenn P. Masser, hereby certify that I have this 11th day of May 2023 caused a true and correct copy of the foregoing Notice and Order to Show Cause to be served upon all parties of record in this proceeding in accordance with the requirements of Rule 33.31 of the General Rules of Administrative Practice and Procedure, 1 Pa. Code § 33.31 (relating to service by the agency).

CERTIFIED MAIL, ELECTRONIC RETURN RECEIPT REQUESTED AND FIRST-CLASS MAIL, POSTAGE PREPAID:

PostMeds Inc
3121 Diablo Ave
Hayward, CA 94545
9171.9690.0935.0253.8568.95

/s/ Glenn P. Masser
Glenn P. Masser
Prosecuting Attorney
Commonwealth of Pennsylvania
Department of State
P. O. Box 69521
Harrisburg, PA 17106-9521
(717) 783-7200

DOS Prothonotary
May 10 2023

DocuSign Envelope ID: 660533CB-A6C4-4E95-9C2C-6E586D48D9DF

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
POSTMEDS INC. dba TRUEPILL and/or TRUEPILL f/k/a POSTMEDS INC.	)	
	)	
Non-Resident Pharmacy Permit Number: 114861	)	**CASE NO: 22-L-0114**

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975), § 41-22-12(f), the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** has violated the provisions of law set out in the Statement.

2. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** shall pay an administrative fine in the amount of Three Thousand Dollars ($3,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** attempt to discharge the same. Payments shall be made payable to Alabama State Board of Pharmacy and mailed to 111 Village Street, Birmingham, Alabama 35242.

3. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama

DocuSign Envelope ID: 660533CB-A6C4-4E95-9C2C-6E586D48D9DF

Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), §20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** further waives any objection to the attorney for the Board preparing, drafting, or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** hereby releases the Board, its members, agents, representatives, servants, and employees from any and all liability, claims, damages, fees, or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.'s** permit, including, but not limited to revocation.

6. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** acknowledges and agrees that it has read this Consent Order and that it fully understands the terms, conditions, and contents of the same. **PostMeds Inc. dba Truepill and/or**

DocuSign Envelope ID: 660533CB-A6C4-4E95-9C2C-6E586D48D9DF

Truepill f/k/a PostMeds Inc. acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and agrees that it had the right to seek advice of counsel before executing this Consent Order.

DONE this the 6th of June, 2023.

PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.

BY: Donny Simkin
Donny Simkin

ITS: General Counsel, Truepill, Inc.

James Hoover
Counsel for **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.**

DONE this the 8th of JUNE, 2023.

ALABAMA STATE BOARD OF PHARMACY

By:
Robert M. Colburn, Jr., R. Ph., President

Jennifer Muro Neumann,
Attorney for the Alabama State Board of Pharmacy

OF COUNSEL:
Jennifer Muro Neumann, PC
Post Office Box 381082
Birmingham, AL 35238
(205) 451-3092

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 22-183
PostMeds, Inc dba Truepill	)	
	)	
Registration No. 22-117859	)	

AMENDED SUMMARY ORDER

NOW on this 20th day of January, 2023, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of PostMeds, Inc dba Truepill ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Amended Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 22-104228 which entitled Respondent to operate as a non-resident pharmacy in the State of Kansas.

2. On November 6, 2019, the ownership of Respondent's non-resident pharmacy changed.

3. On May 22, 2020, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 3, 2020 with an expiration date of June 30, 2021. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?"

Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

4. On June 1, 2021, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 21, 2021 with an expiration date of June 30, 2022. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?" Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

5. Due to staffing challenges, personnel turnover and administrative oversight resulting from its early, rapid growth and restructuring and the corresponding COVID-19 pandemic, Respondent mistakenly failed to report the 2019 ownership change and related disclosures to the Board in its May 22, 2020 and June 1, 2021 renewal applications.

6. On April 18, 2022, the Board received notification from Respondent of an ownership change and several past disciplinary actions not previously reported to the Board including: North Carolina Board of Pharmacy Consent Order of Discipline dated March 8, 2022; California State Board of Pharmacy Letter of Admonishment dated January 23, 2020; California State Board of Pharmacy Citation and Fine dated June 16, 2020; California State Board of Pharmacy Citation and Fine Order of Abatement dated August 25, 2021; Alabama State Board of Pharmacy Final Order dated October 25, 2021; California State Board of Pharmacy Citation and Fine dated January 24, 2019; and California State Board of Pharmacy Citation dated December 16, 2019.

7. On April 28, 2022, the Board received from Respondent a Form BA-22 Non-Resident Pharmacy Registration Application ("Respondent's Application"), notifying of the change in ownership effective November 6, 2019, and applying for a new non-resident pharmacy registration under the new ownership.

8. On May 20, 2022, the Board approved Respondent's Application and issued Respondent the new Non-Resident Pharmacy Registration No. of 22-117859 ("Respondent's Registration") under their new ownership.

9. Prior to receiving the ownership change application, registrant provided a letter notifying of the late ownership change, as well as unreported discipline. Ownership change application completed indicating discipline had occurred and providing details of discipline (5 occurrences).

10. In mitigation, Respondent states that it has invested in additional staff, engaged internal and external legal counsel and implemented training efforts to prevent any such reporting oversights in the future.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against a registration on any ground that would authorize the board to take action against the registration of a pharmacy under K.S.A. 65-1627, and amendments thereto.

3. Pursuant to K.S.A. 65-1627(e)(1), the Board may take action against the registration of a pharmacy upon a finding that such pharmacy has been operated in such manner

that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith.

4. Pursuant to K.S.A. 65-1627(e)(4), the Board may take action against the registration of a pharmacy upon a finding that the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country.

5. Pursuant to K.S.A. 65-1657, no nonresident pharmacy shall ship, mail, or deliver, in any manner, prescription drugs to a patient in this state unless registered with the Board as a nonresident pharmacy.

6. Pursuant to K.S.A. 65-1645(f), registrations shall not be transferable.

7. Pursuant to K.A.R. 68-2-9, each registrant shall notify the executive secretary of the Board in writing of any change in majority ownership of the operation for which the registration was issued within five days after the date the change in ownership becomes effective.

8. Pursuant to K.A.R. 68-2-23, each pharmacy owner shall notify the board in writing within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against the pharmacy or the pharmacy owner or any application, license, registration, or permit held by the pharmacy owner.

9. Respondent's registered facility changed ownership on November 6, 2019 but Respondent did not provide notification or file a new application with the Board until April 18 and 28, 2022, respectively.

10. Respondent's failure to submit the complete change of ownership to the Board until April 2022 is a violation pursuant to K.A.R. 68-2-9 and an unlawful transfer of the previous

registration to the new ownership. Respondent's actions are a violation pursuant to K.S.A. 65-1657 and K.S.A. 65-1627(e)(1), and a basis to take action against Respondent's Registration.

11. Respondent failed to notify the Board of the six disciplinary actions by North Carolina, California, and Alabama until April 18, 2022, nearly one to two years after they were effective, is a violation of K.A.R. 68-2-23 and a basis to take action against Respondent's Registration pursuant to K.S.A. 65-1627(e)(1) and (e)(4).

ORDER

Taking into account the mitigating and corrective actions of Respondent, the Board finds and concludes that Respondent's conduct, as described above, violates the Act and such conduct warrants the imposition of a fine pursuant to K.S.A. 65-1658, in the amount of $3,500.00. Respondent has 30 days from the date of this order to pay the fine.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

1/20/2023
Date

Alex Blasi
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 24th day of January, 2023, deposit in business mail a copy of the foregoing Amended Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

PostMeds, Inc dba Truepill
3121 Diablo Ave
Hayward, CA 94545

and via email to:

Christopher C. Tillery
Seigfreid Bingham, P.C.
ctillery@sb-kc.com
Attorney for Respondent

Brenda L. Head
Disciplinary Counsel for the Kansas Board of Pharmacy

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: CONSENT ORDER

POSTMEDS, INC.

LOUISIANA PHARMACY PERMIT NO. 7761 Case No. 21-0456

****

CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy (hereinafter referred to as the "Board") on March 16, 2022 at the Board office, 3388 Brentwood Drive, Baton Rouge, LA 70809, in the matter of POSTMEDS, INC. (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 7761, 3121 Diablo Ave., Hayward, CA 94545-2701, with attorney Skip Philips and Postmeds Corporate Counsel Donnie Simkin appearing on behalf of Respondent.

WHEREAS, WHEREAS, on August 27, 2018, the Louisiana Board of Pharmacy issued a non-resident pharmacy permit, PHY.007761-NR, to Postmeds Inc. At that time, Postmeds Inc. was 31.5% owned by Mohammad Umar Afridi, 31.5% owned by Siddharth Viswanathan, 16.5% owned by Initialized III L.P., and 20.5% owned by others with no individual owner holding more than 4%. On December 17, 2021 the Board received an "Application for New Louisiana Pharmacy Permit for Nonresident Pharmacy" from Postmeds, Inc. d/b/a Truepill. Accompanying correspondence and organization chart detailed a 100% change in the ownership structure of Postmeds Inc., effective November 6, 2019. Postmeds Inc. went from being owned 31.5% by Mohammad Umar Afridi, 31.5% by Siddharth Viswanathan, 16.5% by Initialized III L.P., and 20.5% by others with no individual owner holding more than 4%, to being owned 100% by Truepill, Inc.

WHEREAS, the Board alleges that such actions constitute violations of the following:

La. R.S. 37:1241 (A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

La. R.S. 37:1221(B). No out-of-state pharmacy providing pharmacy services to residents of this state shall open, establish, operate, or maintain a pharmacy, located out-of-state, unless the pharmacy is issued a permit by the board.

La. R.S. 37:1222(A). A person applying for a permit to open, establish, operate, or maintain a pharmacy, within or outside of this state, shall complete an application in such form and contain such data as the board may require, and complete such other requirements as deemed necessary by the board, including but not limited to designation and identification of a pharmacist-in-charge.

La. R.S. 37:1222(E). A permit to operate a pharmacy shall not be transferable.

La. R.S. 37:1232(A). A pharmacy located outside this state which does business in this state within the meaning of this Chapter, shall hold a current pharmacy permit as provided in this Chapter. The pharmacy shall be designated a "nonresident pharmacy" and the permit shall be designated a "nonresident pharmacy permit."

LAC, Title 46: LIII §1101(A). Individuals, partnerships, corporations, limited liability companies, or associations desiring to operate a pharmacy in Louisiana, or outside the state where prescriptions drugs/devices are dispensed and delivered to Louisiana residents, shall execute an application for a pharmacy permit for their particular classification of pharmacy.

LAC, Title 46: LIII §1135(A)(1)(e). The holder of a pharmacy permit shall notify the board, in writing, prior to the transfer of ownership, in order for the board to complete an inspection of the pharmacy premises. A change of ownership of a pharmacy is evident under the following conditions: a 50 percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original permit or the last renewal application.

LAC, Title 46: LIII §1135(A)(2). The new owner(s) of the pharmacy shall submit a properly completed pharmacy permit application, with appropriate fee, to the board.

LAC, Title 46: LIII §1135(A)(4). Pharmacy permits are not transferable from the original holder(s) of the permit to the new owner(s).

LAC, Title 46: LIII §2305(A). The out-of-state pharmacy shall apply for a permit and annual permit renewals on forms provided by the board.

LAC, Title 46: LIII §2307(C). Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

To facilitate the submission of this Consent Agreement, Respondent does not contest the allegations and agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

POSTMEDS, INC., holder of Louisiana Pharmacy Permit No. 7761, is ordered to pay a fine of $10,000.00 and to reimburse the Board $250.00 for administrative costs, and $324.48 for investigative costs with total payment due the Board of $10,574.80, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter, waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing and to judicial review of this Consent Agreement. Moreover, at no time shall Respondent request the expungement, rescission or removal of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, Matt Davis-Ratner, authorized to act on behalf of and acting on behalf of **POSTMEDS, INC.**, understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

[*Remainder of page intentionally left blank; signature page to follow.*]

SIGNED, AGREED TO AND ENTERED ON THIS 6th DAY OF April, 2022.

POSTMEDS, INC.
Louisiana Pharmacy Permit No. 7761

Matt Davis-Ratner

BY: Matt Davis-Ratner
Authorized Representative

Harry J. Philips

HARRY J. "SKIP" PHILIPS
Taylor Porter
450 Laurel St, 8th Floor
Baton Rouge, LA 70801
Attorney for Respondent

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

Carlos Finalet

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

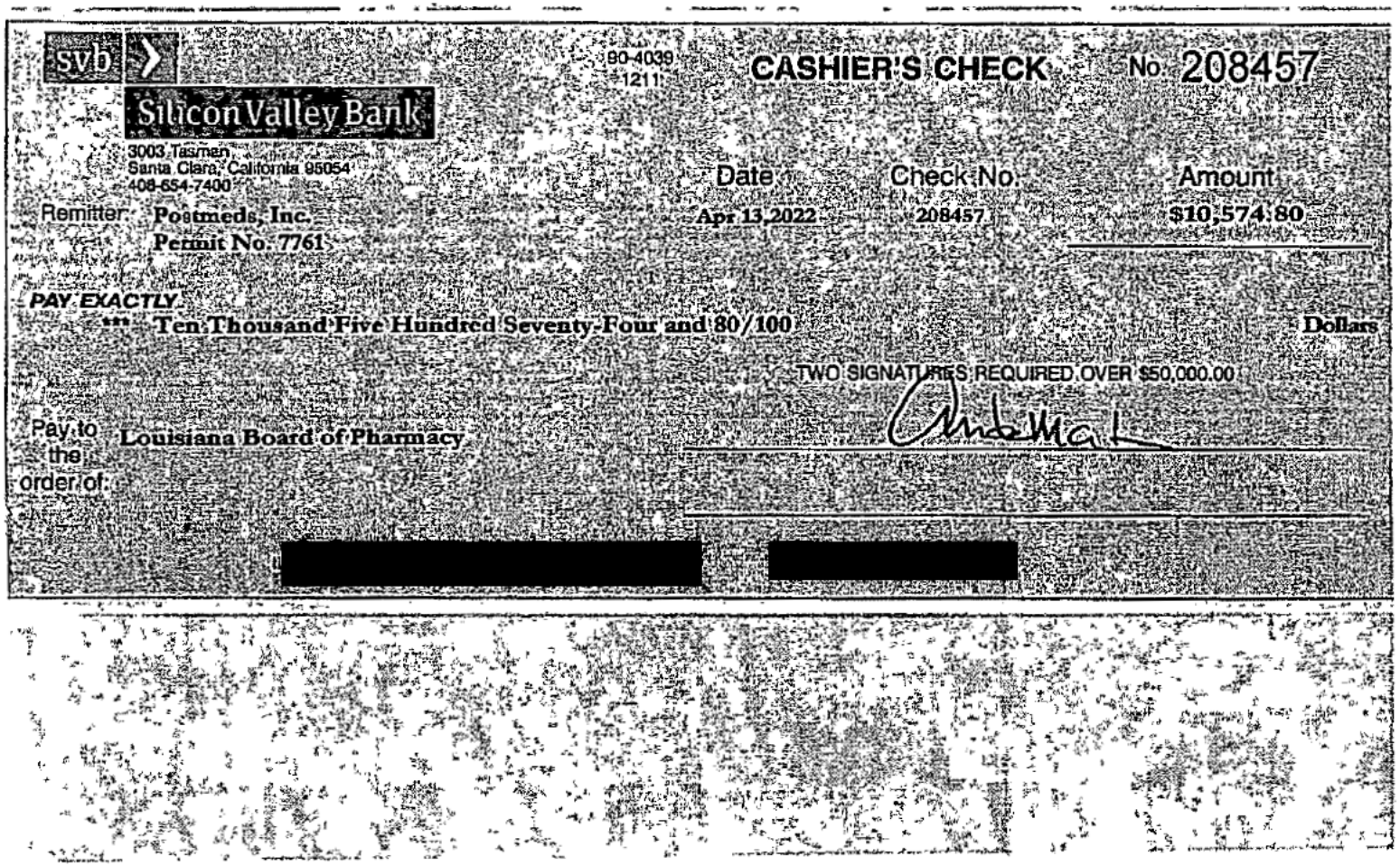
ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on May 11, **2022**, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Marty R McKay

Marty R. McKay
Hearing Officer for the Board



svb

Silicon Valley Bank

3003 Tasman
Santa Clara, California 95054
408-654-7400

90-4039
1211

CASHIER'S CHECK

No 208457

Date	Check No.	Amount
Apr 13,2022	208457	$10,574.80

Remitter: Postmeds, Inc.
Permit No. 7761

PAY EXACTLY

*** Ten Thousand Five Hundred Seventy-Four and 80/100 Dollars

TWO SIGNATURES REQUIRED OVER $50,000.00

Pay to the order of: Louisiana Board of Pharmacy

[redacted]

[redacted]

STATE OF NORTH CAROLINA
NORTH CAROLINA BOARD OF PHARMACY

IN THE MATTER OF	)	
	)	
POSTMEDS, INC. d/b/a Truepill,	)	**CONSENT ORDER**
	)	**OF DISCIPLINE**
Permit No. 13413 and Its Successor Permit(s).	)	

THIS MATTER came to be considered before a member of the North Carolina Board of Pharmacy (hereinafter, the "Board") pursuant to 21 N.C.A.C. 46 .2008. The Conference was scheduled for Thursday, February 24, 2022, and, after appropriate notice, was heard on that day by Board member Wallace E. Nelson. Respondent PostMeds, Inc. was informed of its right to be present at the pre-hearing conference and declined. The Board's General Counsel, Clinton R. Pinyan, represented the Board.

Respondent has agreed to waive a formal hearing in the above-referenced matter. It stipulates and agrees to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. By its consent, Respondent also stipulates that it waives its right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order as a basis for the action taken. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. On November 20, 2017, the Board issued Permit No. 13413 to Respondent PostMeds, Inc. d/b/a Truepill (Permit No. 13413) ("PostMeds").

2. On PostMeds' initial permit application, its then-pharmacist manager, Mohammad Umar Afridi, submitted an inaccurate statement that he was the sole owner and officer of PostMeds. In fact, PostMeds now acknowledges that Afridi and Siddharth

Viswanathan each owned 47 percent of PostMeds on November 20, 2017, with others owning six percent, and that Viswanathan was also an officer of PostMeds.

3. Viswanathan and the minority owners' interests would not have raised questions about the permit application in this particular case. If PostMeds had disclosed the true ownership and officers of PostMeds, the Board still would have granted PostMeds a permit. However, it was an inaccurate statement that Afridi, as the person who submitted the application, knew was inaccurate. That statement prevented the Board from vetting Viswanathan as the owner of the pharmacy. Because of the inaccuracy of the representations, the initial permit was void ab initio.

4. In November 2019, PostMeds went through a corporate restructuring. During that restructuring, Truepill, Inc. was created as a holding company for PostMeds. At that time, Truepill, Inc. became the sole owner of PostMeds. Afridi, Viswanathan and the other former direct owners of PostMeds became indirect owners with the same ownership interests in the holding company, Truepill, Inc., that they had before the transfer of ownership.

5. This restructuring required PostMeds to submit a transfer of ownership application and have that application granted before the restructuring closed. PostMeds failed to do this. Therefore, even if the initial permit had been valid (which it was not), it would have become invalid upon the corporate restructuring.

6. Insertion of a new holding company between the ultimate owners and PostMeds would not have raised questions about the permit application in this particular case. The ownership interests of the ultimate owners did not change. If PostMeds had disclosed the new holding company, the Board still would have granted the transfer of ownership. However,

PostMeds failed to submit the transfer of ownership application or otherwise disclose the interests of Truepill, Inc.

7. In each of its subsequent renewals, PostMeds failed to correct the ownership information that it had inaccurately submitted on its initial application or to list Truepill, Inc., as the direct owner of the pharmacy.

8. On November 4, 2021, counsel for PostMeds informed the Board that its "current ownership information on file with the North Carolina Board of Pharmacy is out of date." Upon follow-up questioning, the next day, PostMeds disclosed that it should have submitted a transfer of ownership application in November 2019. It further was apparent from the ownership information that PostMeds provided that Afridi made inaccurate representations about ownership and officers on PostMed's initial application that had never been corrected.

9. PostMeds agreed to stop shipping any drugs, devices or medical equipment into the State of North Carolina until the matter was resolved. It further agreed to stop shipping or dispensing any drugs, devices or medical equipment from six other pharmacies under its ownership until the matter was resolved (even though those pharmacies did not receive permits until after the transfer of ownership had occurred, and so did not suffer from the same problem).

10. PostMeds submitted a transfer of ownership application promptly.

11. Although PostMed's disclosure of its inaccuracies was tardy, its remedial actions are a mitigating factor in this matter.

CONCLUSIONS OF LAW

1. Reporting of correct and complete ownership information on an initial pharmacy permit application or a renewal application is material, indeed essential, to the Board's ability to ensure that a pharmacy will provide services safely and competently to the public.

2. PostMeds made inaccurate statements about its ownership and officers on its initial application, which it failed to correct at any point through its 2022 renewal. That initial permit was therefore void ab initio and violated G.S. § 90-85.38(b).

3. The creation of Truepill, Inc. as a holding company further triggered a requirement to report the ownership change and obtain a successor permit, and to do so before the closing of the transaction that created Truepill, Inc. The transaction "result[ed] in a different person . . . owning more than 50 percent interest in the permit holder . . . ." 21 NCAC 46.1603. Failure to apply for and obtain a successor permit prior to the transaction, and a continuing failure to disclose the ownership interest of Truepill, Inc., violated G.S. § 90-85.38(b).

IT IS THEREFORE ORDERED:

PostMeds was in violation of G.S. § 90-85.38(b) in North Carolina from November 20, 2017 until at least November 4, 2021. Respondent PostMed's Permit No. 13413 was **VOID** from the time that it was granted on November 20, 2017. G.S. § 90-85.38(c).

Respondent PostMed's change of ownership application is **APPROVED** as a successor permits to Permit No. 13413 (the "Successor Permit") with the following **CONDITIONS:**

1. PostMeds shall provide timely advance notice of any contemplated change in ownership to the current pharmacist-manager and any future pharmacist-manager(s) of the Successor Permit. PostMeds shall consult with the Successor Permit's pharmacist-manager(s) to determine whether any contemplated transaction triggers the need to obtain new permits. PostMeds shall authorize the Successor Permit's pharmacist-manager(s) to take any necessary action to update that ownership information with the Board or to apply for new permits. If a contemplated transaction triggers the need for new permits, PostMeds shall not complete that

transaction unless and until either the Board issues new permits or PostMeds ceases all practice of pharmacy at the permitted location.

2. The Successor Permit shall violate no laws governing the practice of pharmacy or the distribution of drugs.

3. The Successor Permit shall violate no rules or regulations of the Board.

4. If the Successor Permit fail to comply with any term or condition of this Order, it may be subject to additional disciplinary action by the Board.

This is the 8th day of March, 2022

NORTH CAROLINA BOARD OF PHARMACY

By: /s/ William A. Mixon
William A. Mixon
President

Respondent PostMeds, Inc. has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. Respondent freely, knowingly and voluntarily waives its right to such a hearing by entering into this Consent Order.

Respondent understands and agrees that by entering into this Consent Order, it certifies that it has read the foregoing Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions that may be taken concerning this matter.

Respondent further understands that should it violate the terms and conditions of this Consent Order, the Board may take additional action.

Respondent understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

Respondent understands that it has the right to have counsel of its choice review and advise them with respect to their rights and this Consent Order, and represents that it enters this Consent Order after consultation with counsel or after knowingly and voluntarily choosing not to consult with counsel. Respondent further agrees that the person who is executing this Consent Order has been duly authorized by any required corporation action to execute on behalf of Respondent.

CONSENTED TO BY:

_____ Date 3/7/22

Printed Name: Matt Davis-Ratner

Title: General Counsel

STATE OF _____

_____ COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the above-named representative of PostMeds, Inc. personally appeared before me this day, and acknowledged the due execution of the foregoing document.

Date:_____

_____
Notary Public

_____

My commission expires:_____

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

August 25, 2021

TRUEPILL
ATTN: FRANCESCO CONSOLE, PIC
3121 DIABLO AVE
HAYWARD, CA 94545

RE: CI 2020 89223
TRUEPILL
PHY 56100

The attached Citation CI 2020 89223, has been issued to TRUEPILL, PHY 56100. A copy has been sent to the pharmacy, and a copy is being sent to the pharmacist-in-charge for informational purposes only. As pharmacist in charge it is your responsibility to insure the pharmacy's compliance with the term(s) and condition(s) of the citation by the date(s) ordered, and to ensure the pharmacy's compliance with all pharmacy laws.

The Citation references the specific statutes and regulations violated, and defines each violation charged. The Citation details the conduct that resulted in the issuance of the citation. In addition the citation may also include information regarding fine(s) assessed. If fine(s) have been assessed, the citation specifies the amount and the specific violation for which the fine was levied.

If you have any questions please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

Sincerely

Joshua Monforte
Citation and Fine Analyst

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE
ORDER OF ABATEMENT

COPY

Citation Number	Name, License No
CI 2020 89223	TRUEPILL, PHY 56100

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1714 subd. (b)	Operational Standards and Security; pharmacy responsible for pharmacy security	$5,000.00
Bus. & Prof. Code § 4169 subd. (a)(2)/Health & Safety Code § 111295	Prohibited Acts; Purchase, trade, sell, or transfer dangerous drugs to that the person knew or reasonably should have known were adulterated.../It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated	Citation without a fine

CONDUCT:

California Code of Regulations 1714, section b states, (b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy. Specifically, Truepill Pharmacy, PHY56100, located at 3121 Diablo Ave, Hayward, CA 94545 was in violation when they failed to keep dangerous drugs stored according to policy and procedure 2001.4, Oversight of Pharmacy Safety, which states: "The Pharmacy will make all attempts at maintaining a room temperature below 85F and ideally between 68-77F". Between 7/1/2020 and 9/14/2020, on numerous occasions, dangerous drug storage temperatures, summarized in Table 2, exceeded the recommended storage temperatures. The most egregious of these temperature spikes were:

a) On 8/13/2020, in the cage area of the warehouse, dangerous drugs were stored approximately 161 hours over 77 F and 47 hours over 85F.
b) On 9/6/2020, in the cage area of the warehouse, dangerous drugs were stored approximately 59 hours over 77 F and 17 hours above 85F.
c) On 8/13/2020, in the Parata Automated dispensing machine located in the warehouse, dangerous drugs were stored for approximately 163 hours above 77 F and 44 hours above 85 F.

Business and Professions Code 4169 section (a), subdivision (2) states, A person or entity shall not do any of the following: (2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code as it relates to Health and Safety Code 111295 which states, It is unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug or device that is adulterated. Specifically, Truepill Pharmacy, PHY56100, located at3121 Diablo Ave, Hayward, CA 94545 was in violation when they used the MKT calculation alone instead of in conjunction with manufactures stability data as stated in USP <1079>, which provides guidance for assessing possible adulteration to dangerous drugs stored at the pharmacy due to excessive heat. In particular, USP<1079> states, "Knowing the MKT for an excursion is useful for evaluating the potential impact on product quality. However, it is also essential to know the upper and lower temperature limits of any excursion. If these extreme temperatures are outside available stability data, it may not be possible to predict the quality impact of the excursion with any confidence regardless of the MKT. At higher temperatures the kinetics of degradation may change or new degradation reactions may occur. Truepill Pharmacy did not consider the manufacture's stability data for at least 72 dangerous drugs stored in the cage area of the warehouse which were held and offered for sale when determining if a dangerous drug was adulterated by the extreme heat, summarized in Table 3. For each one of the 72 dangerous drugs, the maximum temperature for storage was listed by the manufacturer as 77F or storage information was not listed. As there was no stability temperature for at least the 72 drugs in question and per USP<1079>, the MKT cannot be without the stability data, these drugs which were held and offered for sale were adulterated.

ORDER OF ABATEMENT

By the Abatement date/payment date submit to the Board the following:

- Either (1) full payment of the assessed fine(s) in the amount of $5,000.00; or payment in the amount of $1,000.00 and (2) provide proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within ninety (90) days.

COPY

If you choose option (2), within 90 days of this citation, you shall submit proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations. Any failure to do so shall be deemed a failure to meet the abatement requirements of this citation.

If you timely submit proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within 90 days from the date the citation was issued, this citation shall be reduced to $1,000.00 and proof of compliance of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations shall be considered satisfactory abatement of the citation.

If you fail to submit proof of compliance of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within 90 days from the date the citation was issued, the stay shall be lifted and the fine(s) in the amount of $5,000.00 shall be due and owing from you within thirty (30) days of any such failure.

CITATION ISSUED ON: August 25, 2021	TOTAL AMOUNT OF FINE(S): $5,000.00
PROOF OF ABATEMENT AND PAYMENT OF FINE(S) DUE BY: September 24, 2021	

COPY

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

January 23, 2020

VIA CERTIFIED MAIL

LETTER OF ADMONISHMENT

TRUEPILL
ATTN: MOHAMMAD UMAR AFRIDI, CEO
3121 DIABLO AVE
HAYWARD, CA 94545

RE: CI 2019 84877
TRUEPILL
PHY 56100

This LETTER OF ADMONISHMENT is being issued pursuant to Business and Professions Code section 4315 for failure to comply with the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the board's website at www.pharmacy.ca.gov, under Forms and Publications.)

The Board of Pharmacy has completed its investigation in the above referenced matter. All documentation and/or statements relating to the investigation have been accepted and included in an Investigation Report on file in this office. Facts contained in this report lead to the conclusion that the following violations of pharmacy laws or regulations have occurred:

JURISDICTION: Bus. & Prof. Code § 4315; 1764/56.10(a) - Unauthorized disclosure of prescription and medical information

Unauthorized disclosure of prescriptions: California Code of Regulations section 1764 states in pertinent part that no pharmacist shall exhibit, discuss, or reveal the contents of any prescription or any medical information furnished by the prescriber with any person other than the patient or his or her authorized representative and Civil Code section 56.10 subdivision (a) states, in pertinent part, no provider of health care shall disclose medical information regarding a patient of the provider of health care without first obtaining an authorization. Truepill Pharmacy was not in compliance with these regulations. Specifically, on 4/17/2019, Truepill Pharmacy (PHY56100) located at 3121 Diablo Avenue in Hayward, CA shipped prescription RX#1186395 to the wrong person. The prescription was intended for AR but was shipped to the address of MS in error. Also, Truepill Pharmacy shipped prescriptions to patients with a shipping label showing the return address of NuRx located at 6838 Ellicott Drive in East Syracuse, NY and from Apostrophe located at 330 2nd Street in Oakland, CA. NuRx and Apostrophe are not licensed pharmacies and prescription packages returned as undeliverable to these locations would cause the disclosure of medical information without authorization.

Shipping prescriptions to an unauthorized person violates California Code of Regulations section 1764 and Civil Code 56.10.

If you wish to contest this Letter of Admonishment, you may do so by submitting, within 30 days of the date of service of this Letter of Admonishment, namely February 22, 2020, the attached "Request for an Office Conference" form. If an office conference is not requested, compliance with the Letter of Admonishment shall not constitute an admission of the violations described in the Letter of Admonishment.

Unless it is dismissed following an office conference or you receive other instructions from the Board in writing, Pharmacy Law requires that you maintain and have readily available for inspection a copy of this Letter of Admonishment and any written corrective action plan, if any, for at least three years from the date of issuance at the top of this letter. The Letter of Admonishment will be considered a public record for purposes of disclosure for three years from issuance. The issuance of this Letter of Admonishment does not limit the board's ability to pursue other disciplinary or administrative action under Business and Professions Code section 4315, subdivision (f).

If you have any questions regarding this Letter of Admonishment, please contact Barbera Schleicher, Public Inquiry Analyst at (916) 518-3081.

Sincerely

Virginia Herold
Executive Officer
Board of Pharmacy

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

MODIFIED CITATION AND FINE

Citation Number	Name, License No
CI 2017 78633	TRUEPILL (FORMERLY POSTMEDS INC.), PHY 56100

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059 subd. (a)/Bus. & Prof. Code § 4067 subd. (a)	Furnishing dangerous drugs without a prescription/Internet; Dispensing Dangerous Drugs or Devices without Prescription; No person shall dispense or furnish, or cause to be furnished dangerous drugs...on the internet...without a prescription issued pursuant to a good faith examination	Citation without a fine
Bus. & Prof. Code § 4174	Dispensing on order of nurse practitioner or person of similar status.	Citation without a fine

CONDUCT:

Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Business and Professions Code 4059 (a) states in pertinent part a person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. In conjunction with Business and Professions Code 4067 (a) which states no person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination of a human or animal, or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations and (f) for the purposes of this section, "good faith prior examination" includes the requirements for a physician and surgeon in Section 2242. In conjunction with Business and Professions Code 2290.5 (a) For purposes of this division, the following definitions shall apply: (3) "Health care provider" means either of the following: (A) a person who is licensed under this division. Between 4/1/2018 to 10/31/2018, Postmeds Inc. (PHY56100) located at 3121 Diablo Ave. Hayward, CA dispensed prescriptions issued by prescribers who were not licensed in California. Specifically, 2 prescriptions were issued by Nurse Practitioner Jenny Ingle; 9 prescriptions were issued by Dr. Brook Randal; 6 prescriptions were issued by Dr. Jessica Rubino and 4 prescriptions were issued by Dr. Sudhi Trye. These prescribers were not licensed in California at the time the prescriptions were initiated and shipped to a California resident. Postmeds pharmacy dispensed the prescriptions issued by unlicensed prescribers to

California residents in violation of Business and Professions Code 4059 (a) and Business and Professions Code 4067 (a).

Dispensing by Pharmacist Upon Order of Nurse Practitioner: Business and Professions Code 4174 states in pertinent part notwithstanding any other law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section 4052.1, 4052.2, 4052.3, or 4052.6. Postmeds Inc. (PHY56100) located at 3121 Diablo Ave. Hayward, CA dispensed prescriptions issued by Nurse Practitioners and Physicians Assistants who had not yet entered into an established standardized procedure or protocol developed by a supervising physician. Between 4/1/2018 and 10/31/2018, the following prescribers issued prescriptions to Postmeds without an established protocol in place: Physician's Assistant Leanne Mays issued 8 prescriptions and Physician's Assistant Susan Owen issued 6 prescriptions. Between 4/1/2018 and 10/31/2018, the following prescribers issued prescriptions to Postmeds entering into a protocol after the prescriptions were issued: Nurse Practitioner Joni Gunzburger issued 4,782 prescriptions; Nurse Practitioner Cristin Hackel issued 10,819 prescriptions and Nurse Practitioner Jessica Horwitz issued 4,711 prescriptions. Postmeds Pharmacy dispensed the prescriptions issued by Nurse Practitioners and Physicians Assistants who had not yet entered into standardized procedures or protocols as required by Business and Professions Code 4174.

CITATION ISSUED ON: June 16, 2020	TOTAL AMOUNT OF FINE(S): $0.00

PAYMENT OF FINE(S) DUE BY: July 16, 2020

9

9A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Covetrus North America, LLC

Physical Address: 5999 Bixby Road

City: Canal Winchester State: OH Zip: 43110

Mailing Address (if different from physical address): 400 Metro Place N, Suite 200

City: Dublin State: OH Zip: 43017

Telephone: 614-553-4025 Website: covetrus.com

Name of Designated Representative (DR): Jeffrey Hitchcock

Licensing Company Email: cvet-na-licensing@covetrus.com DR Email: jeffrey.hitchcock@covetrus.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2/2024	5/8/24	VA	Abington	Washington
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
1:24-mj-00009-PMS		Western District of Virginia		
Reason/Charge				
Introduction of Misbranded Drugs into Interstate Commerce				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
		Agreement		
Name of Business/Industry/Entity				
Covetrus North America, LLC				

Provide explanation below:

On Feb. 12th, Covetrus North America resolved a criminal investigation that was conducted by the United States Attorney's Office for the Western District of Viriginia regarding the distribution of misbranded prescription veterinary medication. Distribution of veterinary prescription medication generally requires a closed supply chain in which every entity that possesses the medication is legally authorized to do so. Certain states, including Virginia, consider shipment of these products from a non-pharmacy, such as a distribution center, to a non-authorized location as being outside of the approved closed supply chain and thus misbranded.
The investigation concluded that Covetrus North America shipped prescription veterinary medication to locations that were not authorized to receive them. All veterinary prescription drugs must be dispensed either by a pharmacy pursuant to a valid prescription issued by a veterinarian or dispensed directly by a veterinarian. Our Large Animal Pharmacy, which is currently active in 49 states, is designed to comply with this requirement.

Throughout this investigation, we fully cooperated with the U.S. Attorney's office. In resolving the investigation, Covetrus North America has agreed to pay the federal government in excess of $22 million and pay $1 million to the Virginia Department of Health Professions for their assistance to the United States during the investigation. Sentencing is scheduled for May 8th and we expect to be subject to certain compliance requirements and may be placed on probation for a specified period of time.

Philip Mario Lombardi
Original Signature (electronic, copies or stamps not accepted)

6/6/24
Date

covetrus

June 3, 2024

To the State Board:

On Feb. 12th, Covetrus North America resolved a criminal investigation that was conducted by the United States Attorney's Office for the Western District of Virginia regarding the distribution of misbranded prescription veterinary medication.

Distribution of veterinary prescription medication generally requires a closed supply chain in which every entity that possesses the medication is legally authorized to do so. Certain states, including Virginia, consider shipment of these products from a non-pharmacy, such as a distribution center, to a non-authorized location as being outside of the approved closed supply chain and thus misbranded.

The investigation concluded that Covetrus North America shipped prescription veterinary medication to locations that were not authorized to receive them. All veterinary prescription drugs must be dispensed either by a pharmacy pursuant to a valid prescription issued by a veterinarian or dispensed directly by a veterinarian. Our Large Animal Pharmacy, which is currently active in 49 states, is designed to comply with this requirement.

Throughout this investigation, Covetrus fully cooperated with the U.S. Attorney's office. In resolving the investigation, Covetrus North America agreed to pay the federal government in excess of $22 million and pay $1 million to the Virginia Department of Health Professions for its assistance to the United States during the investigation.

On May 8, Covetrus was sentenced to a one-year probation period, to which the government did not object. The company will be subject to certain compliance requirements in connection with this probationary period with which we fully cooperate.

Thank you.

Tamika S. Simmons

Tamika S. Simmons
Chief Regulatory and Compliance Officer
Covetrus North America, LLC

CLERK'S OFFICE U.S. DISTRICT COURT
AT ABINGDON, VA
FILED
FEB 09 2024
LAURA A. AUSTIN, CLERK
BY: L. Bondurant
DEPUTY CLERK

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA	)	
	)	**Criminal No.** 1:24mj9
v.	)	
	)	**Violations: 21 U.S.C. §§ 331(a),**
COVETRUS NORTH AMERICA LLC	)	**333(a)(1), and 352(f)(1)**

INFORMATION

INTRODUCTION

1. Defendant COVETRUS NORTH AMERICA LLC ("COVETRUS NA") is a Delaware corporation with its principal place of business in Dublin, Ohio. COVETRUS NA was formerly known as Butler Animal Health Supply, LLC and was a subsidiary of Henry Schein, Inc. In February 2019, Henry Schein, Inc. spun-off its animal health business, including Butler Animal Health Supply LLC, which in turn merged with Vets First Choice to create a separate entity named Covetrus, Inc. As part of that spin-merger, Butler Animal Health Supply, LLC became a subsidiary of Covetrus, Inc., and was re-named Covetrus North America LLC. Covetrus, Inc., through its wholly-owned subsidiary, is the ultimate sole member controlling COVETRUS NA. COVETRUS NA dispenses, distributes, and sells, among other products, veterinary prescription drugs to customers across the United States. Specifically, COVETRUS NA obtains prescription drugs for animals from manufacturers for further distribution to veterinarians, farms, feedlots, and others.

2. The Food and Drug Administration ("FDA") of the United States Department of Health and Human Services ("HHS") regulates the distribution and labeling of all drugs, including animal drugs, shipped or received in interstate commerce through enforcement of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C § 301, et seq. ("FDCA"). Veterinary

prescription drugs are drugs intended for use by animals that, because of their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary for their use, are not safe for animal use except under the professional supervision of a licensed veterinarian. 21 U.S.C. § 353(f)(1)(A).

3. Under the FDCA, a drug is misbranded if, among other things, its labeling does not bear "adequate directions for use." 21 U.S.C. § 352(f)(1). Adequate directions for use is defined as "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5 (emphasis added). Prescription veterinary drugs by definition can only safely be used under the professional supervision of a licensed veterinarian and therefore they must qualify for an exemption to this requirement in order to move in interstate commerce. These exemptions are set out in 21 C.F.R. Part 201, Subpart D ("Exemptions from Adequate Directions for Use").

4. Veterinary prescription drugs are exempt from the requirement that their labeling contain adequate directions for use if they meet all enumerated conditions, including that they be distributed through a closed supply chain in which every entity that possesses a prescription drug must have legal authorization to do so. See 21 C.F.R. § 201.105 (a)(1) (a veterinary prescription drug must be in the possession of: a person lawfully engaged in the manufacture, transportation, storage or wholesale distribution of drugs; a retail pharmacy or other person authorized under state law to dispense veterinary prescription drugs; or a licensed veterinarian for use in the course of his professional practice). Moreover, the veterinary prescription drug must be dispensed in accordance with 21 U.S.C. § 353(f), i.e., pursuant to a lawful order of a licensed veterinarian in the course of the veterinarian's professional practice. 21 U.S.C. § 353(f)(1) & 21 C.F.R. § 201.105 (a)(2). In other words, all veterinary prescription drugs must be dispensed (a)

by a pharmacy pursuant to a valid prescription issued by a veterinarian or (b) dispensed directly by a veterinarian.

5. In the Commonwealth of Virginia and certain other states, veterinary prescription drugs may only be shipped to locations authorized by the state. Shipment of prescription drugs from a non-pharmacy to a non-authorized location is outside of the approved closed supply chain and, accordingly, such prescription drugs are not exempt from the requirement that their labeling contain adequate directions for use. The shipments in question from COVETRUS NA failed to include adequate directions for use and accordingly, were misbranded.

6. The FDCA's restrictions on veterinary prescription drugs not only protect animals from the potential harms of prescription drugs, but are, in part, to prevent overuse of antibiotics and other prescription drugs which can lead to development of drug-resistant bacteria and microbes. In addition, the FDCA's restrictions also ensure that drugs are shipped to locations where the drugs will be properly stored to ensure the drugs remain viable and to prevent diversion. Also, as to drugs used by animals that are in the human food supply, the restrictions protect the human food supply from unsafe drug residue in the edible tissues of animals sold for slaughter. Common causes of illegal residue include: (1) exceeding the drug's approved dose; (2) using a shorter withdrawal period than what is stated on the drug's label (if a higher than approved dose is given, the labeled withdrawal period may not be enough to allow the drug in the edible tissues to deplete to levels that are at or below the tolerance); (3) using a drug in an extra-label manner (for indications and dosages outside the approved labeling) without a veterinarian's involvement; (4) giving a drug not approved for that species; and (5) using an unapproved route of administration. Drug residue in the nation's food supply is concerning because: (1) they may contribute to antibiotic resistance in the human population, rendering

human drugs less effective to treat human disease and contributing to the mutations of "superbugs"; and (2) they may cause allergic reactions in individuals with certain drug allergies.

7. From March 2019 to 2021, COVETRUS NA caused misbranded veterinary prescription drug shipments to be made in interstate commerce to various locations in the Commonwealth of Virginia and certain other states by distributing veterinary prescription drugs from its wholesale locations directly to end users in states where such shipments were illegal. COVETRUS NA shipped these misbranded veterinary drugs to unauthorized users/locations. The list of unauthorized customers included locations such as equine, humane society, large animal practice, mixed practice 50/50, mobile vet practices, and personal accounts. COVETRUS NA obtained not less than $21,534,091 (twenty-one million five hundred thirty-four thousand ninety-one dollars) from such shipments. Its profits from such shipments were a small percentage of the amount received.

COUNT ONE

Introduction of Misbranded Drugs into Interstate Commerce
21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1)

The United States Attorney charges that:

8. The Introduction is realleged and incorporated by reference into this Count.

9. From March 2019 to December 2021, in the Western District of Virginia and elsewhere, COVETRUS NORTH AMERICA LLC ("COVETRUS NA") introduced and delivered for introduction, and caused the introduction and delivery for introduction, into interstate commerce, of veterinary prescription drugs that were misbranded in that the drugs' labeling did not bear adequate directions for the use of such drugs.

10. The Offense Conduct was the following:

a. COVETRUS NA distributed veterinary prescription drugs directly from their non-pharmacy locations to various end-users; and

b. COVETRUS NA distributed veterinary prescription drugs to locations that were not authorized locations to which prescription drugs could legally be shipped.

c. Since these veterinary prescription drugs were not lawfully distributed, they failed to qualify for the exemption from the requirement that they bear labeling containing adequate directions for lay use. Accordingly, such shipments were shipments of misbranded drugs.

d. The Offense Conduct does not include shipments of products containing xylazine.

11. All in violation of Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1).

NOTICE OF FORFEITURE

12. Upon conviction of the offense alleged in this Information, COVETRUS NA shall forfeit to the United States veterinary prescription drugs that were misbranded or became misbranded as a result of COVETRUS NA's conduct, pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461.

13. Because the above-described forfeitable property has been transferred and sold to third parties and cannot be located upon the exercise of due diligence, the United States intends to seek forfeiture of $21,534,091 (twenty-one million five hundred thirty-four thousand ninety-one dollars) pursuant to 21 U.S.C. § 853(p).

DATED: February 9, 2024

Randy Ramseyer

for CHRISTOPHER R. KAVANAUGH
United States Attorney

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA	)	
	)	
v.	)	**Criminal No. _____**
	)	
COVETRUS NORTH AMERICA LLC.	)	

PLEA AGREEMENT

COVETRUS NORTH AMERICA LLC (EIN: 37-1507466) has entered into a Plea Agreement with the United States of America, by counsel, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure ("Fed. R. Crim. P."). The terms and conditions of this Plea Agreement are as follows:

1. CHARGE TO WHICH COVETRUS NORTH AMERICA LLC IS PLEADING GUILTY AND WAIVER OF RIGHTS

COVETRUS NORTH AMERICA LLC ("COVETRUS NA") will enter a plea of guilty to Count One of the Information charging it with violating Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1) in the Western District of Virginia by introducing and delivering for introduction, and causing the introduction and delivery for introduction, into interstate commerce of veterinary prescription drugs that were misbranded.

COVETRUS NA understands, and the parties agree and stipulate, the maximum statutory penalty is a fine of $3,230,114 (three million two hundred thirty thousand one hundred fourteen dollars), pursuant to Title 18, United States Code, Section 3571(d), and a period of probation of five (5) years, pursuant to Title 18, United States Code, Section 3561(c)(2). In addition, COVETRUS NA's assets are subject to forfeiture. COVETRUS NA understands fees may be imposed to pay for probation and there will be a $125 (one hundred twenty-five dollars) special assessment for Count One, pursuant to Title 18, United States Code, Section 3013(a)(1)(B)(iii). COVETRUS NA's attorneys have informed it of the nature of the charge and the elements of the charge that must be proved by the United States beyond a reasonable doubt before COVETRUS NA could be found guilty as charged.

COVETRUS NA admits and agrees that all of the statements and allegations in the Information are true and correct.

COVETRUS NA acknowledges COVETRUS NA has had all of its rights explained to it. COVETRUS NA expressly recognizes that, as a corporation, it may have the following constitutional rights and by voluntarily pleading guilty COVETRUS NA knowingly waives and gives up these valuable constitutional rights:

- The right to plead not guilty and persist in that plea.
- The right to a speedy and public jury trial.
- The right to assistance of counsel at that trial and in any subsequent appeal.

- The right to remain silent at trial.
- The right to testify at trial.
- The right to confront and cross-examine witnesses. The right to present evidence and witnesses.
- The right to compulsory process of the court.
- The right to compel the attendance of witnesses at trial. The right to be presumed innocent.
- The right to a unanimous guilty verdict. The right to appeal a guilty verdict.

COVETRUS NA is pleading guilty as described above because it is in fact guilty and because COVETRUS NA believes it is in its best interest to do so and not because of any threats or promises, other than the terms of this Plea Agreement, described herein, made in exchange for its plea of guilty. COVETRUS NA agrees all of the matters set forth in the Information are true and correct.

COVETRUS NA agrees, and hereby consents, pursuant to Title 18, United States Code, Section 3401 and Federal Rule of Criminal Procedure 58(b)(3)(A), to a magistrate judge taking COVETRUS NA's guilty plea, sentencing COVETRUS NA, and entering judgment against COVETRUS NA. COVETRUS NA understands it has a right to trial, judgment, and sentencing by a district judge and a right to trial by jury. Knowing these rights, COVETRUS NA expressly consents to be tried before the magistrate judge and expressly and specifically waives trial, judgment, and sentencing by a district judge.

COVETRUS NA understands the plea is being entered in accordance with Fed. R. Crim. P. 11(c)(1)(C).

2. SENTENCING PROVISIONS

The parties agree the 2023 version of the United States Sentencing Commission Guidelines Manual ("U.S.S.G.") is the appropriate Guidelines Manual to utilize. According to U.S.S.G. § 8C2.1, the organizational fine provisions do not apply to the count of conviction in this case, which is a misdemeanor under 21 U.S.C. § 333(a)(1).

The parties agree and stipulate:

a. the fine shall be $1,000,000 (one million dollars);

b. COVETRUS NA shall pay $1,000,000 (one million dollars) to the Virginia Department of Health Professions ("DHP") in recognition of direct assistance provided by DHP to the United States during the investigation;

c. COVETRUS NA shall forfeit $21,534,091 (twenty-one million five hundred thirty-four thousand ninety-one dollars); and

d. COVETRUS NA shall serve a term of probation of one to three years, as determined by the Court.

The Court will determine what terms and length of probation are appropriate and the parties

will be free to argue for which terms and length of probation they believe are appropriate. COVETRUS NA understands and agrees if its probation is revoked, it may be resentenced and a total aggregate fine up to the statutory maximum may be imposed.

The parties agree if the Court refuses to accept this Plea Agreement with the agreed-upon sentence, COVETRUS NA will be free to withdraw its guilty plea. Acceptance of this Plea Agreement by the Court includes acceptance of each of the sentencing provisions and financial obligations described herein. In the event the Court refuses to accept this Plea Agreement and COVETRUS NA withdraws its guilty plea within ten days of being notified of the Court's refusal, nothing in this Plea Agreement shall be deemed a waiver of the provisions of Federal Rule of Evidence ("Fed. R. Evid.") 410. Under these circumstances, the United States will move to dismiss the Information without prejudice and the United States may file any charges it could have filed in the absence of the plea agreement. COVETRUS NA agrees to toll the statute of limitations between the date of the entry of the plea and the filing of any such charges.

3. FINANCIAL OBLIGATIONS

COVETRUS NA agrees and understands any of the money paid pursuant to this Plea Agreement will be returned if, and only if, the Court refuses to accept this Plea Agreement with the agreed- upon sentence and, as a result, COVETRUS NA withdraws its guilty plea. If the Court rejects this Plea Agreement and COVETRUS NA withdraws its guilty plea, the United States will return all money paid by COVETRUS NA, without interest, not more than thirty (30) days after COVETRUS NA withdraws its guilty plea and notifies the United States Attorney's Office for the Western District of Virginia ("USAO"), in writing, it wishes to have the money returned.

In addition, in accordance with 18 U.S.C. § 3572(d)(3), COVETRUS NA will notify the Court of any material change in COVETRUS NA's economic circumstances that might affect COVETRUS NA's ability to pay any amounts payable under this Plea Agreement.

a. Payments

On or before January 4, 2024, COVETRUS NA will make the following disbursements:

(1) $1,000,000 (one million dollars) to the Virginia Department of Health Professions. These funds must be remitted in the form of certified funds made payable to the "Treasurer of Virginia." The comment section of the check should note "DHP-Enforcement" in recognition of direct assistance provided to the United States during the investigation; and

(2) $21,534,091 (twenty-one million five hundred thirty-four thousand ninety-one dollars) in full satisfaction of the forfeiture money judgment. These funds must be remitted in the form of certified funds made payable to the U.S. Marshals Service, Asset Forfeiture Unit, 247 Federal Building, 210 Franklin Road, S.W., Roanoke, Virginia.

Within 7 days of the entry of COVETRUS NA's guilty plea, COVETRUS NA will make the following disbursements:

(1) $125 (one hundred twenty-five dollars) to the Clerk, U.S. District Court, Abingdon, Virginia, as payment of the special assessment; and

(2) $1,000,000 (one million dollars) to the Clerk, U.S. District Court, Abingdon, Virginia, as payment of the fine.

b. Forfeiture

COVETRUS NA agrees to the entry of a forfeiture money judgment in the amount of $21,534,091 (twenty-one million five hundred thirty-four thousand ninety-one dollars) in United States currency ("Forfeiture Money Judgment") pursuant to 21 U.S.C. §§ 334 and 853(p), and 28 U.S.C. § 2461(c). COVETRUS NA agrees that the value of the quantities of prescription drugs which were misbranded in violation of 21 U.S.C. § 331(a) totaled at least $21,534,091 (twenty-one million five hundred thirty-four thousand ninety-one dollars) in United States currency.

COVETRUS NA acknowledges and agrees the quantities of the drugs which were misbranded in violation of 21 U.S.C. § 331(a) cannot be located upon exercise of due diligence, or have been transferred or sold to, or deposited with, a third party, placed beyond the jurisdiction of the Court, substantially diminished in value, or commingled with other property which cannot be divided without difficulty. Accordingly, COVETRUS NA agrees the government is entitled to forfeit as substitute assets any other assets of COVETRUS NA up to the value of the now missing directly forfeitable assets, pursuant to 21 U.S.C. § 853(p). Payment in full of the Forfeiture Money Judgment shall satisfy any and all forfeiture obligations that COVETRUS NA may have as a result of this guilty plea. COVETRUS NA consents to the entry of an Order of Forfeiture pursuant to Rule 32.2 of the Federal Rules of Criminal Procedure forfeiting the above-referenced Forfeiture Money Judgment.

COVETRUS NA agrees to sign any documentation necessary and to cooperate fully with the United States to accomplish the forfeiture. COVETRUS NA agrees to forfeit all interest in these funds and to take whatever steps are necessary to pass clear title of these funds to the United States.

COVETRUS NA agrees not to file a claim in any forfeiture proceeding or to contest, in any manner, the forfeiture of said assets. COVETRUS NA agrees not to file or interpose any claim or to assist others to file or interpose any claim to any property against which the government seeks to execute the Forfeiture Money Judgement in any administrative or judicial proceeding.

COVETRUS NA understands and agrees forfeiture of this property is proportionate to the degree and nature of the offense. COVETRUS NA freely and knowingly waives any and all constitutional and statutory challenges to any forfeiture carried out in accordance with this Plea Agreement on any grounds, including, but not limited to, that the forfeiture constitutes an excessive fine or punishment. COVETRUS NA further understands and agrees this forfeiture is separate and distinct from, and is not in the nature of, or in lieu of, any monetary penalty or other monetary judgment that may be imposed by the court.

c. Restitution

The parties agree and stipulate, pursuant to 18 U.S.C. § 3663(a)(1)(B)(ii), that no restitution

will be ordered.

4. ADDITIONAL OBLIGATIONS

Unless the Court rejects this Plea Agreement and, as a result, COVETRUS NA withdraws its plea, COVETRUS NA agrees to: (1) accept responsibility for its conduct; (2) not attempt to withdraw its guilty plea; (3) not deny it committed the crime to which it has pled guilty; (4) comply with any reasonable request of the United States Attorney's Office and (5) not make or adopt any arguments or objections to the presentence investigation report that are inconsistent with this Plea Agreement.

COVETRUS NA will not (1) make any public statement or (2) make any statement or take any position in litigation in which any United States department or agency is a party, contradicting any statement or provision set forth in the Plea Agreement or its attachments. If COVETRUS NA inadvertently makes a public statement that in whole or in part contradicts any such statement or provision, COVETRUS NA may avoid being in violation of this Plea Agreement by promptly publicly repudiating such statement. For the purposes of this paragraph, the term "public statement" means any statement made or authorized by COVETRUS NA's directors, officers, employees, or attorneys and includes, but is not limited to, a statement in (1) a press release, (2) public relations material, or (3) COVETRUS NA websites. Notwithstanding the above, COVETRUS NA may avail themselves of any legal or factual arguments available (1) in defending litigation brought by a party other than the United States or (2) in any inquiry, complaint, notice of violation, investigation or proceeding brought by a state entity or by the United States Congress. This paragraph does not apply to any statement made by any individual in the course of any actual or contemplated criminal, regulatory, administrative, or civil case initiated by any governmental or private party against such individual.

5. WAIVER OF RIGHT TO APPEAL AND COLLATERALLY ATTACK THE JUDGMENT AND SENTENCE IMPOSED BY THE COURT

If the Court accepts this Plea Agreement, COVETRUS NA agrees COVETRUS NA will not appeal the conviction or sentence imposed. COVETRUS NA is knowingly and voluntarily waiving any right to appeal and is voluntarily willing to rely on the Court in sentencing it, pursuant to the terms of Fed. R. Crim. P. 11(c)(1)(C). COVETRUS NA expressly waives its right to appeal as to any and all issues in this matter and waives any right it may have to collaterally attack, in any future proceeding, any order issued in this matter, unless such appeal or collateral attack cannot be waived, by law. COVETRUS NA understands the United States expressly reserves all of its rights to appeal, but if the United States initiates a direct appeal of the sentence imposed, COVETRUS NA may file a cross appeal of that same sentence. COVETRUS NA agrees and understands if it files any court document (except for an appeal or collateral attack based on an issue that cannot be waived, by law) seeking to disturb, in any way, any order imposed in the case such action shall constitute a failure to comply with a provision of this Plea Agreement.

6. INFORMATION ACCESS WAIVER

COVETRUS NA agrees to waive all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any

records pertaining to the investigation or prosecution of this case, including, without limitation, any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act of 1974, 5 U.S.C. § 552a. However, if a third party obtains any records pertaining to the investigation or prosecution of this case under the Freedom of Information Act, COVETRUS NA shall have the right to request copies of such disclosed records.

7. ADMISSIBILITY OF STATEMENTS

COVETRUS NA understands any statements made on its behalf (including, but not limited to, this Plea Agreement and its admission of guilt) during or in preparation for any guilty plea hearing, sentencing hearing, or other hearing and any statements made, in any setting, may be used against COVETRUS NA by the United States in this or any other proceeding. COVETRUS NA knowingly waives any right it may have under the Constitution, any statute, rule or other source of law to have such statements, or evidence derived from such statements, suppressed or excluded from being admitted into evidence in this or any other proceeding. If, and only if, the Court rejects this Plea Agreement, and, as a result, COVETRUS NA withdraws its plea, COVETRUS NA will not be bound by the waivers set forth in this section of the Plea Agreement.

8. SUCCESSOR LIABILITY

COVETRUS NA agrees if, during the Term, it undertakes any material change in corporate form, including if it sells, merges, or transfers any portion of its business operations material to COVETRUS NA's consolidated operations as they existed as of January 31, 2023, whether such change is structured as a sale, asset sale, merger, transfer, or other material change in corporate form, it shall include in any contract for sale, merger, transfer, or other change in corporate form a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement unless the USAO-WDVA otherwise agrees in writing. COVETRUS NA shall provide notice to the USAO-WDVA at least 60 (sixty) days prior to undertaking any such sale, merger, transfer, or other change in corporate form. Nothing herein shall restrict COVETRUS NA from indemnifying (or otherwise holding harmless) the purchaser or successor in interest for penalties or other costs arising from any conduct that may have occurred prior to the date of the transaction, so long as such indemnification does not have the effect of circumventing or frustrating the enforcement purposes of this Agreement, as determined by the USAO-WDVA.

9. COMPLETION OF PROSECUTION

Pursuant to Fed. R. Crim. P. 11(c)(l)(A), so long as COVETRUS NA complies with all of its obligations under this Plea Agreement, the United States agrees, other than the charge in the attached Information, it shall not further criminally prosecute COVETRUS NA for any federal criminal charges or forfeiture action with respect to any Offense Conduct set forth in the Information.

Nothing in this Plea Agreement affects the administrative, civil, criminal, or other tax liability of any entity or individual and this Plea Agreement does not bind the Internal Revenue Service of the Department of Treasury, the Tax Division of the United States Department of Justice, or any other government agency with respect to the resolution of any tax issue.

10. LIMITATION OF PLEA AGREEMENT

This Plea Agreement is limited to the United States Department of Justice and does not bind any other federal, state, or local authority.

11. COMPLIANCE AND REMEDIAL MEASURES

COVETRUS NA agrees to comply with the Corporate Compliance Program Agreement attached hereto as Attachment B.

12. COOPERATION

COVETRUS NA acknowledges that its ongoing and future cooperation is important and a material fact underlying the United States' decision to enter into this Plea Agreement. COVETRUS NA agrees to continue to cooperate fully and actively with the United States regarding any matter, including, but not limited to, matters involving (a) current and former COVETRUS NA personnel, and (b) other entities who operate in the same commercial segment as COVETRUS NA.

Nothing in this Plea Agreement shall be construed to require COVETRUS NA to waive any attorney-client privilege or work-product protection.

13. REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THIS PLEA AGREEMENT

COVETRUS NA understands, agrees, and stipulates if: (1) COVETRUS NA attempts to withdraw its plea; (2) COVETRUS NA fails to comply with any provision of this Plea Agreement; (3) COVETRUS NA's conviction is set aside, for any reason; (4) COVETRUS NA fails to execute all required paperwork; and/or (5) the Court rejects the plea agreement, the United States may, at its election, pursue any or all of the following remedies: (a) declare this Plea Agreement void; (b) file, by indictment or information, any charges which were filed and/or could have been filed concerning the matters involved in the instant investigation; (c) refuse to abide by any stipulations and/or recommendations contained in this Plea Agreement; (d) not be bound by any obligation of the United States set forth in this Plea Agreement, including, but not limited to, those obligations set forth in the section of this Plea Agreement titled "COMPLETION OF PROSECUTION;" and (e) take any other action provided for under this Plea Agreement or by statute, regulation or court rule.

COVETRUS NA hereby waives its right under Fed. R. Crim. P. 7 to be proceeded against by indictment and consents to the filing of an information against it concerning any charges filed pursuant to this section of this Plea Agreement. COVETRUS NA hereby waives any statute of limitations argument as to any such charges. COVETRUS NA hereby waives any double jeopardy, speedy trial, or statute of limitations defense it may have as to any reinstated, newly filed, or non- dismissed charges described in this section of this Plea Agreement. COVETRUS NA agrees the provisions of this section are contractual obligations between the United States and COVETRUS NA and are severable from the plea agreement and survive any Court's rejection of the plea agreement.

The remedies set forth above are cumulative and not mutually exclusive. If the United

States pursues any of its permissible remedies as set forth in this Plea Agreement, COVETRUS NA will still be bound by its obligations under this Plea Agreement.

14. EFFECTIVE REPRESENTATION

COVETRUS NA has discussed the terms of this Plea Agreement and all matters pertaining to the charges against it with its attorneys and is fully satisfied with its attorneys and its attorneys' advice. At this time, COVETRUS NA has no dissatisfaction or complaint with its attorneys' representation. COVETRUS NA agrees to make known to the Court no later than at the time of sentencing any dissatisfaction or complaint COVETRUS NA may have with its attorneys' representation.

15. EFFECT OF AUTHORIZED SIGNATURE ON BEHALF OF COVETRUS NA

COVETRUS NA understands its Authorized Corporate Officer's signature on this Plea Agreement constitutes a binding offer by it to enter into this Plea Agreement. COVETRUS NA understands the United States has not accepted COVETRUS NA's offer until the authorized representative of the United States has signed this Plea Agreement.

16. GENERAL UNDERSTANDINGS

COVETRUS NA understands a presentence investigation will be conducted and sentencing recommendations independent of the USAO will be made by the presentence preparer.

COVETRUS NA understands the United States and COVETRUS NA retain the right, notwithstanding any provision in this Plea Agreement, to inform the probation office and the Court of all facts, to address the Court with respect to the nature and seriousness of the offense and the offender, to respond to any questions raised by the Court, to correct any inaccuracies or inadequacies in the presentence report, and to respond to any statements made to the Court.

COVETRUS NA willingly stipulates there is a sufficient factual basis for the Court to accept the plea.

COVETRUS NA understands this Plea Agreement does not apply to any crimes or charges not addressed in this Plea Agreement.

COVETRUS NA has not been coerced, threatened, or promised anything other than the terms of this Plea Agreement, described above, in exchange for its plea of guilty. COVETRUS NA understands its attorneys will be free to argue any mitigating factors on its behalf to the extent they are not inconsistent with the terms of this Plea Agreement. COVETRUS NA understands COVETRUS NA will have an opportunity to have a representative address the Court prior to sentence being imposed.

This writing, the Corporate Compliance Program Agreement (attached as Attachment B), and the Agreed Order of Forfeiture (attached as Attachment C) are the complete and only agreements between the United States and COVETRUS NA concerning resolution of this matter. In addition, COVETRUS NA has no objection to the filing of the Information.

The agreements and documents listed in this section set forth the entire understanding between the parties and constitute the complete agreement between the United States Attorney for the Western District of Virginia and COVETRUS NA and no other additional terms or agreements shall be entered except and unless those other terms or agreements are in writing and signed by the parties. These agreements supersede all prior understandings, promises, agreements, or conditions, if any, between the United States and COVETRUS NA. COVETRUS NA consents to public disclosure of all of the agreements and other documents referenced in this section.

COVETRUS NA has consulted with its attorneys and fully understands its rights. COVETRUS NA has read this Plea Agreement and carefully reviewed every part of it with its attorneys. COVETRUS NA understands this Plea Agreement and COVETRUS NA voluntarily agrees to it. Being aware of all of the possible consequences of its plea, COVETRUS NA has independently decided to enter this plea of its own free will and is affirming that agreement on this date by the signature of its Authorized Corporate Officer ("Officer") below.

The Officer, by signing below, hereby certifies to the following:

(1) The Officer is fully authorized to enter into this Plea Agreement on behalf of COVETRUS NA;

(2) The Officer has read the entire Plea Agreement and documents referenced herein and discussed them with COVETRUS NA's Board of Directors;

(3) COVETRUS NA understands all the terms of this Plea Agreement and those terms correctly reflect the results of plea negotiations;

(4) COVETRUS NA is fully satisfied with COVETRUS NA's attorneys' representation during all phases of this case;

(5) COVETRUS NA is freely and voluntarily pleading guilty in this case;

(6) COVETRUS NA is pleading guilty as set forth in this Plea Agreement because it is guilty of the crime to which it is entering its plea; and

(7) COVETRUS NA understands it is waiving its right to appeal the judgment and conviction in this case.

COVETRUS NA acknowledges its acceptance of this Plea Agreement by the signature of its counsel and Officer. A copy of a certification by the Board of Directors of Covetrus, Inc., the ultimate sole member, through its wholly-owned subsidiary, of COVETRUS NA, authorizing the Officer to execute this Plea Agreement and all other documents to resolve this matter on behalf of COVETRUS NA is attached as Attachment A.

Date: February 8, 2024

Benjamin Wolin
President and CEO of Covetrus, Inc.
Authorized Corporate Officer

COVETRUS NORTH AMERICA, LLC

Counsel has fully explained to the Board of Directors of Covetrus, Inc., the ultimate sole member, through its wholly-owned subsidiary, of COVETRUS NA, the facts and circumstances of the case; all rights with respect to the offense charged in the Information; possible defenses to the offense charged in the Information; all rights with respect to the applicability of the Sentencing Guidelines; and the consequences of entering into this Plea Agreement and entering a guilty plea. Counsel has reviewed this entire Plea Agreement and documents referenced herein with the client, through its Officer. COVETRUS NA understands the terms and conditions of this Plea Agreement, and COVETRUS NA's decision to enter into this Plea Agreement is knowing and voluntary. COVETRUS NA's execution of and entry into the Plea Agreement is done with Counsel's consent.

Date: February 8, 2024

Warren Hamel
Venable LLP
Counsel for Covetrus North America, LLC

Date: February 9, 2024

Randy Ramseyer
Assistant United States Attorney

WRITTEN ACTION OF

THE BOARD OF DIRECTORS OF CVET TOPCO GP, LLC.

The undersigned, being all of the members of the Board of Directors (the "Board") of CVET Topco GP, LLC ("CVET Topco"), a Delaware limited liability company, by written consent in lieu of a formal meeting pursuant to Section 18-302(d) of the Delaware Limited Liability Company Act (the "Act") and the Amended and Restated Limited Liability Company Agreement of the Company, dated as of October 13, 2022 (the "LLC Agreement"), do hereby consent to the adoption of the following resolutions. Capitalized terms used but not defined herein shall have the meanings set forth in the LLC Agreement.

PLEA AGREEMENT

WHEREAS, CVET Topco is the owner of Covetrus, Inc., a Delaware corporation (the "Company"); and

WHEREAS, the Company is the ultimate sole controlling member of Covetrus North America LLC ("Covetrus North America"); and

WHEREAS, Covetrus North America and the Company have been in discussions with the U.S. Attorney's Office for the Western District of Virginia ("USAO-WDVA") to resolve its investigation into Covetrus North America, among other things, having Covetrus North American enter into a Plea Agreement (the "Agreement"); and

WHEREAS, the Company is required to obtain the approval of the Board prior to any direct or indirect subsidiary of the Company resolving such investigation and entering into the Agreement; and

WHEREAS, the Board has been provided with copies of the Agreement and has determined that it is in the best interest of the Company to authorize Covetrus North America to enter into the Agreement.

WHEREAS, Ben Wolin is not currently an officer of Covetrus North America but has been acting as an authorized representative of Covetrus North America in connection with discussions with the USAO-WDVA and requires authorization to execute the Agreement.

NOW, THEREFORE, BE IT RESOLVED, that the Board hereby approves Covetrus North America entering into the Agreement and authorizes Benjamin Wolin, Chief Executive Officer of the Company, to execute and deliver the Agreement on behalf of Covetrus North America, with such ministerial changes as he may approve, such approval to be conclusively evidenced by the execution of the changed Agreement; and further

RESOLVED, that the Board hereby approves Covetrus North America pleading guilty to the charge specified in the Agreement in the U.S. District Court for the Western District of Virginia; and further

RESOLVED, that Mr. Wolin is hereby authorized and directed to execute and deliver all other documents necessary to carry out the provisions of the Agreement; and further

RESOLVED, that Mr. Wolin, or his designated representative, is hereby authorized to appear on behalf of Covetrus North America and enter such guilty plea; and further

RESOLVED, that Mr. Wolin is hereby authorized and directed to acknowledge on behalf of the Company and Covetrus North America that the Agreement and related documents (the "Documents") fully set forth the agreement made between Covetrus North America and the USAO-WDVA, and that no additional promises or representations have been made to the Company or Covetrus North America by any officials of the USAO-WDVA in connection with the Agreement, other than those set forth in the Documents; and further

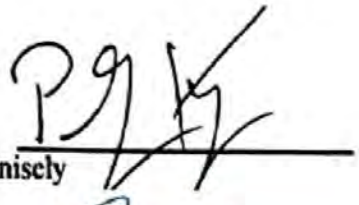
RESOLVED, that (i) the President and Chief Executive Officer of the Company, (ii) the Chief Financial Officer of the Company, or (iii) any of their written designees, respective successors or current or future officers of the Company holding the same or similar titles are authorized and directed to make any payments on behalf of Covetrus North America that are required in connection with the Agreement; and further

RESOLVED, that the officers of the Company and of Covetrus North America be, and each of them hereby is authorized and empowered, in the name and on behalf of the Company and Covetrus North America, respectively, to make all such arrangements, to do and perform all such acts and things, and to execute and deliver all such certificates and such other instrument and documents as they may deem appropriate in order to effectuate fully the purpose of each and all of the foregoing resolutions, and that any and all actions taken heretofore and hereafter to accomplish such purposes, all or singular, be, and they hereby are approved, ratified and confirmed; and further

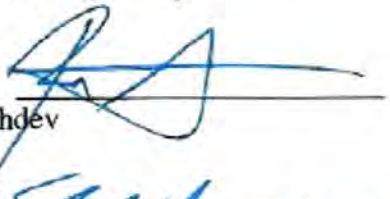
RESOLVED, that any actions taken by any of the officers of the Company or of Covetrus North America on behalf of Covetrus Nort America in connection with the Agreement prior to the date of the foregoing resolutions adopted hereby that are within the authority conferred hereby are ratified, confirmed and approved,

INTENTIONALLY LEFT BLANK

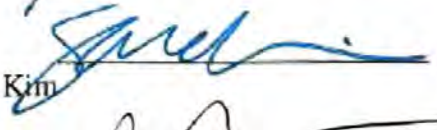
IN WITNESS WHEREOF, the undersigned have executed this written action to be effective as of the date first written above.



Philip Kniscly



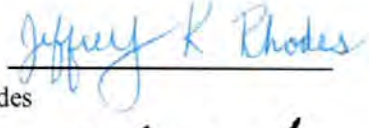
Ravi Sachdev



Sarah Kim



Kendall Garrison



Jeffrey Rhodes



Scott Anderson



Steve Morgan



Ben Wolin

CORPORATE COMPLIANCE PROGRAM AGREEMENT

The following Covetrus North America, LLC ("Covetrus NA" or the "Company") Corporate Compliance Program Agreement ("Corporate Compliance Program Agreement") has been prepared pursuant to the Plea Agreement between the Company and the United States Attorney's Office for the Western District of Virginia ("USAO-WDVA"). Compliance with all the terms and standards of the Corporate Compliance Program Agreement is a condition of the Plea Agreement and shall continue for a period of forty-eight months ("Term").

Applicability and Purpose

1. This Corporate Compliance Program Agreement shall be incorporated into the Plea Agreement by reference, and compliance with the terms of the Corporate Compliance Program Agreement will be a condition of the Plea Agreement.

2. Any proposed modifications to this Corporate Compliance Program Agreement must be made in writing and signed by the Company and the designated signatory for the USAO-WDVA.

3. The Corporate Compliance Program Agreement does not in any way release the Company from complying with any applicable federal or state statutes and/or regulations, and does not limit the imposition of any sanctions, penalties or any other actions available under those state or federal statutes and regulations.

4. Defendant COVETRUS NORTH AMERICA LLC is a Delaware corporation with its principal place of business in Dublin, Ohio. COVETRUS NA was formerly known as Butler Animal Health Supply, LLC and was a subsidiary of Henry Schein, Inc. In February 2019, Henry Schein, Inc. spun-off its animal health business, including Butler Animal Health Supply LLC, which in turn merged with Vets First Choice to create a separate entity named Covetrus, Inc. As part of that spin-merger, Butler Animal Health Supply, LLC became a subsidiary of Covetrus, Inc., and was re-named Covetrus North America LLC. Covetrus, Inc., through its wholly-owned subsidiary, is the ultimate sole member controlling COVETRUS NA. In addition, CVET Topco GP, LLC is the owner of Covetrus, Inc.

The Corporate Compliance Program Agreement

5. The Company and the USAO-WDVA agree that the Company shall undertake the following voluntary compliance measures. The Corporate Compliance Program Agreement does and will continue to contain policies and procedures designed to prevent, detect, and correct violations of federal and state statutes and/or regulations concerning federal prescription drug distribution, including but not limited to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*. and FDA requirements. These policies and procedures shall be designed to ensure

that the Company complies with, among other things, the FDCA's prohibitions against causing the introduction into interstate commerce of a drug that is misbranded or otherwise violates the FDCA.

6. *Compliance Officer*. The Company shall maintain a Compliance Officer for the Term. During the Term, the Compliance Officer shall be authorized to oversee compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution, including but not limited to the FDCA, FDA requirements, and the requirements of the Corporate Compliance Program Agreement. The Compliance Officer is, and shall continue to be, responsible for developing and implementing policies, procedures and practices designed to address compliance with the requirements set forth in this Corporate Compliance Program Agreement, with federal and state statutes and/or regulations concerning federal prescription drug distribution and FDA requirements. The Compliance Officer shall be a member of senior management of the Company, and shall report directly to the President of the Company. The Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters directly to the President of the Company, and the CEO and Board of Directors of Covetrus, Inc., which, through its wholly-owned subsidiary, is the ultimate sole member of Covetrus North America LLC (hereinafter the "Board") or any authorized committee thereof, and shall be authorized to report on such matters to the Board at any time. In addition to the reporting obligations set out in this paragraph, the Compliance Officer will continue to report to the General Counsel, but will not be subordinate to the Chief Financial Officer of either COVETRUS NA or Covetrus, Inc. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by the Company as well as for any obligations created under the Corporate Compliance Program Agreement. Any non-compliance job responsibilities of the Compliance Officer must not interfere with the Compliance Officer's ability to perform the duties outlined in the Corporate Compliance Program Agreement.

7. *Compliance Committee*. Prior to the execution of the Plea Agreement, the Company formed a Compliance Committee (hereafter "Compliance Committee") which, in conjunction with the Compliance Officer, assists in the implementation and enhancement of the compliance program. The Company shall maintain the Compliance Committee for the Term. The Compliance Committee shall include, at a minimum, the Compliance Officer and other members of senior management necessary to meet the requirements of the Corporate Compliance Program Agreement (e.g., senior executives of relevant departments, such as legal, regulatory, audit, human resources, and operations.) The Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the Company's risk areas and shall oversee monitoring of internal and external compliance-related audits and investigations). The Compliance Committee shall meet at least quarterly.

8. *Board of Directors Compliance Obligations*. Effective from the date of the entry of the guilty plea and continuing throughout the Term, the Board of Directors of Covetrus, Inc., as the ultimate sole member of COVETRUS NA through its wholly-owned subsidiary ("Board"), will oversee the Company's compliance program. The Board shall oversee the Company's compliance program, including at a minimum:

a. the Company's obligations under the Corporate Compliance Program Agreement

b. receiving updates about adoption and implementation of policies, procedures and practices designed to ensure compliance with the FDCA and FDA requirements,

c. evaluating the effectiveness of the compliance program; and

d. shall report quarterly to the Board of Directors of CVET Topco GP, LLC regarding the status of the Corporate Compliance Program.

9. The Company shall continue to evaluate its current business to ensure that it is not currently receiving, distributing, or handling misbranded or unapproved federal prescription drugs. Should the Company find it is receiving, distributing, or handling misbranded or unapproved federal prescription drugs, it shall take necessary steps to remediate any such conduct.

10. The Company shall continue to enhance its current training program to ensure that pertinent employees are familiar with the requirements of the FDCA and FDA requirements that could potentially apply to the Company's conduct.

11. The Company will put in place processes to (a) encourage employees to report suspected non-compliant activities by the Company, customers, or others and to (b) acknowledge or otherwise recognize employees for reporting confirmed non-compliant activity, as appropriate.

12. The Company will maintain, or as necessary establish, policies and procedures designed to ensure effective investigation of any complaints and/or potential deficiencies relating to compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution, including but not limited to the FDCA and FDA requirements. Such policies and procedures shall include, but are not limited to:

a. Training and providing guidance to all pertinent employees as to the requirement to report all information regarding potential non-compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution or FDA requirements to the Compliance Officer, who in turn will review and determine whether corrective actions are required; and

b. Tracking allegations and remediation action plans regarding potential non-compliance with federal and state statutes and/or regulations concerning federal prescription drug distribution or FDA requirements to identify issues that may require corrective actions.

13. Within 60 days of the end of the Company's fiscal year, Covetrus Inc.'s President

and CEO and Covetrus NA's President will certify under oath, after reasonable inquiry as determined by the USAO-WDVA, to (a) the USAO-WDVA during the Term and (b) the United States Probation Office for any period during which the Company is on probation, that (1), the Company fully complied with all federal laws and regulations pursuant to the Food, Drug, and Cosmetic Act ("FDCA") in the preceding year, or in the alternative, (2) list all non-compliant activity and the steps taken by the company to remedy such non-compliant activity. Any listing of non-compliant activity shall not be considered by the USAO-WDVA or the Probation Officer as a per se violation of the terms of probation or the Plea Agreement. Instead, other factors may be taken into account, including whether the conduct violated policies the Company has adopted, whether the Company provided training addressing the subject matter of the reported conduct, whether it was an isolated or systemic occurrence, the Company's response, and any remedial actions taken after the Company learned of the conduct reported.

Non-Compliance

14. The Corporate Compliance Program Agreement is part of the Plea Agreement and adherence to it will be an enforceable condition.

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA	)	**Criminal No. _____**
	)	
v.	)	
	)	
COVETRUS NORTH AMERICA LLC	)	

AGREED ORDER OF FORFEITURE

IT IS HEREBY ORDERED THAT:

A. Pursuant to Rule 32.2(b)(1)(A) of the Federal Rules of Criminal Procedure, the evidence of record and the guilty plea to Count One of the Information, misbranding a drug, in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1), the defendant shall forfeit to the United States quantities of prescription veterinary drugs that were misbranded when introduced into interstate commerce and/or when being held for sale in interstate commerce, pursuant to 21 U.S. C. § 334 and 28 U.S.C. § 2461.

B. Pursuant to the defendant's plea agreement, because the above-described forfeitable property, as a result of the defendant's acts, has been transferred or sold to third parties and cannot be located upon the exercise of due diligence, a money judgment in the amount of $21,534,091 (twenty-one million five hundred thirty-four thousand ninety-one dollars) is hereby entered against the defendant as a substitute asset pursuant to 21 U.S.C. § 853(p).

C. On or before January 4, 2024, the defendant will voluntarily remit payment in the amount of $21,534,091 (twenty-one million five hundred thirty-four thousand ninety-one dollars) in full satisfaction of the money judgment by remitting certified funds made payable to the U.S. Marshals Service, Asset Forfeiture Unit, 247 Federal Building, 210 Franklin Road, S.W., Roanoke, Virginia 24011.

D. As payments are voluntarily being remitted to the United States, notice and publication are not required.

E. The Court shall retain jurisdiction to enforce this Order, and to amend it as necessary, pursuant to Fed. R. Crim. P. 32.2(e).

F. Pursuant to Fed. R. Crim. P. 32.2(b)(4), this Order of Forfeiture shall become final as to the defendant at sentencing and shall be made a part of the sentence and included in the judgment.

ENTERED THIS _____ DAY OF_____, 2024.

_____
UNITED STATES MAGISTRATE JUDGE

SEEN AND AGREED TO:

For Covetrus North America LLC:

_____
Benjamin Wolin
President and CEO of Covetrus, Inc.
Authorized Corporate Officer
Covetrus North America LLC

_____
Warren Hamel
Venable LLP
Counsel for Covetrus North America LLC

For the United States:

_____
for Krista Frith
Assistant United States Attorney

CLERK'S OFFICE U.S. DISTRICT COURT
AT ABINGDON, VA
FILED

FEB 21 2024

LAURA A. AUSTIN, CLERK
BY: K. Baldwin
DEPUTY CLERK

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA)
)
v.)
)
COVETRUS NORTH AMERICA LLC)

Criminal No. 1:24 mj 9

AGREED ORDER OF FORFEITURE

IT IS HEREBY ORDERED THAT:

A. Pursuant to Rule 32.2(b)(1)(A) of the Federal Rules of Criminal Procedure, the evidence of record and the guilty plea to Count One of the Information, misbranding a drug, in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1), the defendant shall forfeit to the United States quantities of prescription veterinary drugs that were misbranded when introduced into interstate commerce and/or when being held for sale in interstate commerce, pursuant to 21 U.S. C. § 334 and 28 U.S.C. § 2461.

B. Pursuant to the defendant's plea agreement, because the above-described forfeitable property, as a result of the defendant's acts, has been transferred or sold to third parties and cannot be located upon the exercise of due diligence, a money judgment in the amount of $21,534,091 (twenty-one million five hundred thirty-four thousand ninety-one dollars) is hereby entered against the defendant as a substitute asset pursuant to 21 U.S.C. § 853(p).

C. On or before January 4, 2024, the defendant will voluntarily remit payment in the amount of $21,534,091 (twenty-one million five hundred thirty-four thousand ninety-one dollars) in full satisfaction of the money judgment by remitting certified funds made payable to the U.S. Marshals Service, Asset Forfeiture Unit, 247 Federal Building, 210 Franklin Road, S.W., Roanoke, Virginia 24011.

D. As payments are voluntarily being remitted to the United States, notice and publication are not required.

E. The Court shall retain jurisdiction to enforce this Order, and to amend it as necessary, pursuant to Fed. R. Crim. P. 32.2(e).

F. Pursuant to Fed. R. Crim. P. 32.2(b)(4), this Order of Forfeiture shall become final as to the defendant at sentencing and shall be made a part of the sentence and included in the judgment.

ENTERED THIS 21st DAY OF February, 2024.

Pamela Meade Sargent
UNITED STATES MAGISTRATE JUDGE

SEEN AND AGREED TO:

For Covetrus North America LLC:

Benjamin Wolin
President and CEO of Covetrus, Inc.
Authorized Corporate Officer
Covetrus North America LLC

Warren Hamel
Venable LLP
Counsel for Covetrus North America LLC

For the United States:

Randy Ramseyer
for Krista Frith
Assistant United States Attorney

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: FELIX PHARMACEUTICALS PVT LTD
Address: 25-28, NORT WALL QUAY City: Dublin State: Ireland Zip:
Name: VETOQUINOL
Address: 4250 N SYLVANIA City: Fort Worth State: TX Zip: 76137
Name: CRONUS PHARMA
Address: 2 TOWER CENTER BLVD SUITE 1101A City: East Brunswick State: NJ Zip: 08816
Name: CP MEDICAL, INC.
Address: 1775 Corporate Drive City: Norcross State: GA Zip: 30093

Section 4: Publicly Traded Corporation

State of Incorporation: n/a
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): WA Butler Company
Corporation/Organization Name:
Mailing Address: 400 Metro Place
City: Dublin State: OH Zip: 43017
Telephone: 614-659-1728 Email: cvet-na-licensing@covetrus.com
Contact Person Name: Philip Mario Lombardi

Section 6: Partnership

Partnership Name: n/a
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: n/a
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** ✓	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** none		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. ✓	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ ✓		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ No individuals own 10% or more		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** ✓	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ ✓	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). ✓	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. N/A		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. N/A		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Covetrus North America, LLC

Facility Name

Philip Mario Lombardi

Print Name of Authorized Person Submitting Application

Philip Mario Lombardi

Original signature of Authorized Person (copies or stamps not accepted)

6/6/24

Date

Board Use Only	Date Received: 6/11/24	Amount: $1000-CK#

NABP ACCREDITED
DRUG DISTRIBUTOR

Covetrus North America, LLC

located at

5999 Bixby Rd, Canal Winchester, OH 43110

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

05/29/2024 - 05/28/2027
Period of Accreditation

Covetrus North America, LLC Officers								
Name	Title	Home Address	Business Address	DOB	SS #	Phone	Drivers License	% Ownership
Matthew Yordy	President	[redacted]	400 Metro Place North Dublin, OH 43017	[redacted]				
Ajoy Karna	CFO and Treasurer		400 Metro Place North Dublin, OH 43017					
Tamika Simmons	Secretary		400 Metro Place North Dublin, OH 43017					
Philip Mario Lombardi	Vice President of Operations and Logistics Services		400 Metro Place North Dublin, OH 43017					

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "COVETRUS NORTH AMERICA, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIRST DAY OF NOVEMBER, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "COVETRUS NORTH AMERICA, LLC" WAS FORMED ON THE THIRTY-FIRST DAY OF MARCH, A.D. 2005.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

3947992 8300

SR# 20233865137

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204493527

Date: 11-01-23

STATE OF OHIO
BOARD OF PHARMACY

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until June 30, 2025.

Covetrus North America

5999 Bixby Rd

Canal Winchester, OH 43110-8542

License Number: 0130000419

Wholesaler - Category 2

Expiration Date: June 30, 2025

CLASS: Wholesaler - Category 2
BUSINESS TYPE: FS – Full Service

Responsible Person – Print, sign and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person
Jeffrey Hitchcock	Jeffrey Hitchcock

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request on your Ohio eLicense Dashboard - https://elicense.ohio.gov/oh_homepage.

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

eLicense.Ohio.gov
(/OH_HomePage)

Scheduled Maintenance - The eLicense Ohio application will be temporarily unavailable on Saturday, May 18th from 10:00 PM until 10:30 PM EST for maintenance.

Have a licensing question? Contact your licensing board or check their website. Help desk representatives are not trained to answer licensing questions.

Technical Support - Help desk representatives are available to answer login or registration questions by calling (855) 405-5514 weekdays from 8:00 am to 5:00 pm EST.

Callers may experience extended wait times due to the high number of calls. If you're unable to wait for a representative, you can leave a call back number.
If you're experiencing technical issues with the eLicense website, make sure you are using Google Chrome or Mozilla Firefox as your browser on a desktop or laptop device.

License Look Up

PRINTER FRIENDLY VERSION

Covetrus North America

The search results for the license holder are listed to the right.

Current Date & Time
5/17/2024 10:50 AM

Status
Active

Sub-Status

Sub-Category
FS – Full Service

Board
Board of Pharmacy

License Type
Wholesaler - Category 2

License Number
0130000419

License Issue Date
11/23/2021

License Effective Date
07/01/2023

License Expiration Date
06/30/2025

Street Address
5999 Bixby Rd

Zipcode
43110-8542

City
Canal Winchester

State
OH

Country
United States

Board Action

No

Current date & time: **5/17/2024 10:50 AM**

Disclaimer: The Joint Commission and NCQA consider on-line status information as fulfilling the primary source verification requirement for verification of licensure in compliance with their respective credentialing standards.

SUPPORT (OH_SUPPORTPAGE)

REGISTRATION GUIDE (/SERVLET/SERVLET.FILEDOWNLOAD?FILE=015T0000000UG2L)

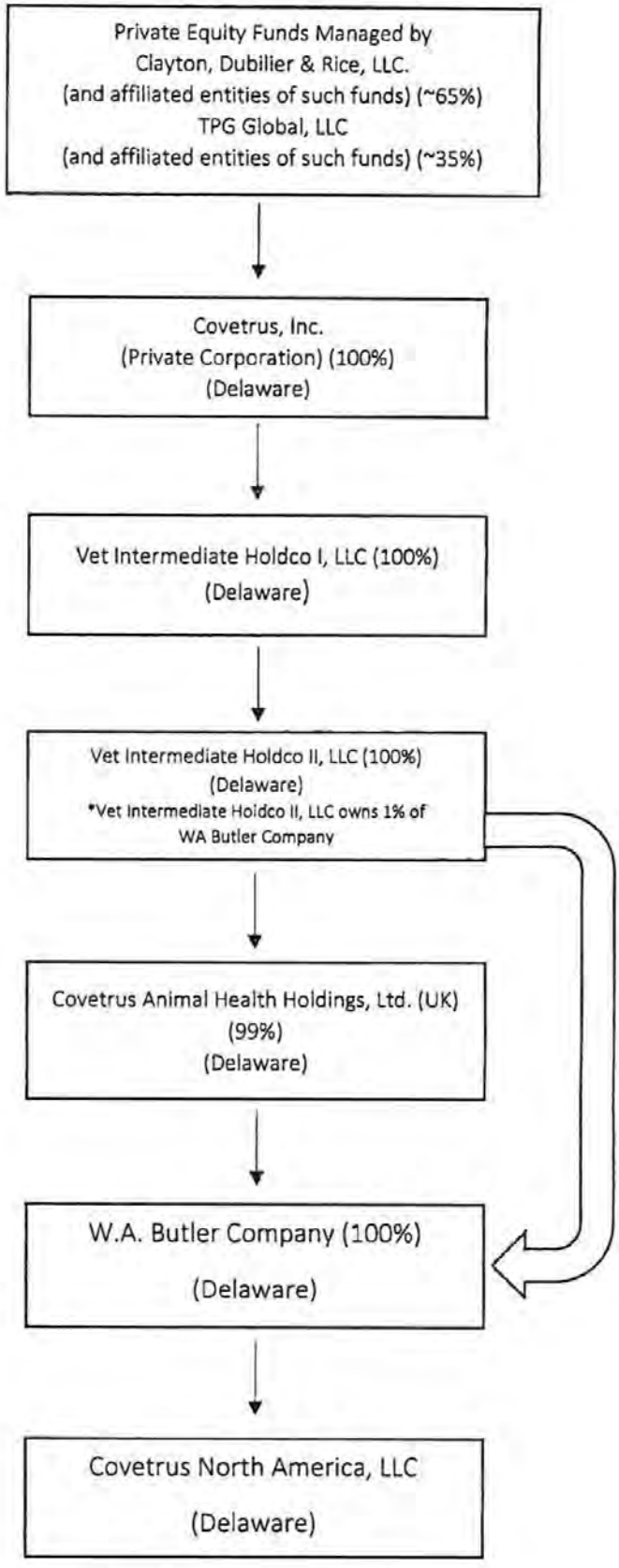
CONTACT (OH_CONTACTUS)

PRIVACY NOTICE (OH_PRIVACYNOTICE)

WWW.OHIO.GOV (HTTP://WWW.OHIO.GOV)

GENERAL TERMS (OH_GENERALTERMS)

Covetrus North America, LLC Business Organizational Structure



CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 02/23/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Northeast, Inc. New York NY Office One Liberty Plaza 165 Broadway, Suite 3201 New York NY 10006 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	ProAssurance Specialty Insurance Company	17400
INSURER B:	Starr Indemnity & Liability Company	38318
INSURER C:	The Continental Insurance Company	35289
INSURER D:		
INSURER E:		
INSURER F:		

INSURED
Covetrus, Inc.
12 Mountfort Street
Portland ME 04101 USA

COVERAGES **CERTIFICATE NUMBER:** 570104016659 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY			1000100099241	03/01/2024	03/01/2025	EACH OCCURRENCE	$2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$100,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						MED EXP (Any one person)	$5,000
	X POLICY PRO-JECT LOC						PERSONAL & ADV INJURY	$2,000,000
	OTHER:						GENERAL AGGREGATE	$4,000,000
							PRODUCTS - COMP/OP AGG	Excluded
B	AUTOMOBILE LIABILITY			1000639300241 (AOS)	03/01/2024	03/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$2,000,000
B	X ANY AUTO			1000639301241 (MA)	03/01/2024	03/01/2025	BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	X Comp/Coll $1,000							
C	X UMBRELLA LIAB X OCCUR			7036813655	03/01/2024	03/01/2025	EACH OCCURRENCE	$10,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$10,000,000
	DED RETENTION							
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			1000004069 (AOS)	03/01/2024	03/01/2025	X PER STATUTE OTH-ER	
B	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? N (Mandatory in NH)	N/A		1000004071 (FL,MA)	03/01/2024	03/01/2025	E.L. EACH ACCIDENT	$1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000
A	Products Liability			N24ME380001	03/01/2024	03/01/2025	Aggregate Limit Each Occurrence	$10,000,000 $10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Covetrus, Inc.
12 Mountfort Street
Portland ME 04101 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast, Inc.

Holder Identifier :

Certificate No : 570104016659

©1988-2015 ACORD CORPORATION. All rights reserved.

AGENCY CUSTOMER ID: 570000078389
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Covetrus, Inc.
POLICY NUMBER: See Certificate Number: 570104016659	
CARRIER: See Certificate Number: 570104016659 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER	
INSURER	
INSURER	
INSURER	

ADDITIONAL POLICIES If a policy below does not include limit information, refer to the corresponding policy on the ACORD certificate form for policy limits.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	WORKERS COMPENSATION							
B		N/A		1000004067 AZ,CT,IA,NJ,NY,NC,TX,VT	03/01/2024	03/01/2025		
B		N/A		1000004070 (WI Retro)	03/01/2024	03/01/2025		

© 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

CERTIFICATE OF PROPERTY INSURANCE

DATE (MM/DD/YYYY) 02/07/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

PRODUCER
Aon Risk Services Northeast, Inc.
New York NY Office
One Liberty Plaza
165 Broadway, Suite 3201
New York NY 10006 USA

CONTACT NAME:
PHONE (A/C. No. Ext): (866) 283-7122 FAX (A/C. No.): (800) 363-0105
E-MAIL ADDRESS:
PRODUCER CUSTOMER ID #: 570000078389

INSURED
Covetrus North America, LLC
400 Metro Place North
Dublin OH 43017 USA

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A: Factory Mutual Insurance Co.	21482
INSURER B:	
INSURER C:	
INSURER D:	
INSURER E:	
INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570103880375 **REVISION NUMBER:**

LOCATION OF PREMISES / DESCRIPTION OF PROPERTY (Attach ACORD 101, Additional Remarks Schedule, if more space is required)

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	COVERED PROPERTY	LIMITS
A	X PROPERTY	1123507	01/31/2024	01/31/2025	BUILDING	
	CAUSES OF LOSS / DEDUCTIBLES				PERSONAL PROPERTY	
	BASIC / BUILDING				BUSINESS INCOME	
	BROAD / CONTENTS				EXTRA EXPENSE	
	SPECIAL				RENTAL VALUE	
	EARTHQUAKE				BLANKET BUILDING	
	WIND				BLANKET PERS PROP	
	X FLOOD $500,000				BLANKET BLDG & PP	
	X ALL RISK-Subject to Exclusions				X Loss Limit	$150,000,000
					X Flood - Aggregate	$150,000,000
	INLAND MARINE	TYPE OF POLICY				
	CAUSES OF LOSS / NAMED PERILS	POLICY NUMBER				
	CRIME					
	TYPE OF POLICY					
	BOILER & MACHINERY / EQUIPMENT BREAKDOWN					

SPECIAL CONDITIONS / OTHER COVERAGES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

US Industrial REIT II
c/o Commercial Advisors
5101 Wheelis Drive, Suite 320
Memphis TN 38117 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Aon Risk Services Northeast, Inc.

Holder Identifier :

CERTIFICATE NUMBER: 570103880375

© 1995-2015 ACORD CORPORATION. All rights reserved.

AGENCY CUSTOMER ID: 570000078389

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Covetrus North America, LLC
POLICY NUMBER	
See Certificate Number: 570103880375	
CARRIER / **NAIC CODE**	**EFFECTIVE DATE:**
See Certificate Number: 570103880375	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 24 **FORM TITLE:** Certificate of Property Insurance

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER	
INSURER	
INSURER	
INSURER	

ADDITIONAL POLICIES If a policy below does not include limit information, refer to the corresponding policy on the ACORD certificate form for policy limits.

INSR LTR	TYPE OF INSURANCE	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	COVERED PROPERTY	LIMITS
	PROPERTY					
A		1123507	01/31/2024	01/31/2025	Named Storm Limit	Included
					Earth Movement -	$150,000,000

The ACORD name and logo are registered marks of ACORD

© 2008 ACORD CORPORATION. All rights reserved.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 015223879

Application/License No. _____

COVETRUS NORTH AMERICA, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5999 Bixby Road Canal Winchester, OH 43110 (Address of Applicant/Principal), as PRINCIPAL, and LIBERTY MUTUAL INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of MA (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 25, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 25th day of April, 2024.

APPLICANT/PRINCIPAL
COVETRUS NORTH AMERICA, LLC

Authorized Representative

SURETY COMPANY
LIBERTY MUTUAL INSURANCE COMPANY

Surety Company's Representative

Sandra Diaz, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Grace Laterza

Witness Halina Kazmierczak

Countersigned by:

Nevada Resident Agent Aklima Noorhassan,
NV Non-Resident Agent
License No. 3163993

Posted February 20, 2020

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual. SURETY

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8210937- 015009

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Debra A Deming, Sandra Diaz, Vilma Gonzalez, Peter Healy, Pablo Garcia Horcajo, Jennifer L. Jakaitis, Francesca Kazmierczak, Aklima Noorhassan, Anne Potter, Frances Rodriguez, Valorie Spates, Susan A. Welsh, Beverly A. Woolford

all of the city of New York state of NY each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 6th day of November, 2023

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 6th day of November, 2023 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 25th day of April, 2024

By: _____
Renee C. Llewellyn, Assistant Secretary

LMS-12873 LMIC OCIC WAIC Multi Co 02/21

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com

Liberty Mutual. SURETY

LIBERTY MUTUAL INSURANCE COMPANY

FINANCIAL STATEMENT – DECEMBER 31, 2023

Assets	
Cash and Bank Deposits	$1,850,245,073.00
*Bonds – U.S Government	$3,859,565,383.00
*Other Bonds	$21,048,805,773.00
*Stocks	$19,937,271,802.00
Real Estate	$122,228,711.00
Agents' Balances or Uncollected Premiums	$8,208,660,427.00
Accrued Interest and Rents	$186,906,667.00
Other Admitted Assets	$15,677,869,683.63
Total Admitted Assets	**$70,891,553,519.63**

Liabilities	
Unearned Premiums	$10,298,963,305.00
Reserve for Claims and Claims Expense	$28,848,537,243.00
Funds Held Under Reinsurance Treaties	$360,714,151.00
Reserve for Dividends to Policyholders	$1,310,198.00
Additional Statutory Reserve	$296,126,000.00
Reserve for Commissions, Taxes and Other Liabilities	$7,622,413,466.63
Total	**$47,428,064,363.63**
Special Surplus Funds	$209,508,757.00
Capital Stock	$10,000,075.00
Paid in Surplus	$13,834,867,488.00
Unassigned Surplus	$9,409,112,836.00
Surplus to Policyholders	$23,463,489,156.00
Total Liabilities and Surplus	**$70,891,553,519.63**

* Bonds are stated at amortized or investment value; Stocks at Association Market Values.
The foregoing financial information is taken from Liberty Mutual Insurance Company's financial statement filed with the Massachusetts Department of Insurance.

I, TIM MIKOLAJEWSKI, Assistant Secretary of Liberty Mutual Insurance Company, do hereby certify that the foregoing is a true, and correct statement of the Assets and Liabilities of said Corporation, as of December 31, 2023, to the best of my knowledge and belief.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of said Corporation at Seattle, Washington, this 8th day of March, 2024.

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS

Timothy A. Mikolajewski

Timothy A. Mikolajewski, Assistant Secretary

LMS-1262/LMIC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Covetrus North America, LLC — MDEG License # (if applicable): _____

Physical Address: 5999 Bixby Road

City: Canal Winchester — State: OH — Zip: 43110

Mailing Address (if different from physical address): 400 Metro Place N

City: Dublin — State: OH — Zip: 43017

Telephone: 614-553-4025 — Website: covetrus.com

Licensing Company Email: cvet-na-licensing@covetrus.com

Section 2: Personal Information

First: Jeffrey — Middle: O'Neill — Last: Hitchcock

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Canal Winchester — State: OH — Zip: 43110

Telephone: [redacted] — Email: jeff.hitchcock@covetrus.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Midway University		10/14 - 12/17	
Address	**City**	**State**	**Zip**
512 East Stephens Street	Midway	KY	40347
Diploma/Degree obtained, if any			
Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/18 - present	[redacted]	Canal Winchester	OH	43110
4/14 - 10/18		Lexington	KY	40511
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Covetrus North America, LLC (f/k/a Butler Animal Health and Henry Schein)			12/14 - present	
Business Address		**City**	**State**	**Zip**
5999 Bixby Road		Canal Winchester	OH	43110
Phone	**Title**		**Number of Employed Hours**	
614-553-4025	Sr. Operations Manager		18,000 +	
Description of Duties				
Responsible for all aspects of facility operations including receiving, storing, shipping of pharmaceuticals, employee management.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2008-02-03	2008-09-04	NY	Vestal	Brooome

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
08020013	Vestal Town Court, SUNY Police Binghamton

Reason/Charge
Failure To Keep To The Right, Driving While Intoxicated

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Jeffrey Hitchcock	Misdemeanor / Infraction

Name of Business/Industry/Entity
n/a

Provide explanation below:

Sentence Conditional discharge
Fine Amount: $300 Status: Paid in Full
License Suspended 90 Day(s)

Original Signature (electronic, copies or stamps not accepted)

5/6/2024
Date

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/27/10	8/8/11	NY	Brighton	Monroe
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
10110111		Monroe County Sheriffs Office, Brighton Town Court- Monroe County		
Reason/Charge				
Driving While Intoxicated				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Jeffrey Hitchcock			Misdemeanor / Infraction	
Name of Business/Industry/Entity				
n/a				

Provide explanation below:

Speed Violation:Exceed 55 MPH, Driving While Intoxicated- 1st Offense
Sentence Conditional discharge Term: 12 Day(s)
Fine Amount: $500 Status: Paid in Full
License Revoked

Original Signature (electronic, copies or stamps not accepted)

5/6/2024
Date

I, Jeffrey Hitchcock, **certify that as the MDEG Administrator for**

Covetrus North America, LLC,

that I (initial that you have read and meet the following requirements):

1. JH Have a high school diploma or its equivalent;
2. JH Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JH Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JH Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeffrey Hitchcock
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/6/2024
Date

Board Use Only	Date Received: 6/11/24

Canal Winchester Employee List

Worker	Email Address	Business Title
Alyssa Hettinger	[redacted]	Manager, Inbound Operations
Barry Bassetti		DC Team Member
Codey Markovich		DC Team Lead
David Murray		Manager, Transportation Operations
Izzy Nekic		Business Analyst
Jeff Hitchcock		Sr. Manager, NDSC Canal Winchester
JORGE SANDOVAL [C]		DC Team Member – Outbound
Joseph Johnson		DC Team Member
JUAN COLORADO [C]		DC Team Member – Outbound
Khem Adhikari		DC Team Member
Mamadou Dembele [C]		DC Team Member – Outbound
Martin Collins		DC Team Member
Matt Baughman		Manager, Outbound Operations
Phillip Calhoun		DC Team Lead
Subash Chamlagai		DC Team Member
Teria Westerviller (On Leave)		DC Team Member

10

10A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☒ Nevada ☐ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Corstasis USA LLC

Physical Address: 3535 Executive Terminal Way STE 110

City: Henderson State: NV Zip: 89052

Mailing Address (if different from physical address): 3535 Executive Terminal Way STE 110

City: Henderson State: NV Zip: 89052

Telephone: (951) 545-9054 Website: https://corstasis.com/

Name of Designated Representative (DR): Benjamin Esque

Licensing Company Email: Ben@corstasis.com DR Email: ben@corstasis.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

9/23/21
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No Suppliers Sold, Dispensed or Distributed w/i the last year

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NV

Parent Company (if any): CORSTASIS THERAPEUTICS INC.

Corporation/Organization Name: Corstasis USA LLC

Mailing Address: 3535 Executive Terminal Way STE 110

City: Henderson State: NV Zip: 89052

Telephone: (951) 545-9054 Email: info@corstasis.com

Contact Person Name: Benjamin Esque

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	x	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner **owning more than 10% of the business stocks/shares.** Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Corstasis USA LLC

Facility Name

Benjamin Esque

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

9/23/24

Date

Board Use Only	Date Received: 10/3/24	Amount: $1000 ck 2170

Theresa Carey

From: Ben Esque <ben@corstasis.com>
Sent: Monday, June 17, 2024 11:35 AM
To: Bronte Woodlan
Subject: Fw: Labeler Code Request Approved

[External]

Ben Esque
CEO
Corstasis Therapeutics

[redacted]
http://www.corstasis.com

From: edrls@fda.hhs.gov <edrls@fda.hhs.gov>
Sent: Tuesday, June 11, 2024 12:48 PM
To: Ben Esque <ben@corstasis.com>
Subject: Labeler Code Request Approved

eDRLS - Electronic Drug Registration & Listing System

Current Date: 11-JUN-2024
Labeler DUNS: 117457315
Labeler Name: Corstasis Therapeutics Inc.
Labeler Code Assigned: 84388

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. **The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

Labeler - Corstasis USA LLC (119325696) NDC Labeler Code: 84388

Contact	Address	Telephone Number	Email Address
Ben Esque	Address: 3535 Executive Terminal Dr City, State, Zip: Henderson, NV, 89052 Country: USA	+1-951-545-9054	ben@corstasis.com

Labeler Detail

Name	Address	ID/FEI	Business Operations
Corstasis USA LLC	Address: 3535 Executive Terminal Dr City, State, Zip: Henderson, NV, 89052 Country: USA	119325696	distributes drug products under own private label(Distributes human prescription drug products)

Revised: 8/2024

Corstasis USA LLC

CORSTASIS
THERAPEUTICS

Company Information

Corstasis USA LLC
3535 Executive Terminal Way STE 110
Henderson, NV 89052
(951) 545-9054
https://corstasis.com/
Ben@corstasis.com

FEIN: 99-3920315
State of Formation: NV
Date Incorporated: 7/10/2024
Filing Number: 20244176766

Ownership Information

Corstasis USA LLC is 100% owned by Corstasis Therapeutics, Inc.

Parent Company Address: 3535 Executive Terminal Way STE 110, Henderson, NV 89052
Parent Company Phone: [redacted]
Parent Company FEIN: 83-3795334

Officers

Benjamin Esque, CEO
Business Address: 3535 Executive Terminal Way STE 110, Henderson, NV 89052
Business Phone: (951) 545-9054
Email: Ben@corstasis.com

[redacted]

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Corstasis USA LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 07/10/2024, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 07/12/2024.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202407124799700
You may verify this certificate online at https://www.nvsilverflume.gov/home

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Filed in the Office of	Business Number
FVAguilar	**E41767672024-6**
	Filing Number
	20244176766
Secretary of State	Filed On
State Of Nevada	**07/10/2024 16:44:51 PM**
	Number of Pages
	2

Formation - Limited-Liability Company

- ☑ NRS 86 - Articles of Organization Limited-Liability Company
- ☐ NRS 86.544 - Registration of Foreign Limited-Liability Company
- ☐ NRS 89 - Articles of Organization Professional Limited-Liability Company
- ☐ NRS 86.555 - Registration of Professional Foreign Limited-Liability Company

1. Name Being Registered in Nevada: (See instructions)	**Corstasis USA LLC**
2. Foreign Entity Name: (Name in home jurisdiction)	
3. Jurisdiction of Formation: (Foreign Limited-Liability Companies)	**3a)** Jurisdiction of formation: **3b)** Date formed: **3c)** I declare this entity is in good standing in the jurisdiction of its formation. ☐
4. Registered Agent for Service of Process*: (check only one box)	☑ Commercial Registered Agent (name only below) ☐ Noncommercial Registered Agent (name and address below) ☐ Office or position with Entity (title and address below) **C T CORPORATION SYSTEM**** Name of Registered Agent **OR** Title of Office or Position with Entity **701 S CARSON ST STE 200** Street Address — **Carson City** City — Nevada **89701** Zip Code Mailing Address (If different from street address) City — Nevada Zip Code
4a. Certificate of Acceptance of Appointment of Registered Agent:	*I hereby accept appointment as Registered Agent for the above named Entity. If the registered agent is unable to sign the Articles of Incorporation, submit a separate signed Registered Agent Acceptance form.* **X Matthew Taylor** — **07/10/2024** **Authorized Signature of Registered Agent or On Behalf of Registered Agent Entity** — Date
5. Management: (Domestic Limited-Liability Companies only)	Company shall be managed by: (check one box) ☑ Manager(s) **OR** ☐ Member(s)
6. Name and Address of each Manager(s) or Managing Member(s): (NRS 86 and NRS 86.544, see instructions) **Name and Address of the Original Manager(s) and Member(s):** (NRS 89, see instructions) IMPORTANT: A certificate from the regulatory board must be submitted showing that each individual is licensed at the time of filing.	1) **Ben Esque** (Name) **3535 Executive Terminal Drive Suite 110** (Address) — **Henderson** (City) — **NV** (State) — **89052** (Zip Code)
7. Dissolution Date: (Domestic only)	Latest date upon which the company is to dissolve (if existence is not perpetual):

This form must be accompanied by appropriate fees.

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Formation - Limited-Liability Company

Continued, Page 2

8. Purpose/ Profession to be Practiced: (NRS 89 only)

9. Series and/or Restricted Limited-Liability Company: (Optional)

Check box if a Series Limited-Liability Company ☑

Domestic Limited-Liability Company"s only: The Limited-Liability Company is a Restricted Limited-Liability Company ☐

10. Records Office: (Foreign Limited-Liability Companies)

Address City State Zip code

Country

11. Street Address of Principal Office: (Foreign Limited-Liability Companies)

Address City State Zip code

Country

12. Name, Address and Signature of the Organizer: (NRS 86. NRS 89 -Each Organizer must be a licensed professional.)

*Foreign Limited-Liability Company - In the event the designated Agent for Service of Process resigns and is not replaced or the agent's authority has been revoked or the agent cannot be found or served with exercise of reasonable diligence, then the Secretary of State is hereby appointed as the Agent for Service of Process.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the Office of the Secretary of State.

Name and Signature of Manager or Member: (NRS 86.544 only)

See instructions

Scott Davis	United States
Name	Country

[redacted]	HALEIWA	HI	96712
Address	City	State	Zip/Postal Code

X **Scott Davis**

(attach additional page if necessary)

AN INITIAL LIST OF OFFICERS MUST ACCOMPANY THIS FILING

Please include any required or optional information in space below:

(attach additional page(s) if necessary)

This form must be accompanied by appropriate fees.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. F192114

Application/License No. _____

CORSTASIS USA LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 3535 EXECUTIVE TERMINAL WAY STE 110, HENDERSON, NV, 89052 (Address of Applicant/Principal), as PRINCIPAL, and Great American Insurance Company (Surety Company), a corporation organized under the laws of the state of Ohio (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 301 E 4th Street CINCINNATI OH 45202 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on Sep 08, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 29th day of August, 20 24.

APPLICANT/PRINCIPAL

CORSTASIS USA LLC

Authorized Representative

SURETY COMPANY

Great American Insurance Company

Surety Company's Representative

John D. Weisbrot, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

GREAT AMERICAN INSURANCE COMPANY®

Administrative Office: 301 E 4TH STREET • CINCINNATI, OHIO 45202 • 513-369-5000 • FAX 513-723-2740

The number of persons authorized by
this power of attorney is not more than THREE

No. 0 21243

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That the GREAT AMERICAN INSURANCE COMPANY, a corporation organized and existing under and by virtue of the laws of the State of Ohio, does hereby nominate, constitute and appoint the person or persons named below, each individually if more than one is named, its true and lawful attorney-in-fact, for it and in its name, place and stead to execute on behalf of the said Company, as surety, any and all bonds, undertakings and contracts of suretyship, or other written obligations in the nature thereof; provided that the liability of the said Company on any such bond, undertaking or contract of suretyship executed under this authority shall not exceed the limit stated below.

Name	Address	Limit of Power
JOHN D. WEISBROT MELISSA L. MCDADE STEVEN M. VARGA	ALL OF PIPERSVILLE, PENNSYLVANIA	ALL $10,000,000

This Power of Attorney revokes all previous powers issued on behalf of the attorney(s)-in-fact named above.

IN WITNESS WHEREOF the GREAT AMERICAN INSURANCE COMPANY has caused these presents to be signed and attested by its appropriate officers and its corporate seal hereunto affixed this 19TH day of OCTOBER, 2020.

Attest

Assistant Secretary

GREAT AMERICAN INSURANCE COMPANY

Divisional Senior Vice President

MARK VICARIO (877-377-2405)

STATE OF OHIO, COUNTY OF HAMILTON - ss:

On this 19TH day of OCTOBER, 2020 before me personally appeared MARK VICARIO, to me known, being duly sworn, deposes and says that he resides in Cincinnati, Ohio, that he is a Divisional Senior Vice President of the Bond Division of Great American Insurance Company, the Company described in and which executed the above instrument; that he knows the seal of the said Company; that the seal affixed to the said instrument is such corporate seal; that it was so affixed by authority of his office under the By-Laws of said Company, and that he signed his name thereto by like authority.

SUSAN A KOHORST
Notary Public
State of Ohio
My Comm. Expires
May 18, 2025

This Power of Attorney is granted by authority of the following resolutions adopted by the Board of Directors of Great American Insurance Company by unanimous written consent dated June 9, 2008.

RESOLVED: That the Divisional President, the several Divisional Senior Vice Presidents, Divisional Vice Presidents and Divisonal Assistant Vice Presidents, or any one of them, be and hereby is authorized, from time to time, to appoint one or more Attorneys-in-Fact to execute on behalf of the Company, as surety, any and all bonds, undertakings and contracts of suretyship, or other written obligations in the nature thereof; to prescribe their respective duties and the respective limits of their authority; and to revoke any such appointment at any time.

RESOLVED FURTHER: That the Company seal and the signature of any of the aforesaid officers and any Secretary or Assistant Secretary of the Company may be affixed by facsimile to any power of attorney or certificate of either given for the execution of any bond, undertaking, contract of suretyship, or other written obligation in the nature thereof, such signature and seal when so used being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

CERTIFICATION

I, STEPHEN C. BERAHA, Assistant Secretary of Great American Insurance Company, do hereby certify that the foregoing Power of Attorney and the Resolutions of the Board of Directors of June 9, 2008 have not been revoked and are now in full force and effect.

Signed and sealed this 29th day of August, 2024.

Assistant Secretary

S1029AH (03/20)

To verify the bond please visit https://www.suretybond.org/validate/?code=Wldk2QgQ1HBUQISQJ/XU1XVw&transaction=XFkG0VQV16cwheQwRcVV4022

GREAT AMERICAN.
INSURANCE GROUP

Great American Insurance Group Tower
301 E. Fourth St.
Cincinnati, OH 45202

GAIG.com

Financial Division

GREAT AMERICAN INSURANCE COMPANY

STATEMENT OF ASSETS, LIABILITIES AND CAPITAL & SURPLUS
AS OF DECEMBER 31, 2023

ADMITTED ASSETS		LIABILITIES, CAPITAL AND SURPLUS		
Bonds	$ 5,823,826,242	Unpaid losses and loss expenses		$ 5,894,983,582
Stocks	1,237,341,409	Reserve for underwriting expenses		409,340,848
Mortgage loans on real estate	710,228,304	Reserve for unearned premiums		2,012,934,616
Real estate (net of encumbrances)	2,008,971	Ceded reinsurance premiums payable		204,344,750
Cash and short-term investments	468,843,467	Funds held under reinsurance treaties		899,657,448
Other invested assets	2,336,668,473	Provision for reinsurance		37,574,400
Receivable for securities	474,176	Retroactive reinsurance ceded		(67,170,073)
Investment income due and accrued	60,912,415	Other liabilities		212,548,168
Agents' and premium balances	867,397,942	Total liabilities		9,604,213,759
Reinsurance recoverable on loss payments	145,881,301			
Federal income taxes	14,692,309			
Net deferred tax asset	34,470,095			
Receivable from affiliates	28,828,823			
Receivable from Federal Crop Insurance Corporation	747,280,659			
Company owned life insurance	197,050,712	Capital stock	$ 15,440,600	
Funds held as collateral	47,607,564	Paid in surplus	903,529,318	
Funded deductibles	33,104,908	Special surplus funds	57,081,006	
Other admitted assets	34,841,617	Unassigned funds	2,211,194,704	
		Policyholders' surplus		3,187,245,628
Total	$ 12,791,459,387	Total		$ 12,791,459,387

Securities have been valued on the basis prescribed by the National Association of Insurance Commissioners.

STATE OF OHIO

COUNTY OF HAMILTON

Judith E. Gill, Vice President and Controller, and Stephen Beraha, Assistant Vice President and Assistant Secretary, being duly sworn, each for himself deposes and says that they are the above described officers of the Great American Insurance Company of Cincinnati, Ohio; that said Company is a corporation duly organized, existing and engaged in business as a Surety by virtue of the laws of the State of Ohio and has duly complied with all the requirements of the laws of said state applicable to said Company and is duly qualified to act as Surety under such laws; that said Company has also complied with and is duly qualified to act as Surety under Public Law 97-258 enacted September 13, 1982 (96 Stat. 1047 as amended: 31 U.S.C. 9304-9308); that to the best of their knowledge and belief the above statement is a full, true and correct Statement of the Assets, Liabilities and Capital & Surplus of the said Company as of December 31, 2023.

Subscribed and sworn to before me

this 23rd day of April, 2024.

Judith E. Gill
Controller

Assistant Secretary

Valerie Smith
Public Notary

VALERIE SMITH
Notary Public
State of Ohio
My Comm. Expires
October 17, 2026

CONFIRMATION OF ADHERENCE TO STATUTES – NV DESIGNATED REPRESENTATIVE COMMUNICATION

From: Theresa Carey <theresa.carey@twolabs.com>
Sent: Tuesday, October 15, 2024 3:06:16 PM
To: Ben Esque <ben@corstasis.com>
Subject: FW: Nevada Wholesaler Application-Corstasis USA LLC - NV Business ID:NV20243157469

Hi Ben!

Are you able to confirm/respond to the below? If believe confirmation via email would be sufficient – I can forward on to Nevada. Thank you!

4. A representative of a wholesaler designated pursuant to this section:
(a) Must be actively involved in and aware of the actual daily operation of the wholesaler;
(b) Must be employed full-time in a managerial level position with the wholesaler;
(c) Must be physically present at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leave, vacation leave and other authorized absences;
(d) May serve in this representative capacity for only one wholesaler at a time;

Theresa Carey
Account Manager
PharmaLicense

TwoLabs
PHARMA SERVICES

110 Riverbend Avenue | Suite 100 | Powell, OH | 43065
mobile [redacted] | **fax** 866.259.4324
website | email | LinkedIn

From: Ben Esque <ben@corstasis.com>
Sent: Tuesday, October 15, 2024 6:21 PM
To: Theresa Carey <theresa.carey@twolabs.com>
Subject: Re: Nevada Wholesaler Application-Corstasis USA LLC - NV Business ID:NV20243157469

[External]

Yes yes yes yes

Ben Esque
CEO
Corstasis Therapeutics
www.Corstasis.com
[redacted]

CORSTASIS
THERAPEUTICS

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Corstasis USA LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 3535 Executive Terminal Way STE 110

City Henderson State NV Zip 89052

Mailing Address (if different from physical address) 3535 Executive Terminal Way STE 110

City Henderson State NV Zip 89052

Telephone (951) 545-9054 Website https://corstasis.com/

Licensing Company Email Ben@corstasis.com

Section 2: Personal Information

First Benjamin Middle Smith Last Esque

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 3535 Executive Terminal Way STE 110

City Henderson State NV Zip 89052

Telephone (951) 545-9054 Email ben@corstasis.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	Not Applicable	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of California, Riverside		09/98-08/01	
Address	**City**	**State**	**Zip**
900 University Ave	Riverside	CA	92521
Diploma/Degree obtained, if any			
BS Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Golden West College		09/96 - 08/98	
Address	**City**	**State**	**Zip**
15744 Goldenwest St	Huntington Beach	CA	92647
Diploma/Degree obtained, if any			
AA Gen studies			

School Name		From - To (MM/YY – MM/YY)	
Valencia High School		09/90-06/94	
Address	**City**	**State**	**Zip**
27801 Dickason Dr	Valencia,	CA	91355
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/22 - present	[redacted]	Huntington Beach	CA	92648
01/13-2/22		Huntington BH	CA	92646

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Corstasis USA LLC			01/19- present
Business Address	**City**	**State**	**Zip**
3535 Executive Terminal Way STE 110	Henderson	NV	89052
Phone	**Title**	**Number of Employed Hours**	
(951) 545-9054	CEO	40/week	
Description of Duties			
see resume			

Business Name			From - To (MM/YY – MM/YY)
Corstasis Therapeutics, Inc			01/21 - present
Business Address	**City**	**State**	**Zip**
3535 Executive Terminal Way STE 110	Hendserson	NV	89052
Phone	**Title**	**Number of Employed Hours**	
(951) 545-9054	CEO	40/week	
Description of Duties			
see resume			

Business Name			From - To (MM/YY – MM/YY)
Acutus Medical, Inc			03/20-05/22
Business Address	**City**	**State**	**Zip**
2210 Faraday Ave #100,	Carlsbad	CA	92008
Phone	**Title**	**Number of Employed Hours**	
(442) 232-6080	Vice President	40/week	
Description of Duties			
see resume			

Business Name			From - To (MM/YY – MM/YY)
Abiomed, Inc			04/17-03/20
Business Address	**City**	**State**	**Zip**
22 Cherry Hill Dr	Danvers	MA	01923
Phone	**Title**	**Number of Employed Hours**	
	Enterprise Account Manager	40/week	
Description of Duties			
see resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

BEN ESQUE

[redacted]

PROFESSIONAL PROFILE:

- Integrity based Decision Maker
- Results and Performance Driven, Sense of Urgency
- Strategic Thinker, Intellectually Curious, Solutions Oriented
- Able to create Strong, Collaborative Cross Functional Working Relationships
- Big Picture Orientation with Attention to Detail
- Prudent Risk Taker
- Commitment to Organization and Talent Development

EXPERIENCE:

Corstasis Therapeutics Inc. and Corstasis USA LLC 01/2019 – Present

Founder/CEO

- Partnered with domain experts to define ideal cardiovascular drugs to be delivered via the intranasal route of administration. Built Scientific Advisory Board of domain experts
- Built company from concept to reality.
- Identified and Hired team of world class consultants: Regulatory, Legal, Chemistry, Manufacturing, Quality.
- From concept to IND in less than 3 years. First clinical study completed 9/24/22. Completed Pivotal T
- Raised $19.7 Million over 3 rounds. Led all aspects of the capital raises which involved 75 investors.
- Completed Pivotal Trial and Commercial Scale Manufacturing Manufacturing

ACUTUS Medical (NASDAQ: AFIB)

Vice President/General Manager, Interventional Electrophysiology 03/2020 – 01/2022

- General Manager for the AcQcross Transeptal product line. Responsibilities included product design, development and iteration. Manufacturing and Quality with profit and loss responsibilities
- Global Training and Development Leader – Designed Virtual Training program during COVID 19
- Lead Global sales and marketing for the AcQcross transeptal product line.
- Participated in Go public road show events.
- Licensed AcQcross Transeptal Franchise to Medtronic - $50 Million Upfront + Milestones

ABIOMED (ABMD)

Enterprise Account Manager – Orange County, San Diego, Inland Empire, Hawaii, Yuma 03/2014 – 03/2020

- Top 10% 3 of 5 years, Top 25% 2 of 5 years.
- People Leader responsible for a team of clinical support specialists.
- Impella devices on patients in the Cath Lab, CVOR, and ICU settings
    - - Personally supported 693 Impella patients (Top 10 all time at ABMD)
- Launched 29 new Impella programs; call points include C Suite, ICU, Cath Lab, and Operating Room
    - Promoted 3 times in 5 years

EDWARDS LIFESCIENCES (EW)

Group Manager, MedTech Training, Trans-catheter Heart Valves Division 03/2012 – 03/2014

- Designed, developed, and led first ever new hire training programs at EW THV
- Led Sapien XT clinical training
- Designed, developed, and led Trans-apical Launch Meeting

- Identified, Validated, Implemented CT the first 3D Reconstruction case planning tool for TAVR cases.
- Led the design, training, and roll out of the Therapy Awareness Program (TAP)
- Implemented Cloud Based Training and File Sharing

JOHNSON & JOHNSON / CORDIS CORPORATION
WW Sales Training & Development Manager 03/2010 – 03/2012

- Designed, developed, and led 12 Multinational Cardiovascular and Endovascular new hire Sales Mastery Courses
- Designed, developed, and led Cardiology portion of National Training Meeting - Led the Cardio and Endo portions of National Sales Meetings in Canada, the UK, and Europe
- Conducted Field Training Rides, increased Rep and Management Performance, and led Division Meetings
- Provided Distance Based Coaching to mentees and the Field Organization as a whole
- Collaborated directly with the Marketing Organization and Field Teams to create and implement succinct marketing tools, and optimized the strategy and approach. Won the "Little Big Dog Award" twice for impactful contributions to Marketing Organizations
- Led Marketing Strategic and Sales Training Portions of Regional Sales Meetings

JOHNSON & JOHNSON / CORDIS CORPORATION
Sr. Sales Representative / Field Sales Trainer 02/2007 – 03/2010

- Sales Rep of the Year 2009
- Achieved 200+ % Growth in Cypher Stent sales since joining Cordis despite the launch of new DES
- Succeeded by Growing Volume and Maintaining ASP

KOS PHARMACEUTICALS
Sr. Territory Manager / District Sales Trainer 02/2005 – 02/2007

- Championed a formulary win with IEHP, the second largest Medi-Cal account in Southern California
- Call points: Hospital, Cardiology, Endo, Nephro, IM, FP, Podiatry
- President's Club Award Winner 2006

SANKYO PHARMA
Sales Representative II / District Team Leader 07/2002 – 02/2005

- President's Club Award Winner 2004
- Completed Management Development Training
- Promoted to Divisional Sales Trainer

ADP – AUTOMATIC DATA PROCESSING
District Manager 09/2000 – 07/2002

- Finished FY' 02 151 % of plan, 4/32 in Regional Ranking
- Responsible for acquiring new accounts through Cold Calling, Foot Canvassing, and implementation of Targeted Marketing Campaigns
- Managed Territorial Database of 200+ accounts ensuring Client Retention and satisfaction - Probed existing clients for additional business
- Developed solid Referral Based relationships with CPA community, financial institutions, and other Business to Business channels

EDUCATION:

UNIVERSITY of CALIFORNIA / RIVERSIDE
BS – Business Administration 03/2001

- 4 years Intercollegiate Baseball 2 years Division I
- Personally Financed ½ of College Tuition
- Completion of the Registered Cardiac Invasive Specialist (RCIS) Course

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		x
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

9/23/21
Date

I, Benjamin Esque, **certify that as the designated representative for**

Corstasis USA LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. BE I am at least 21 years of age;
3. BE I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. BE I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. BE I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. BE I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. BE I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Benjamin Esque

Print Name (First, Last)

Esque

~~Original Signature~~ (electronic, copies or stamps not accepted)

9/23/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Benjamin Esque

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/23/24

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Orange

I, Benjamin Esque, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/23/24

Date

Subscribed and Sworn to before me this 23 day of Sept, 2024

Notary Public Signature

See attached Notary Form

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of ORANGE

Subscribed and sworn to (or affirmed) before me on this 23 day of SEPTEMBER, 20 24, by BENJAMIN ESQUE,
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

BETH FAAS
Notary Public - California
Orange County
Commission # 2389445
My Comm. Expires Jan 4, 2026

(Seal) Signature Beth Faas

Corstasis USA LLC

Sole Employee:

- Benjamin Esque

10B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		■ Nevada ☐ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Stericycle, Inc.

Physical Address: 1655 Milan Drive

City: McCarran State: NV Zip: 89437

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: 801-971-2042 Website: stericycle.com

Name of Designated Representative (DR): _____

Licensing Company Email: jbarr@stericycle.com DR Email: _____

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	■ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Destruction only

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Walgreens
Address: 108 Wilmot Rd City: Deerfield State: IL Zip: 60015

Name: MED-Projects
Address: 1800 M St NW Ste 400 City: Washington State: DC Zip: 20036

Name: Cleveland Clinic Foundation
Address: 6801 Brecksville Rd City: Independence State: OH Zip: 44131

Name: Kaiser Permanente
Address: Bellflower Blvd City: Downey State: CA Zip: 90242

Section 4: Publicly Traded Corporation

State of Incorporation: Deleware
Parent Company (if any): N/A
Corporation Name: Stericycle, Inc.
Mailing Address: 2355 Waukegan Road
City: Bannockburn State: IL Zip: 60015
Telephone: 512-213-7089 Email:
Contact Person Name: Joel Barr

Date of SEC Registration: | SEC Registration Number: 4955 | Stock Exchange Symbol: SRCL

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Stericycle, Inc.

Facility Name

Richard M. Moore

Print Name of Authorized Person Submitting Application

Richard M. Moore

Original signature of Authorized Person (copies or stamps not accepted)

06-25-2024

Date

Board Use Only	Date Received: 7/8/24	Amount: $1000-00

Stericycle®
We protect what matters.

Officer List

Officers	**2355 Waukegan Road, Bannockburn, IL, 60015**
Cindy J. Miller	President and Chief Executive Officer
Janet H. Zelenka	Executive Vice President, Chief Financial Officer & Chief Information Officer
Richard M. Moore	Executive Vice President, North American Operations
S. Cory White	Executive Vice President and Chief Commercial Officer

Please see above list of the four executive officers with direct or indirect responsibility for, and oversight of, the permitted activity.

File Number 5617-389-7

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

I, **Alexi Giannoulias,** *Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that*

STERICYCLE, INC., INCORPORATED IN DELAWARE AND LICENSED TO TRANSACT BUSINESS IN THIS STATE ON NOVEMBER 20, 1990, APPEARS TO HAVE COMPLIED WITH ALL THE PROVISIONS OF THE BUSINESS CORPORATION ACT OF THIS STATE, AND AS OF THIS DATE, IS A FOREIGN CORPORATION IN GOOD STANDING AND AUTHORIZED TO TRANSACT BUSINESS IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 29TH *day of* MAY *A.D.* 2024 .

SEAL OF THE STATE OF ILLINOIS
UNION NATIONAL INDUSTRIAL STATE
1868 1818
AUG. 26TH 1818

Authentication #: 2415003918 verifiable until 05/29/2025
Authenticate at: https://www.ilsos.gov

Alexi Giannoulias
SECRETARY OF STATE

Storey County
Community Development
PO Box 526
Virginia City, NV 89440

Account #: 211324

2025

County of Storey

BUSINESS LICENSE

Date Issued: 7/01/2024
Class: GENERAL
Expires: 6/30/2025

This License is Granted to:

STERICYCLE INC.
2355 WAUKEGAN RD.
BANNOCKBURN IL 60015

STERICYCLE INC., having paid the required Storey County business license fee(s) in the amount of $ 710.00 is hereby granted permission to transact business under the GENERAL license for the period 7/01/2024 through 6/30/2025 in conformance with and subject to the County Commissioners of Storey County, Nevada.

~ COUNTERSIGNED ~

Jennifer McCain
Storey County Comptroller

Pete Renaud
Building Official

THIS LICENSE MUST BE DISPLAYED IN A CONSPICUOUS PLACE

****NON-TRANSFERABLE****

Phone (775)-847-0966 ~ Fax (775) 847-0935 ~ buslic@storeycounty.org

Stericycle-Employees

FIRST NAME	LAST NAME	ID#
EFRAIN	ACEVEDO	[redacted]
KAYLIE	BALLARD	
BELA	BRUSZT	
Brown	Matthew	
KEITH	CALLAWAY	
JASMIN	CONE	
JOSHUA	COVELLO	
BRAXTON	CROWSON	
HOLLY	DAVIS	
CONNER	DUNN	
JARED	FOLEY	
TODD	HONEYCUTT	
EDUARDO	HERNANDEZ-FLORES	
KHRISTOPHER	KEATES	
DENNIS	KENNEDY	
ROSA	LOPEZ	
LOUIS	MARTINEZ JR	
RACHEL	NASON	
RIZZA	POCHOP	
OSWALDO	QUINONEZ	
FELICIA	RAMIREZ	
ADAM	SANCHEZ	
RUBEN	SOTO	
DASHAWN	SPENCE	
MICHAEL	THIGPEN	
JOSE	VALDIVIA	
VANCE	WALKER	
LEROY	WILLIAMS	
JESS	BARNETT	
SAM	DENNIS	
ANTHONY	GOMEZ	
BLAKE	NELSON	
SAMUEL	SMITH	
LOGAN	WATSON	
KEVIN	WASKIEWICZ	
MARK	JAMISON	
SAVANNAH	VALLES	
MICHAEL	DUPONT	

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2023
or
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission File Number 1-37556

Stericycle, Inc.

(Exact name of registrant as specified in its charter)

Delaware	36-3640402
(State or other jurisdiction of incorporation or organization)	*(IRS Employer Identification Number)*

2355 Waukegan Road
Bannockburn, Illinois 60015
(Address of principal executive offices, including zip code)
(847) 367-5910
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	SRCL	Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes x No ☐
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No x
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15-(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ☐
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definition of "large accelerated filer", "accelerated filer" "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒	Accelerated filer ☐	Non-accelerated filer ☐
Smaller reporting company ☐	Emerging Growth Company ☐	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒
If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.☐
Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1b.☐
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ☐ NO ☒
The aggregate market value of voting and non-voting common equity held by non-affiliates computed by reference to the price at which common equity was last sold as of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2023): $4,267,283,457.
On February 23, 2024 there were 92,567,104 shares of the Registrant's Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Information required by Items 10, 11, 12, 13 and 14 of Part III of this Report is incorporated by reference from the Registrant's definitive Proxy Statement for the 2024 Annual Meeting of Stockholders.



Table of Contents

	Page No.
PART I.	
Item 1. Business	6
Item 1A. Risk Factors	18
Item 1B. Unresolved Staff Comments	30
Item 1C. Cybersecurity	30
Item 2. Properties	31
Item 3. Legal Proceedings	31
Item 4. Mine Safety Disclosures	31
PART II.	
Item 5. Market Price for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchase of Equity Securities	32
Item 6. [Reserved]	32
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	33
Item 7A. Quantitative and Qualitative Disclosures about Market Risk	45
Item 8. Financial Statements and Supplementary Data	46
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	81
Item 9A. Controls and Procedures	81
Item 9B. Other Information	83
Item 9C. Disclosures Regarding Foreign Jurisdictions that Prevent Inspections	83
PART III.	
Item 10. Directors, Executive Officers and Corporate Governance	84
Item 11. Executive Compensation	84
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	84
Item 13. Certain Relationships and Related Transactions, and Director Independence	85
Item 14. Principal Accountant Fees and Services	85
PART IV.	
Item 15. Exhibits and Financial Statement Schedules	86
Item 16. Form 10-K Summary	89
SIGNATURES	90

Glossary of Defined Terms

Unless the context requires otherwise, the "Company", "Stericycle", "we", "us", or "our" refers to Stericycle, Inc. on a consolidated basis. The Company also uses several other terms in this Annual Report on Form 10-K, most of which are explained or defined below:

Abbreviation	Description
2021 Plan	2021 Incentive Stock Plan
2023 Form 10-K	Annual report on Form 10-K for the year ended December 31, 2023
Adjusted Income from Operations	Income from Operations adjusted for certain items discussed in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations
AI	Artificial Intelligence
APHIS	Animal and Plant Health Inspection Service
ASU	Accounting Standards Update
CARES Act	U.S. Coronavirus Aid, Relief, and Economic Security Act enacted into law on March 27, 2020
CDC	U.S. Centers for Disease Control and Prevention
Clean Air Act	The Clean Air Act of 1970
COR	Cost of Revenues
COSO Criteria	Internal Control Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission
COVID-19	The global coronavirus disease 2019 outbreak, which the World Health Organization declared to be a pandemic
Credit Agreement	Credit Agreement dated September 30, 2021, First Amendment dated April 26, 2022, and Second Amendment dated June 15, 2023, among the Company and certain subsidiaries as borrowers. Bank of America, N.A., as administrative agent, swing line lender, a lender and a letter of credit issuer and the other lenders party thereto, as amended
Credit Agreement Defined Debt Leverage Ratio	As of any date of determination, the ratio of (a) (i) Consolidated Funded Indebtedness as of such date minus (ii) Unrestricted Cash as of such date to (b) Consolidated EBITDA (each as defined in the Credit Agreement) for the period of four fiscal quarters most recently ended on or prior to such date
Credit Facility	The Company's $1.2 billion credit facility due in September of 2026 granted under the terms of the Credit Agreement
CRS	Communication and Related Services (Divested December 2022)
DCF	Discounted Cash Flows
DEA	U.S. Drug Enforcement Administration. The DEA is a division of the DOJ. It is the federal agency which regulates the manufacture, dispensing, storage, and shipment of controlled substances including medications with human abuse potential
DOJ	U.S. Department of Justice
Domestic Environmental Solutions	Hazardous Waste Solutions and Manufacturing and Industrial Services (Divested April 2020)
DOT	U.S. Department of Transportation
DSO	Days Sales Outstanding as reported, defined as the average number of days that it takes a company to collect payment after revenue has been recorded, computed as the trailing twelve months of Revenues for the period ended, divided by the Accounts Receivable balance at the end of the period. Days Sales Outstanding, net of Deferred Revenues is similarly computed except Accounts Receivable balance is netted with Deferred Revenues.
DTSC	U.S. Department of Toxic Substances Control
EBITDA	Earnings Before Interest, Taxes, Depreciation & Amortization. Another common financial term utilized by Stericycle to analyze the core profitability of the business before interest, tax, depreciation and amortization
EHS	Environmental, Health and Safety
Enviri	Enviri Corporation, a Delaware Corporation, formerly known as Harsco Corporation
EPA	U.S. Environmental Protection Agency
ERISA	U.S. Employee Retirement Income Security Act of 1974, as amended by the Multi-Employer Pension Amendments Act of 1980
ERP	Enterprise Resource Planning
ESPP	Employee Stock Purchase Plan, which was approved by stockholders in May 2001 (as amended and restated in May 2017)
EU	European Union
Exchange Act	U.S. Securities Exchange Act of 1934
Expert Solutions	Recall and Return Services (Divested December 2020)
FACTA	U.S. Fair and Accurate Credit Transaction Act
FASB	Financial Accounting Standards Board
FCPA	U.S. Foreign Corrupt Practices Act
FCPA Settlement	FCPA Settlement with the Securities and Exchange Commission, the Department of Justice and Brazilian authorities of approximately $90.0 million and engagement of an independent compliance monitor for 2 years and self-reporting for additional year
FMCSA	U.S. Federal Motor Carrier Safety Administration
GDPR	General Data Protection Regulation
GILTI	Global Intangible Low-Taxed Income
GPO	Group Purchasing Organization
HIPAA	Health Insurance Portability and Accountability Act
HMIWI	Hospital, Medical, Infectious Waste Incinerator
IATA	International Air Transport Association
Indenture	Indenture, dated as of June 14, 2019 between the Company, the guarantors named therein and U.S. Bank National Association, as trustee
International	Operating segment including Belgium, France, Germany, Ireland, Luxembourg, Portugal, Spain, and U.K. The following countries were divested in 2023: Australia, Brazil, Republic of Korea, Romania, Singapore, and UAE

IRS	U.S. Internal Revenue Service
ISO	Incentive Stock Options
NOL	Net Operating Losses
North America	Operating segment including U.S., Canada and Puerto Rico
NOV	Notice of Violation
OSHA	U.S. Occupational Safety and Health Act of 1970
Other Costs	Represents corporate enabling and shared services costs, annual incentive and stock-based compensation
Pension Protection Act	Pension Protection Act of 2006
PFA	Pre-filing agreement with the IRS
PHMSA	U.S. Pipeline Hazardous Materials Safety Administration
Plan	401(k) defined contribution retirement savings plan
PPE	Personal Protective Equipment
PSU	Performance-based Restricted Stock Unit
Purchase Agreement	Stock Purchase Agreement, dated as of February 6, 2020, by and between Stericycle, Inc., and the Harsco Corporation (now known as Enviri) and CEI Holding LLC, a Delaware limited liability company and subsidiary of Harsco Corporation (now known as Enviri)
RCRA	U.S. Resource Conservation and Recovery Act of 1976
ROU	Right-of-Use
RSU	Restricted Stock Unit
RWCS	Regulated Waste and Compliance Services, a business unit that provides regulated medical waste services
S&P	Standard & Poor's
SEC	U.S. Securities and Exchanges Commission
Senior Notes	5.375% ($600.0 million) Senior Notes due July 2024 and 3.875% ($500.0 million) Senior Notes due January 2029
Series A	Series A Mandatory Convertible Preferred Stock, par value $0.01 per share
SG&A	Selling, general and administrative expenses
SID	Secure Information Destruction Services, a business unit that provides confidential customer material shredding services and recycling of shredded paper
SOFR	Secured Overnight Financing Rate - benchmark interest rate that replaced LIBOR
SOP	Sorted Office Paper
SQ Settlement	Small quantity medical waste customers class action settlement of $295.0 million
Tax Act	U.S. Tax Cuts and Jobs Act of 2017
Term Facility	Aggregate amount of commitments made by any lender under the terms of the Credit Agreement
Term Loans	Advances made by any lender under the Term Facility
TSA	Transition Services Agreement
UAE	United Arab Emirates
U.K.	United Kingdom
UPS	United Parcel Service, Inc.
U.S.	United States of America
USDA	U.S. Department of Agriculture
U.S. GAAP	U.S. Generally Accepted Accounting Principles

PART I

Disclosure Regarding Forward-Looking Statements

This document may contain forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995. When we use words such as "believes", "expects", "anticipates", "estimates", "may", "plan", "will", "goal", or similar expressions, we are making forward-looking statements. Forward-looking statements are prospective in nature and are not based on historical facts, but rather on current expectations and projections of our management about future events and are therefore subject to risks and uncertainties, which could cause actual results to differ materially from the future results expressed or implied by the forward-looking statements. Factors that could cause such differences include, among others, inflationary cost pressure in labor, supply chain, energy, and other expenses, decreases in the volume of regulated wastes or personal and confidential information collected from customers, and disruptions resulting from deployment of systems, disruptions in our supply chain, disruptions in or attacks on data information technology systems, labor shortages, a recession or economic disruption in the U.S. and other countries, changing market conditions in the healthcare industry, competition and demand for services in the regulated waste and secure information destruction industries, SOP pricing volatility or pricing volatility in other commodities, changes in the volume of paper processed by our secure information destruction business and the revenue generated from the sale of SOP, foreign exchange rate volatility in the jurisdictions in which we operate, changes in governmental regulation of the collection, transportation, treatment and disposal of regulated waste or the proper handling and protection of personal and confidential information, the level of government enforcement of regulations governing regulated waste collection and treatment or the proper handling and protection of personal and confidential information, the outcome of pending, future or settled litigation or investigations, charges related to portfolio optimization or the failure of acquisitions or divestitures to achieve the desired results, the obligations to service substantial indebtedness and comply with the covenants and restrictions contained in our credit agreements and Senior Notes, rising interest rates or a downgrade in our credit rating resulting in an increase in interest expense, political, economic, war, and other risks related to our foreign operations, pandemics and the resulting impact on the results of operations, long-term remote work arrangements which may adversely affect our business, restrictions on the ability of our team members to travel, closures of our facilities or the facilities of our customers and suppliers, weather and environmental changes related to climate change, requirements of customers and investors for net carbon zero emissions strategies, and the introduction of regulations for greenhouse gases, which could negatively affect our costs to operate, failure to maintain an effective system of internal control over financial reporting, as well as other factors described in our filings with the SEC, including the 2023 Form 10-K and subsequent Quarterly Reports on Form 10-Q. As a result, past financial performance should not be considered a reliable indicator of future performance, and investors should not use historical trends to anticipate future results or trends. We disclaim any obligation to update or revise any forward-looking or other statements contained herein other than in accordance with legal and regulatory obligations.

Item 1. Business

Overview

Company Overview

Stericycle, Inc., is a U.S. based business-to-business services company and leading provider of compliance-based solutions that protect people and brands, promote health and well-being and safeguard the environment. Through our family of brands, Stericycle serves customers in North America and Europe with solutions to safely manage materials that could otherwise spread disease, contaminate the environment, or compromise one's identity. To our customers, team members and the communities we serve, Stericycle is a company that protects what matters.

Segments

Our operating segments as of December 31, 2023, are North America and International.

Financial and other information related to our reporting segments is included in *Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* and *Part II, Item 8. Financial Statements and Supplementary Data*; *Note 17 - Segment Reporting*.

Services

Within our operating segments, our revenues are further broken down into these service categories:

Revenue Service Category	Services Offered
Regulated Waste and Compliance Services	• Biohazardous Waste Disposal (including Regulated Medical Waste, Sharps Waste Management and Disposal, Pharmaceutical Waste Management and Disposal, Chemotherapy Waste and Disposal, Controlled Substance Waste Disposal, Healthcare Hazardous Waste, and Integrated Waste Stream Solutions) • Compliance Solutions (including Steri-Safe® Compliance Solutions) • Specialty Services (including MedDrop™ Medication Collection Kiosks, Safe Community Solutions, SafeDrop™ Sharps Mailback Solutions, and Airport and Maritime Waste Services) • Medical Supply Store (including Sharps and disposable Biohazardous Waste Containers, Infection Control Supplies and Seal&Send Medication Mail Back)
Secure Information Destruction Services	• Secure information destruction and compliance solutions (including document, hard drive, and specialty destruction services) under the Shred-it® brand name which includes regular scheduled services (and processing onsite and offsite) and one-time services (including select, priority and express)

Revenues by service category for each of the operating segments were as follows:

In millions

	Year Ended December 31,	
	2023	2022
North America		
Regulated Waste and Compliance Services	$ 1,474.4	$ 1,468.8
Secure Information Destruction Services	781.4	794.3
Total North America Segment	2,255.8	2,263.1
International		
Regulated Waste and Compliance Services	301.4	329.4
Secure Information Destruction Services	102.1	112.2
Total International Segment	403.5	441.6
Total Revenues	$ 2,659.3	$ 2,704.7

See *Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* for further information on changes in revenues.

Portfolio Optimization

We evaluate our portfolio of services on an ongoing basis with a country-by-country and service line-by-service line approach to assess long-term potential and identify potential business candidates for divestiture. Divestitures resulting from this evaluation may cause us to record significant charges, including those related to goodwill, other intangible assets, long-lived assets, and cumulative translation adjustments.

During 2023, we divested eight businesses, demonstrating significant progress in executing our portfolio optimization priority. These divestitures included an International container manufacturer joint venture, our businesses in Brazil, Singapore, Australia, and Republic of Korea, dental recycling business in the Netherlands, SID joint venture in the UAE, and our business in Romania for aggregate net proceeds of approximately $85 million.

On January 31, 2024, we acquired a southeastern U.S. regulated waste business for total consideration of approximately $16 million in cash and a promissory note. This acquisition is considered to be complementary to existing operations and aligns with our portfolio optimization strategy. The acquired business is anticipated to contribute less than 1% to the RWCS revenue service category for 2024.

For additional information regarding acquisitions and Divestiture losses (gains), net, including significant impacts of foreign currency translation adjustments, net, see *Part II, Item 8. Financial Statements and Supplementary Data; Note 3 – Acquisitions; Note 4 – Restructuring, Divestitures, and Asset Impairments* in the Consolidated Financial Statements.

Customers

Our service offerings appeal to a wide range of business customers. Our customers are primarily in the following industries: enterprise healthcare (i.e., hospitals, health systems, and non-affiliate hospitals; and national and corporate healthcare), practices and care providers (i.e., physician offices, surgery centers, veterinary clinics, nursing and long-term care facilities, dental clinics, clinics and urgent care, dialysis centers, and home health organizations), and pharmacy, lab and research centers. We also provide services to airports and seaports, education institutions, funeral homes and crematories, government and military, banks and professional services, and other businesses. While we manage large volumes of waste and other materials, the average volume per customer site is relatively small.

In 2023, no single customer accounted for more than 2% of our total revenues and our top ten customers collectively accounted for approximately 10% of total revenues. No single customer accounted for more than 2% of our total accounts receivable and our top ten outstanding customer balances accounted for approximately 8% of total accounts receivable. We have developed a strong and loyal customer base, with an estimated revenue retention rate of approximately 90% (based on our internal customer attrition analysis) and have been able to leverage these customer relationships to provide additional services.

As of December 31, 2023, Regulated Waste and Compliance Services are provided to customers in the U.S., Canada, Ireland, Portugal, Spain and the U.K. Secure Information Destruction Services under the Shred-it® brand are provided in the U.S., Belgium, Canada, France, Germany, Ireland, Luxembourg, the Netherlands, Portugal, Spain, and the U.K.

In the U.S. and elsewhere, the healthcare industry is evolving to meet competing demands for increased healthcare coverage of a growing and aging population and economic pressures to reduce healthcare costs. As a result of these dynamics, hospital networks are consolidating physician practices into their networks, independent practices are consolidating, while other customers are leveraging GPOs and delivering care through alternative sites of care, such as in-home, to reduce healthcare costs.

Our International RWCS operations generate most of their revenues from large account customers, such as hospitals, publicly funded healthcare organizations and National Trusts versus smaller customers which tend to be more profitable.

Facilities and Fleet

Our worldwide network includes a global fleet of approximately 5,200 route trucks, tractors, collection vans, and small duty vehicles. We operate out of approximately 396 facilities worldwide with properties both leased and owned as described below:

	Autoclave or Alternative Medical Waste Treatment	Medical Waste Incinerator Facilities	Secure Information Destruction Processing	Transfer Stations (RWCS and SID)	Other Locations and/or Administrative Facilities	Total Facilities
North America	49	9	90	139	10	297
International	22	9	15	38	15	99
Total	71	18	105	177	25	396

We are headquartered in Bannockburn, Illinois.

Our Key Business Priorities

Following its founding in 1989, Stericycle grew rapidly through acquisitions as the regulated waste industry developed. Growth from regulated waste acquisitions helped us achieve scale of infrastructure, route density and a leadership position in many of the markets we serve. We also leveraged acquisitions to enter new regional and international geographies and added additional services to our portfolio, including the Secure Information Destruction business in 2015. As we grew and evolved, we operated without centralization and the efficiencies that come from an integrated, modern structure and associated information systems until we shifted our focus to our five key business priorities in 2019.

- ***Quality of revenue*** – We have been executing against our foundational initiatives we launched to drive revenue quality and are executing on: (i) expanding service penetration, (ii) improving customer implementation velocity, and (iii) deepening customer partnerships by developing enhanced solutions.
- ***Operational efficiency, modernization, and innovation*** – We have been executing on our foundational initiatives we launched to drive operational efficiency, modernization and innovation and are executing on: (i) infrastructure and system modernization, (ii) fleet replacement and route and long-haul network improvements and (iii) SafeShield container rationalization and modernization.
- ***ERP implementation*** – We successfully deployed the North America ERP to the U.S. RWCS business in the third quarter of 2023. Almost all of our U.S. team members are now leveraging the new technology. We continue to observe improvement in our team members' performance as they leverage the technology and data flow. We commenced activities for the international system modernization in 2022.
- ***Portfolio optimization*** – We expect to continue evaluating opportunities to further optimize our portfolio through a combination of asset rationalizations and strategic accretive tuck-in acquisitions, which streamline our portfolio of businesses and allow us to focus more deeply on our core businesses. 2023 divestitures primarily included an International container manufacturer joint venture in Spain; our businesses in Brazil, Singapore, Australia, and Republic of Korea; dental recycling business in the Netherlands; SID joint venture in the UAE; and our business in Romania for net proceeds of approximately $85 million.
- ***Debt reduction and leverage improvement*** – We have reduced total net debt to $1.27 billion as of December 31, 2023. In the second quarter of last year, we successfully achieved our goal of reducing our debt leverage below 3 times and have continued to maintain our debt leverage target, finishing 2023 with a debt leverage ratio of 2.85 times.

For further details, refer to *Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* and *Part II, Item 8. Financial Statements and Supplementary Data; Note 3 – Acquisitions, Note 4 – Restructuring, Divestitures, and Asset Impairments,* and *Note 9 – Debt.*

Regulated Waste and Compliance Services

Collection and Transportation

The collection process for regulated waste streams begins at the customer location with waste segregation. To assure regulatory compliance, we educate our customers and will not accept material from customers unless it complies with our waste acceptance protocols and is properly stored or packaged in containers that we have either supplied or approved and is appropriately labeled.

Our team members then collect containers at the customer location via our fleet of vehicles. The majority of collected waste is then transported directly to one of our processing facilities or to one of our transfer stations until it's transported to a processing facility. Our use of transfer stations in a "hub and spoke" configuration improves the efficiency of our collection and transportation operations by expanding the geographic area that a particular processing facility can serve, thereby increasing the utilization of the facility and the volume of waste that it processes.



Processing and Disposal of Regulated Waste

Upon arrival at a processing facility, containers or boxes of regulated waste undergo a quality control process to verify that they do not contain any unacceptable substances. Any container or box that is discovered to contain unacceptable waste goes through a corrective action process which could include redirecting the waste, returning the waste to the customer and/or notifying the appropriate regulatory authorities. From there, regulated waste is processed using one of several treatments or processing technologies, predominantly at one of our facilities:

- ***Autoclaving:*** Autoclaving is the primary method of regulated waste treatment. This process relies on steam at high temperature and pressure to kill pathogens and render materials non-infectious.
- ***Alternative Technologies***: We use several different non-incineration alternatives to autoclaves, predominantly outside of the U.S. The processes used by these technologies are similar, as the regulated waste is heated to a specified temperature for a required time to kill the pathogens and render materials non-infectious. This is not always under pressure. Depending on local requirements, the waste may be shredded before or after treatment to render it unrecognizable.
- ***Incineration:*** While Stericycle strives to use alternative, non-incineration methods for treating medical waste, incineration remains a regulatory requirement and/or a best practice in certain geographies or for certain types of medical waste that need to be chemically destroyed. Incineration burns regulated waste at elevated temperatures and reduces it to ash. Incineration reduces the volume of waste, and it is the recommended treatment and disposal option for some types of regulated waste such as anatomical waste, residues from chemotherapy procedures and non-hazardous pharmaceutical waste. Air emissions from incinerators can contain certain byproducts that are subject to federal, state and in some cases, local regulation. In some circumstances, the ash byproduct of incineration may be regulated.

Upon completion of the treatment process, the resulting waste or incinerator ash is transported for disposal in a landfill owned by unaffiliated third parties.

In several of our incineration facilities, we use different types of waste-to-energy solutions as part of our processes. Stericycle has four incinerators with steam turbines that can generate electricity and reduce the amount of power required from utilities at each site. In the U.K., several of our incinerators export steam to hospitals, where they are co-located, to be used for facility or hot water heating, steam sterilization, and/or laundry services. Similar to exported steam, two of our U.K. incinerators export hot water to nearby hospitals. In the U.K. and Ireland, after medical waste has gone through the alternative treatment process, it is sent for beneficial reuse. This treated waste is sent to cement producers and used as an alternative fuel for cement kilns.

Secure Information Destruction

We leverage a combination of off-site and on-site document destruction methods for one-time and recurring paper shredding. In North America in 2023, approximately 72% of collected documents for secure destruction were sent off-site to geographic consolidating shredding facilities for secure destruction. The remainder of collected documents are shredded on-site with shredding equipment in our vehicles. For both methods, our service offerings leverage cross-cut shredding technology to enhance the security level of destruction and can provide secure chain-of-custody and Proof of Service.

Shredded paper is then sold as SOP for recycling. SOP consists of paper typically generated by offices that contains primarily white paper. White paper is a higher value recyclable than mixed paper, which mainly consists of newspapers or magazines. In 2023, Stericycle collected approximately 462,000 tons of SOP for recycling, a decrease of 11.7% compared to 2022 of approximately 523,000 tons. After excluding the impact of divestitures, we collected approximately 453,000 tons and approximately 500,000 tons in 2023 and 2022, respectively. This resulted in a decline in SOP, excluding divestitures, of approximately 47,000 tons or 9%. During 2023, the average annual SOP price was $174 per ton, as reported by Fastmarkets, a decrease of 26.0% compared to 2022.

Our Business Model and Key Business Attributes

Regulated Business-to-Business Operations

We focus on providing business-to-business services in areas of operations that are highly regulated. By helping our customers maintain compliance with complex regulations, we protect people and brands, promote health and well-being and safeguard the environment. Governmental legislation and regulation require the proper handling and disposal of items such as regulated waste and personal confidential information. Regulated waste can be defined as any material subject to government-imposed guidelines for handling the material for transportation or disposal.

- ***Regulated Medical Waste:*** Regulated medical waste generated from procedures including any items saturated with blood or other potentially infectious materials (OPIM), such as bandages, gauze, or PPE, are considered regulated medical waste.
- ***Trace Chemotherapy Waste:*** Chemotherapy waste includes empty chemo drug vials, syringes and hypodermic needles, spill kits, IV tubing and bags, contaminated gloves and gowns, materials from spill cleanups, or bodily fluids/waste.
- ***Pathological Waste:*** Pathological waste such as human or animal tissues, body parts, and surgical specimens (decanted of formaldehyde, formalin, or other preservatives) are packaged separately.
- ***Sharps Waste:*** Sharps waste such as needles, scalpels, blades, and pipettes that have come in contact with blood, body fluids, or microorganisms.
- ***Pharmaceutical Waste:*** Pharmaceutical waste that may be hazardous or nonhazardous and consists of expired, recalled, or otherwise unused pharmaceuticals.
- ***Controlled Substances Waste:*** Controlled substances waste includes unused, unwanted, or expired pharmaceutical controlled substances.
- ***Healthcare Hazardous Waste:*** Healthcare hazardous waste includes prevalent and well-known waste streams and other wastes generated in smaller quantities that require proper attention, such as flammable liquids, xylene, formalin, aerosols, and universal waste.
- ***Solid Waste and Recycling:*** Solid waste and recycling services.
- ***Maritime Waste:*** Airport and seaport generated waste including gray water, black water, bilge water, sludge, solid waste, recyclable solid waste, RCRA hazardous waste, APHIS waste, and universal waste.
- ***Personal Confidential Information:*** Documents and e-media containing protected healthcare information, financial information, or other confidential information.

Growing Markets

The demand for our services, especially our core services of regulated waste and compliance and secure information destruction, are expected to grow or have historically grown. This growth is driven by multiple factors:

- ***Aging Population and Demographic Changes:*** The average age of the population in the countries in which we operate is rising, driving increases in healthcare demand and the quantity of regulated wastes generated.
- ***Enforcement of Waste Regulations:*** We operate in a highly regulated business where penalties for violations can be costly and high profile, thereby impacting our customers' overall reputation. We believe that many businesses are either unaware of the need for proper training of employees or of applicable regulatory requirements or understaffed or lack the expertise to comply with the regulations, and we seek to help businesses fill this gap.
- ***Regulation of Privacy and Information Security and Concerns over Data Breaches:*** The secure information destruction total addressable market has been driven, in part, by the need for compliance with increasing government regulation and increasing general concern with privacy and information security. Recent regulatory changes reflecting this increased regulatory focus include the European GDPR; California, Colorado, and Virginia's comprehensive consumer privacy legislation; and Canada's Personal Information Protection and Electronic Documents Act. Moreover, the majority of states are working on comprehensive consumer privacy legislation.
- ***Increased Business Focus on Sustainability:*** Businesses continue to realize that a focus on sustainability is increasingly essential to operating efficiently and meeting the increasing demands and expectations of customers and stakeholders for environmental responsibility. Such pressures are driving proper disposal of pharmaceuticals, recycling efforts, shred-all policies for paper and other initiatives supported by our services.

Stable and Recurring Customer Needs Supported by Long-term Contracts

The services we provide most often require service on a routine and scheduled basis. The majority of our customer relationships include long-term contracts ranging from three to five years in length. We have developed a strong and loyal customer base, with a revenue retention rate of approximately 90% (based on our internal customer attrition analysis) in 2023.

Established Network of Processing and Transportation Locations

Our infrastructure network results in an expansive operational network with alternate transportation, treatment, destruction, and recycling options for our customers. The scale of our network also provides us the ability to be the single-source provider for customers with multiple locations across the country and gives us the flexibility to quickly redirect services or operations to another location if the need arises due to severe weather, power outages, or other disruptions.

Our goal is to optimize our facilities with a strategic and standardized operating model. We are analyzing processing capabilities, plant and transportation equipment needs, team member requirements, and potential customer implications or benefits. This planning process also provides opportunities to focus on reducing our environmental impact by optimizing our transportation network to reduce miles driven and overall greenhouse gas impact. We anticipate that modernizing our plant equipment with new efficient technology will also lessen our overall energy consumption per operating cycle. Over the past three years, we have opened several new greenfield autoclave facilities (New Jersey, California, Ireland, and United Kingdom) and completed over 20 upgrade projects, including improvements to autoclaves, shredders, washers and enhanced conveyance, and sharps processing. These new and improved facilities and upgrades represent the initial steps in modernizing our global facility network which we plan to expand in future periods. In 2022, we began constructing a commercial HMIWI in Nevada that we expect to complete in the first half of 2024 and begin testing.

Routing Logistics

While we manage large volumes of waste and secure information for destruction, the average volume per customer site is relatively small and the resulting revenue per stop is low. As such, route logistics and route efficiency are a core focus. Our transportation network provides us with an advantage compared to our competition in many of the markets we serve. Additionally, we have continued to focus on route density and optimization at both the individual truck and geographic market level. By optimizing locations of our new facilities and executing our transportation and long-haul plan, we are now driving fewer miles per month, on average. We expect that the North America ERP implementation will continue to provide greater visibility to data which will continue to enable additional routing and operational efficiencies.

Industry Leadership and Expertise

Based on our infrastructure and revenues, we maintain a leadership position across many of our services lines, including regulated waste and secure information destruction. We employ experienced team members who have a deep understanding of the industries they serve, the regulatory climate and the evolving needs of our customers. We collaborate regularly with a wide range of stakeholders and interest groups. Starting in 2020, the Company took a leadership position related to the management of COVID-19 pandemic waste, supporting our customers and providing industry expertise regarding the effective management of COVID-19 waste. In 2014, we were tasked by the DOT and CDC to dispose of waste from the Ebola outbreak. We proactively work with organizations like the CDC, DEA, EPA, OSHA and many other government and regulatory bodies, including law enforcement. Our experts are frequent speakers at hospital networks and industry trade associations and actively engage in numerous community meetings each year.

Human Capital Management

Workforce Overview

As of December 31, 2023, our workforce is over 13,500 team members, with 97% of them employed full-time. We engage approximately 1,300 global contingent workers, supplementing our team to fill temporary positions or as a part of a temporary-to-permanent recruiting program. The year over year decrease in team members was primarily attributed to divestitures and workforce management through careful hiring, attrition, and targeted workforce reduction.

Our 2023 voluntary turnover rate, excluding turnover due to divestitures, averaged approximately 22%. In 2022 our voluntary turnover rate, excluding turnover due to divestitures, averaged approximately 28%.

As of December 31, 2023, 10% of our total global workforce was covered by collective bargaining agreements or works councils. There are 19 collective agreements in the U.S. and Canada, covering approximately 720 team members or 7% of our North American workforce. Approximately 680 team members outside North America are covered by collective bargaining agreements or works councils. We engage in good faith bargaining with the works councils and unions that represent our team members.

Diversity and Inclusion

At Stericycle, embracing the diversity and inclusion of our workforce is one of our core values. In 2023, approximately 22% of our global workforce were women, including 33% in middle management and 29% in leadership positions (directors and above). The racial and ethnic diversity of our U.S. workforce was comprised of White, 45%; Black or African American, 27%; Hispanic/Latino, 22%; Multi-Ethnic or Other, 4%; and Asian, 2%; with 55% of our team members identifying as minorities.

During 2023, 67% of U.S. new hires and 51% of internal promotions were from federally designated racial or ethnic minority categories. We hired approximately 180 team members during 2023 who identified as U.S. veterans.

We believe our seven employee resource groups (ERGs) help drive engagement and representation and support team members who are Women, Black and African American, Latinx, Veterans, members of the LGBTQ+ (lesbian, gay, bisexual, transgender, and queer) community, young professionals, and team members and their family members who have disabilities. We routinely leverage our ERGs to address important social topics with our team members through "Let's Talk About It" video discussion, "FIERCE Cafe", and other internal discussions. Additionally, during 2023, our ERGs provided educational communications to our team members; hosted speaker events; led company celebrations for Black History Month, Hispanic Heritage Month, Pride Month, Veterans Day, and other days of diversity awareness or celebration; and provided mentoring programs for Women, Black and African Americans, and Veterans. We also launched an Unconscious Bias training program in 2023.

Compensation

In 2023, we continued our market-based compensation analyses which included pay equity analysis and identification of potential pay gaps. We independently consulted with third-parties on our pay practices and policies to ensure equitable pay across employee groups. We remain committed to a routine review of the competitiveness and equity of our team members' compensation, with the next detailed analysis occurring in 2025. Additionally, we continue to monitor and comply with state laws around pay transparency.

Safety

At Stericycle, a commitment to safety is one of our core values. We focus on a comprehensive safety program to protect our team and the communities in which we operate and drive our safety performance.

In 2023, our safety improvement journey included a comprehensive focus on developing centralized procedures, processes and monitoring as well as investment in new training programs to increase safety awareness. During 2023, our safety program included:

- a global expansion of our comprehensive defensive driving program;
- a continuation of our Corporate Integrated Audit Program, ensuring compliance with our policies and procedures as well as applicable laws and regulations;
- a monthly safety global coaching and communications program; and
- a weekly published Safety Exchange with themed procedures and best practices.

To further our safety objective and measure our progress, we track key safety metrics, Total Recordable Incident Rate (TRIR), which is calculated by multiplying the total number of recordable workplace injuries or illnesses by 200,000 and dividing by the total hours worked ((Injuries x 200,000) / Hours), and Severe Vehicle Incident Rate (SVIR), which is calculated by multiplying the total severe vehicle incidents by 200,000 and dividing by the total hours worked ((Injuries x 200,000) / Hours), which are components of team member total compensation.

Our Operating Environment

Competition

The industries and markets in which we operate are highly competitive on pricing and barriers to entry are low. Our competitors consist of many different types of service providers, including national, regional and local companies. Some of these companies provide only a portion of the services of Stericycle - for example, just collection and transportation, but not treatment of regulated waste.

In the regulated waste and secure information destruction industries, another source of competition is on-site management. For regulated waste, some large-quantity waste generators, particularly hospitals, may choose an onsite autoclave or other treatment process. For secure information destruction, many businesses may choose to use small, on-site shredders for their documents. In both regulated waste and secure information destruction, we believe there is no other competitor in North America with Stericycle's overall scale, breadth of services, national transportation network and comprehensive treatment network in our two core businesses.

Governmental Regulation

Stericycle's RWCS and SID services, are subject to numerous regulations, which may evolve over time. We are subject to substantial regulations enacted and enforced by governments within the U.S. and the international jurisdictions in which we conduct operations. In many countries, there are multiple regulatory agencies at the local and national level that oversee our customers and/or our services. The regulatory requirements with which we must comply vary from jurisdiction to jurisdiction. The laws governing our domestic and international operations generally consist of statutes and regulations concerning environmental protection; employee and public health and safety; transportation; document destruction and management; data privacy; ethical business conduct; and the management of regulated waste streams, including regulations that govern the definition, generation, segregation, handling, packaging, transportation, treatment, storage and disposal of regulated waste.

This regulatory framework imposes a variety of compliance requirements, including requirements to obtain and maintain government permits or other authorizations. We maintain governmental permits, registrations and licenses to conduct our business throughout the jurisdictions in which we operate. Our permits vary by jurisdiction based upon our activities within that jurisdiction and on the applicable laws and regulations of that jurisdiction. These permits grant us the authority to, among other things, construct and operate transfer and processing facilities; transport regulated waste within and between relevant jurisdictions; and handle particular regulated substances. Our permits, registrations and licenses may be subject to modification or revocation by the issuing authority and, in some jurisdictions, are subject to periodic renewal. Permit issuance or renewal may also be subject to public participation.

Various U.S. and international laws and regulations related to data privacy and the protection of confidential information also apply to Stericycle's RWCS and SID services, including HIPAA and the CCPA in the U.S. and the GDPR in Europe. In addition, laws governing ethical business practices apply to our business including, but not limited to, the FCPA, and the U.K. Bribery Act. These laws may apply to our business on both a global and local basis and ban unethical behavior such as the payment of bribes to government officials for the purpose of gaining an improper business advantage, improper maintenance of our books and records, as well as other financial transparency requirements.

Environmental Protection

Our business is subject to extensive and evolving environmental regulations in the geographies in which we operate. Generally, the environmental laws that we are subject to regulate the handling, transportation, treatment and disposal of waste, the release or potential release of hazardous substances into the environment, the discharge of pollutants into waterways and the emission of pollutants into the air. The principal environmental laws that govern our operations in the U.S. are the federal Clean Air Act and Clean Water Act, in addition to state laws and regulations governing regulated waste. Examples of environmental laws applicable to our international operations include the Waste Framework Directive, Environmental Liabilities Directive, Industrial Emissions Directive and the Shipments of Waste Regulations in the EU, and the Canadian Environmental Protection Act and related regulations in Canada.

Climate and Sustainability

Consistent with our Company's commitment to sustainability and environmental protection, we have published our 2023 Corporate Social Responsibility Report (CSRR), providing details on our environmental, social and governance (ESG) performance. The information in this report can be found at https://investors.stericycle.com but it does not constitute a part of, and is not incorporated by reference into, this Annual Report on Form 10-K.

Employee Health and Welfare

We are subject to numerous regulations promulgated to protect and promote employee health and welfare through the implementation and enforcement of standards designed to prevent illness, injury and death in the workplace. The primary U.S. federal laws relating to employee health and welfare applicable to our business are overseen by OSHA, which establishes specific employer responsibilities including implementing engineering controls, administrative controls, training, policies and programs to comply with the regulations, and recordkeeping and reporting, all to ensure a safe workplace. Various OSHA standards apply to almost all aspects of our operations and govern such matters as exposure to bloodborne pathogens, hazard communication, and PPE.

Examples of employee health and welfare laws applicable to our international operations include the European Framework Directive on Safety and Health at Work (Directive 89/391 EEC) and various provisions of the Canada Labour Code and related occupational safety and health regulations in the provinces and territories of Canada.

Transportation

Various laws regulating the transportation of waste and other potentially hazardous materials also apply to the services we provide. In the U.S., the DOT has established regulations which deal with two different aspects of transportation: hazardous materials transport and safety in transportation. These regulations are defined within the PHMSA and the FMCSA. We are regularly subject to roadside inspections. These inspections have a cumulative effect on our compliance history and require us to remain in good standing so as not to jeopardize our permits.

Examples of transportation laws applicable to our international operations include the Directive on the Inland Transportation of Dangerous Goods in the EU, and the Transport of Dangerous Goods Act, and related regulations in Canada, and globally the International Maritime Dangerous Goods Code, and the IATA Dangerous Goods Regulations.

Controlled Substances

Our service offerings for the collection, treatment, and disposal of controlled substance waste, from both the healthcare industry and individual consumers, are subject to numerous laws and regulations governed by various regulatory agencies, including the DEA. These regulations typically require our facilities to obtain licenses or registrations, and meet other certain requirements for approval to collect, transport, treat and dispose of controlled substances. These regulations have very prescriptive requirements for security, recordkeeping and reporting. Like other regulatory schemes, registrations/licenses must be kept current, and facilities may be subject to inspection or enforcement.

U.S. and Foreign Local Regulation for Waste Management

We conduct business in all 50 U.S. States and Puerto Rico. Because the U.S. EPA does not regulate medical waste at the federal level, each state has its own regulations related to the handling, treatment and storage of regulated medical waste. Many states have followed requirements similar to the Medical Waste Tracking Act of 1988 or have placed regulated medical waste regulations within solid waste regulations. Regulated Garbage (i.e., international food waste) is another waste stream that is subject to unique regulatory requirements that are promulgated and enforced by the USDA and U.S. Customs and Border Protection. The USDA typically inspects our facilities receiving Regulated Garbage waste on a quarterly basis.

In each state where we operate a processing facility or a transfer station, we are required to comply with varying state and local laws and regulations, which may also require a specific operating plan. In addition, many local governments have ordinances and regulations, such as zoning or wastewater regulations, that affect our operations. Similarly, our international operations are subject to regulations enacted and enforced at the provincial, municipal, and local levels of government in addition to the national regulations with which we must comply.

Insurance and Self-Insurance

The regulated waste industry involves potentially significant risks of statutory, contractual, tort and common law liability claims. Potential liability claims could involve, for example: cleanup costs, personal injury, damage to the environment, employee matters, property damage including fleet vehicles, or alleged negligence or professional errors or omissions in the planning or performance of work. We also could be subject to fines or penalties in connection with violations of regulatory requirements.

We carry insurance that include property, workers compensation, general liability, employer's liability, pollution liability, privacy and security liability, cyber-liability, directors and officers and miscellaneous professional services errors and omissions coverage. We also carry umbrella policies that cover general liability, automobile and employers' liability. We regularly evaluate other lines of coverage to respond to specific business needs but consider our current insurance coverage to be sufficient to meet regulatory as well as customer requirements and to protect our employees, assets and operations.

Patents, Trademarks and Proprietary Rights

Stericycle holds a number of patents or applications in the U.S., Canada, the U.K., and Europe for technologies related to its business, including our patented innovation, SMS Revolution, which modernizes our processing of sharps, and innovations for the recovery of reusable medical devices in a sharps container, various waste container assemblies, a lockable mounting bracket for use with a waste container assembly, and a three-stage shredder.

We own federal registrations for a number of trademarks/service marks including Stericycle®, Shred-it®, We Protect What Matters®, SafeShield®, Steri-Safe®, SafeDrop®, Artech®, Community Shred-it®, Making Sure it's Secure®, Virtual Compliance Partner®, the Stericycle logo service mark consisting of a nine-circle design and the Shred-it logo. We also hold international registrations for Stericycle and the Stericycle and Shred-it logos, among others.







11

11A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

(This application cannot be used by PA's or APRN's)

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☐ Schedule I ☑ Schedule II ☑ Schedule III ☑ Schedule IV ☑ Schedule V

Section 1: Personal Information

First: Jonathan Middle: Joel Last: Runion

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Home Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Degree: DDS Practitioner License #: 8128 Specialty: Dentist

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled substance registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Bionic Smile Khanna PLLC

Practice Address: 4416 S Eastern Ave Suite #:

City: Las Vegas State: NV Zip: 89119

Telephone: 702-868-2274 Fax: 702-369-6980 Email: admin@bionicsmile.com

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	X	
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	X	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	X	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?	X	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

[redacted]

Original Signature (electronic, copies or stamps not accepted)

10.11.24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jonathan Runion — 10.11.24

Print Name [redacted] — Date

10.11.24

Original Signature (electronic, copies or stamps not accepted) — Date

Board Use Only: Date Processed: 10/21/24 Amount: $700.00 CC

Ohio State Dental Board
77 S. High Street, 17th Floor
Columbus, Ohio 43215-6135

(614) 466-2580 Tel
(614) 752-8995 Fax
Dental.Ohio.Gov

Kumar Subramanian DDS, President

November 8, 2022

Jonathan J. Runion, DDS
[redacted]

RE: Case # 17-25-1225

Dear Dr. Runion:

On or about July 26, 2017, you entered into a Consent Agreement with the Ohio State Dental Board, wherein your license to practice dentistry was subject to probationary terms, conditions and limitations for a minimum of five (5) years.

You have complied with the conditions of the Consent Agreement and have fulfilled the probationary terms. Your license to practice dentistry in Ohio is now fully restored.

Your cooperation in this matter has been greatly appreciated.

Sincerely,
OHIO STATE DENTAL BOARD
Supervisory Investigative Panel

KATHY BRISLEY-SEDON, DDS
Secretary

CANISE Y. BEAN, DMD, MPH
Vice Secretary

KBS/CB/hm

Ohio State Dental Board
77 S. High Street, 17th Floor
Columbus, Ohio 43215-6135

(614) 466-2580 Tel
(614) 752-8995 Fax
Dental.Ohio.Gov

November 9, 2017

Jonathan Runion, D.D.S.
[redacted]

Re: In the Matter of Jonathan Runion, D.D.S.

Dear Dr. Runion:

The purpose of this letter is to confirm that at its meeting on November 8, 2017, the Ohio State Dental Board (Board) considered the reinstatement of your license to practice dentistry in the state of Ohio.

The Board voted to REINSTATE your dental license, not to exceed twenty (20) hours per week, until further notice. Please be advised that you are subject to the probationary terms set forth in your Consent Agreement.

If you have any questions or concerns, please contact the Board office.

Sincerely,
OHIO STATE DENTAL BOARD
Supervisory Investigative Panel

PATRICIA P. GUTTMAN, DDS
Secretary

KUMAR SUBRAMANIAN, DDS
Vice Secretary

PG/KS/hm

CONSENT AGREEMENT
BETWEEN
JONATHAN J. RUNION, D.D.S.
AND
THE OHIO STATE DENTAL BOARD

RECEIVED
MAY 18 2016
OHIO DENTAL BOARD

This CONSENT AGREEMENT is entered into by and between, JONATHAN RUNION, D.D.S., (DR. RUNION) and THE OHIO STATE DENTAL BOARD, (BOARD), the state agency charged with enforcing the Dental Practice Act, Chapter 4715 of the Ohio Revised Code.

DR. RUNION voluntarily enters into this AGREEMENT being fully informed of his rights under Chapter 119, Ohio Revised Code, including the right to representation by counsel and the right to a formal adjudication hearing on the issues considered herein.

This CONSENT AGREEMENT is entered into on the basis of the following stipulations, admissions and understandings:

A. The OHIO STATE DENTAL BOARD is empowered by Section 4715.30(A)(10), Ohio Revised Code, to limit, revoke, suspend a certificate or license, refuse to register or reinstate an applicant, or reprimand or place on probation the holder of a certificate or license for "inability to practice under accepted standards of the profession because of physical or mental disability, dependence on alcohol or other drugs, or excessive use of alcohol or other drugs."

B. DR. RUNION is currently licensed to practice dentistry in the State of Ohio, License No. 30.023280.

C. The OHIO STATE DENTAL BOARD enters into this CONSENT AGREEMENT in lieu of formal proceedings based upon any alleged violations of Section 4715.30(A)(10). The BOARD expressly reserves the right to institute formal proceedings based upon any other violations of Chapter 4715 of the Ohio Revised Code whether occurring before or after the effective date of this AGREEMENT.

WHEREFORE, in consideration of the foregoing and mutual promises hereinafter set forth, and in lieu of any further formal proceedings at this time, DR. RUNION knowingly and voluntarily agrees with the BOARD, to the following terms, conditions and limitations:

1. DR. RUNION's license to practice dentistry is indefinitely suspended. It is expressly understood that during this period of suspension the following conditions shall apply:

    a. DR. RUNION may employ a licensed operator, i.e., dentists, and dental hygienists, and dental assistant radiographers to perform dentistry or dental hygiene duties or otherwise treat patient during the period of suspension.

b. DR. RUNION may derive income from a legal or beneficial interest in a dental practice.

c. Continued advertising is permissible during the term of the suspension.

2. The BOARD shall not consider reinstatement of DR. RUNION's license to practice dentistry unless all of the following minimum requirements have been met:

a. DR. RUNION shall provide to the BOARD a written report of evaluation by a treating practitioner, approved by the BOARD, indicating that DR. RUNION is no longer drug or alcohol dependent and is able to practice dentistry in accordance with the accepted standards of the profession. This evaluation shall be in writing and shall state with particularity the basis for such determination

b. DR. RUNION shall provide the BOARD with documentation from an approved treatment provider that he has successfully completed a **minimum of 28 day** residential treatment and is in compliance with any aftercare or outpatient treatment.

c. DR. RUNION shall provide satisfactory documentation of continuous participation in a BOARD approved aftercare program.

d. DR. RUNION shall provide satisfactory documentation of continuous participation in a Caduceus program, no less than one day per week.

e. DR. RUNION shall provide satisfactory documentation of continuous participation in AA or NA, **no less than three days per week**, or as otherwise directed by the BOARD.

f. DR. RUNION shall provide evidence of his attendance in an aftercare program, AA or NA, and Caduceus program to the BOARD to be received by the fifth day of each month.

g. The BOARD considers each week to begin on Sunday and end on Saturday.

Initials 

h. DR. RUNION shall attend ALL required meetings weekly, including vacations, conferences, travel, etc. If for whatever reason, DR. RUNION absolutely cannot attend a required meeting(s) he shall submit a written explanation, including supporting documentation if applicable. The documentation shall be received in the BOARD office as far in advance as possible, or within five (5) days after any missed meeting, for review by the Supervisory Investigative Panel (PANEL) to determine if the absence will be accepted.

i. DR. RUNION shall appear before the BOARD at a regularly scheduled meeting for a reinstatement interview.

j. DR. RUNION shall report to the BOARD, **within one (1) business day**, any relapses in his recovery.

3. Upon reinstatement, DR. RUNION's license shall be subject to the following PROBATIONARY terms, conditions and limitations for a period of five (5) years:

a. DR. RUNION shall obey all federal, state and local laws, and all rules governing the practice of dentistry in Ohio.

b. DR. RUNION shall submit monthly declarations, to be received by **the fifth day of each month**, under penalty of BOARD disciplinary action stating whether there has been compliance with all the conditions of this CONSENT AGREEMENT.

c. DR. RUNION shall appear in person for quarterly interviews before the BOARD or its designated representative, or as otherwise directed by the BOARD.

d. In the event that DR. RUNION should leave Ohio for three (3) continuous months, or reside or practice outside the state, DR. RUNION must notify the BOARD in writing of the dates of departure and return. Periods of time spent outside Ohio will not apply to the reduction of this period under the CONSENT AGREEMENT, unless otherwise determined by motion of the BOARD in instances where the BOARD can be assured that probationary monitoring is otherwise being performed.

Initials _____

e. In the event DR. RUNION is found by the PANEL to have failed to comply with any provision of this CONSENT AGREEMENT, and is so notified of that deficiency in writing, such periods of noncompliance will not apply to the reduction of the probationary period under this CONSENT AGREEMENT.

f. DR. RUNION shall abstain completely from the personal use or possession of drugs, except those prescribed, dispensed or administered to him by another so authorized by law who has full knowledge of DR. RUNION's chemical dependency and the terms of this CONSENT AGREEMENT.

g. DR. RUNION shall abstain completely from the use of alcohol.

h. DR. RUNION shall participate in a BOARD approved aftercare program. Participation must be for a minimum of one (1) year or until successful completion of the program, whichever occurs later. On a monthly basis, DR. RUNION shall submit to the BOARD acceptable documentary evidence of continuing compliance with this program. Failure to comply with any terms or conditions of the aftercare program may result in an automatic suspension of DR. RUNION's license to practice dentistry prior to the issuance of a notice of opportunity and an administrative hearing.

i. DR. RUNION shall maintain participation in AA or NA **no less than three days per week**, or as otherwise directed by the BOARD. On a monthly basis, DR. RUNION shall submit to the BOARD acceptable documentary evidence of continuing compliance with this program. Failure to comply with terms of this paragraph may result in an automatic suspension of DR. RUNION's license to practice dentistry prior to the issuance of a notice of opportunity and an administrative hearing.

j. DR. RUNION shall participate in a Caduceus program, no less than one day per week, for a minimum of fifty-two (52) weeks from the date of reinstatement. On a monthly basis, DR. RUNION shall submit to the BOARD acceptable documentary evidence of continuing compliance with this program.

After attending and submitting proof of his attendance at a Caduceus program for a minimum of fifty-two (52) weeks, DR. RUNION may request permission, in writing, to replace his

Initials

weekly Caduceus meeting with an additional AA or NA meeting for the remainder of his probationary period. Upon receipt of written permission from the BOARD, DR. RUNION shall have the option to attend AA or NA **no less than four days** per week during any week in which no Caduceus program was attended.

k. DR. RUNION shall provide evidence of his attendance in an aftercare program, AA or NA, and Caduceus program to the BOARD to be received **by the fifth day of each month** during his term of probation.

l. The BOARD considers each week to begin on Sunday and end on Saturday.

m. DR. RUNION shall attend ALL required meetings weekly, including vacations, conferences, travel, etc. If for whatever reason, DR. RUNION absolutely cannot attend a required meeting(s) he shall submit a written explanation, including supporting documentation if applicable. The documentation shall be received in the BOARD office as far in advance as possible, or within five (5) days after any missed meeting, for review by the PANEL to determine if the absence will be accepted.

n. Further, the BOARD reserves the right to require and DR. RUNION agrees to submit random blood or urine specimens for analysis upon request and without prior notice. DR. RUNION shall submit to this random test within five (5) hours of being contacted by the BOARD, and shall submit results of such screening to the BOARD within seven (7) business days of the screening. Failure to comply with the terms of this paragraph may result in an automatic suspension of DR. RUNION's license to practice dentistry prior to the issuance of a notice of opportunity and an administrative hearing.

o. DR. RUNION shall report to the BOARD, **within one (1) business day**, any relapses in his recovery.

p. It is expressly agreed that DR. RUNION's license to practice dentistry shall automatically be suspended indefinitely prior to the issuance of a notice of opportunity and an administrative hearing, should any specimen test positive for alcohol/drugs, with the exception of such drugs consistent in such amounts

Initials _____

prescribed, dispensed or administered to him by another so authorized by law who has full knowledge of DR. RUNION's chemical dependency and the terms of this CONSENT AGREEMENT.

Furthermore, it is expressly agreed that DR. RUNION's license to practice dentistry shall be immediately and automatically suspended prior to the issuance of a notice of opportunity and an administrative hearing, should DR. RUNION refuse to submit to a chemical test(s) of his blood, breath, or urine for purposes of determining his alcohol and/or drug content or if he is convicted of an offense involving operation of a vehicle while under the influence of drugs or alcohol.

q. DR. RUNION shall enter into an agreement with Ohio Physician's Health Program ("OPHP") or another Board approved screening program.

r. If DR. RUNION fails to comply with the terms and conditions of this CONSENT AGREEMENT, DR.RUNION may be subjected to an automatic suspension of his license to practice dentistry prior to the issuance of a notice of opportunity and an administrative hearing. In the event that DR. RUNION's license to practice dentistry is automatically indefinitely suspended, during the period of suspension, DR. RUNION **may not**: 1) employ a licensed operator, i.e., dentists, and dental hygienists, and dental assistant radiographers to perform dentistry or dental hygiene duties or otherwise treat patients during the period of suspension, nor may any corporation, business, partnership or business entity owned in part or whole by DR. RUNION employ or enter into a legal contract with a licensed operator to perform dental or dental hygiene duties during the period of this suspension; or, 2) derive income from a legal or beneficial interest in a dental practice.

s. Upon successful completion of his probationary terms, DR. RUNION must appear before the BOARD or its designated representatives before the BOARD will fully restore DR. RUNION's license.

t. DR. RUNION agrees that if, in the discretion of the PANEL, he appears to have violated or breached any term or condition of this CONSENT AGREEMENT, the BOARD has the right to

Initials _____

institute formal disciplinary proceedings for any and all possible violations or breaches, including but not limited to, alleged violations of the laws or rules of Ohio occurring before the effective date of this CONSENT AGREEMENT

Any action initiated by the BOARD based on alleged violations of this CONSENT AGREEMENT shall comply with the Administrative Procedure Act, Chapter 119, Ohio Revised Code.

DR. RUNION acknowledges and understands that this CONSENT AGREEMENT shall be considered a public record as that term is used in Section 149.43, Ohio Revised Code and may be reported to any appropriate data bank or reporting agency. DR. RUNION acknowledges that his social security number will be used if the information is so reported, and DR. RUNION agrees to provide his social security number to the BOARD for such purposes.

DR. RUNION, with the intention of binding himself and his successors in interests and assigns, holds harmless from liability and forever discharges the State of Ohio, the BOARD, and any of their members, officers, attorneys, agents, and/or employees, personally or in their official capacities, from any and all claims that were raised or could have been raised in or relating to this matter, including but not limited to costs, expenses, attorney fees and/or all other damages.

DR. RUNION acknowledges that he has had adequate opportunity to ask questions concerning the terms of this CONSENT AGREEMENT and that all questions asked have been answered in a satisfactory manner.

WHEREFORE, In consideration of the mutual promises contained herein, and subject to the conditions and limitations stated herein, the BOARD hereby foregoes any disciplinary proceeding against DR. RUNION pending successful completion of these terms and conditions.

It is expressly understood that this CONSENT AGREEMENT is subject to ratification by the BOARD prior to signature by the President, Secretary and Vice Secretary and shall become effective upon the last date of signature below.

[redacted]

DR. RUNION, D.D.S.

7.6.17

DATE

Counsel for DR. RUNION

DATE

Initials

OHIO STATE DENTAL BOARD

Constance Clark
CONSTANCE CLARK, R.D.H.
President

7/26/17
DATE

Pat P. Gutt
PATRICIA GUTTMAN, D.D.S.
Secretary

7-26-17
DATE

KUMAR SUBRAMANIAN, D.D.S.
Vice Secretary

07/26/17
DATE

Katherine Bockbrader
KATHERINE BOCKBRADER
Assistant Attorney General

7-24-17
DATE

Initials

U. S. Department of Justice - Drug Enforcement Administration

DEA USE ONLY

File No.

VOLUNTARY SURRENDER OF CONTROLLED SUBSTANCES PRIVILEGES

With the understanding that I am not required to surrender my controlled substances privileges, I freely and under no duress, implied or express, execute this document and choose to take the actions described herein.

☑ In view of my alleged failure to comply with the Federal requirements pertaining to controlled substances, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part;

☐ In view of my desire to terminate handling of controlled substances listed in schedule(s) _____;

I hereby voluntarily surrender my Drug Enforcement Administration Certificate of Registration, unused order forms, and all my controlled substances listed in Schedule(s) II-V as evidence of my intent to relinquish my privilege to handle controlled substances listed in Schedule(s) II-V.

I understand that submission of this document to DEA, including any employee of DEA, shall result in the immediate termination of my registration (and if not all controlled substances privileges are surrendered, be issued a new registration certificate limited to Schedule(s) N/A).

I understand that I am not entitled to a refund of any payments made by me in connection with my registration.

I understand that, beginning on the date that I sign below, I am not authorized to order, manufacture, distribute, possess, dispense, administer, prescribe, or engage in any other controlled substance activities whatsoever, except (if applicable) as limited above.

NAME OF REGISTRANT (Print)	ADDRESS OF REGISTRANT
Dr. Jonathan Runion DDS	1110 Beecher Crossing N., Suite A Gahanna, Ohio 43230
DEA REGISTRATION NO. FR2068965	
SIGNATURE OF REGISTRANT OR AUTHORIZED INDIVIDUAL [redacted]	DATE 9-19-17

WITNESSES

NAME AND DATE	TITLE
[redacted]	SS
NAME AND DATE	TITLE

PRIVACY ACT

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (21 U.S.C 821).

PURPOSE: Permit voluntary surrender of controlled substances.

ROUTINE USES: The Controlled Substances Act Registration Records produce special reports as required for statistical analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
C. Persons registered under the Controlled Substances Act (21 U.S.C. 822 and 957) for the purpose of verifying the registration of customers and practitioners.

EFFECT: Submission of this information is voluntary. There is no effect on the individual if not provided

FORM DEA-104 (11/11) *Previous editions obsolete*

Franklin County Municipal Court

DRUG EDUCATION PROGRAM
ENTRY OF SUCCESSFUL PROGRAM COMPLETION

FILED
Franklin County Municipal Court

AUG 17 2020

LORI M. TYACK, CLERK
By _____ Deputy Clerk

Jonathan Runion — **2020 CRB 4310**
Defendant — **Case Number**

The guilty plea accepted on 3/9/2020 or the above case as required in order to obtain admission to the Drug Education Program (DEP), is hereby vacated on: 8/17/2020. The case is hereby dismissed in accordance with Administrative Order 02-2004 and Local Rule 8.04 due to successful completion of the program by the defendant. The coinciding Community Control on this case is hereby terminated as well.

8/17/2020
Date

Judge David Tyack

CERTIFICATE OF COMPLETION

FRANKLIN COUNTY MUNICIPAL COURT

DEP

8/17/2020

Jonathan Runion

FILED
Franklin County Municipal Court
AUG 17 2020
LORI M. TYACK, CLERK
By _____ Deputy Clerk

Judge David Tyack

RC/H.A.R.T. Staff

IN THE FRANKLIN COUNTY MUNICIPAL COURT
COLUMBUS, OHIO

In re: APPLICATION FOR THE SEALING OF THE RECORDS OF : 2020 CR X 50937

: [redacted]

:

JONATHAN J RUNION : Year/Case No.2020 CR B 004310

[redacted]

FILED
Franklin County Municipal Court
NOV 16 2020
LORI M. TYACK, CLERK
By _____ Deputy Clerk

ENTRY

This matter is before the Court on an application for the sealing of records under R.C. 2953.52.

The Court held a hearing on 11/16/20
The applicant was not present/present/represented by JAMES P. TYACK
The government was not present/represented by _____

Having heard the arguments of the parties and having considered R.C. 2953.52 and any objection by the prosecutor,

☐ the application is **DENIED** based on the Court's finding(s) that:
- ☐ the applicant was not found not guilty or the complaint was not dismissed.
- ☐ criminal proceedings are pending against the applicant.
- ☐ the charge(s) cannot be sealed pursuant to R.C. 2953.61 (multiple charges, same act)
- ☐ the applicant's interests to have the records sealed are outweighed by a legitimate governmental need to maintain the records.

☒ the application is **GRANTED** based on the Court's findings that (1) the applicant was found not guilty or the complaint was dismissed; (2) there are no pending criminal proceedings against the applicant; (3) the interests of the applicant in having the records sealed are not outweighed by any legitimate governmental need to maintain the records.

It is ordered that all official records pertaining to the case be sealed and, except as provided in R.C. 2953.53(D), all index references to the case be deleted.

It is further ordered that no officer or employee of the state, or any political subdivision thereof, shall knowingly release, disseminate, or make available for any purpose involving employment, bonding, or licensing in connection with any business, trade, or profession to any person, or to any department, agency or other instrumentality of the state or any political subdivision thereof, any information or other data concerning any arrest, complaint, trial, hearing, adjudication, conviction, or correctional supervision, the records of which have been sealed pursuant to this order, except as authorized by R.C. 2953.55.

☐ BCI	☐ CPD	☐ FCSO	☐ Applicant	☐ Other:

No Obj. filed
Approved/Disapproved by Prosecuting Attorney

This Entry is a final, appealable order. **IT IS SO ORDERED.**

NOV 16 2020
Date
EXDSM.FRM

JUDGE TYACK

This is to certify that this is a true and accurate copy of the original entry as the same appears upon the records of the court.
Lori M. Tyack, Clerk
1/28/2021
_____ Deputy Clerk

JAMES TYACK
[redacted]

11B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

(This application cannot be used by PA's or APRN's)

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☑ Schedule I ☑ Schedule II ☑ Schedule III ☑ Schedule IV ☑ Schedule V

Section 1: Personal Information

First: John Middle: Henry Last: Vennochi

Date of Birth [redacted] SSN or ITIN [redacted] Sex: ☑ M ☐ F ☐ X

Home Address: [redacted]

City [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Degree: DMD Practitioner License #: 2510 Specialty: General Dentist

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled substance registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): College of Southern Nevada Dental Faculty Practice

Practice Address: 6375 West Charleston Blvd. Suite #: A500

City: Las Vegas State: NV Zip: 89146

Telephone: 702-651-5510 Fax: 702-651-7383 Email: patientservicesdfp@csn.edu

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case # 99-526		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Please see attached

[redacted]

Original Signature (electronic, copies or stamps not accepted)

5/7/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Vennochi

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

5/7/2024

Date

5/7/24

Date

Board Use Only: Date Processed: 5/28/24 Amount: $200-cc

Credentials	Practitioner Name	Speciality Details	Location	Status	Public Health	Action

Full Name :	Vennochi, John Henry , DMD
Primary Office Address :	7180 Cascade Valley Ct, Suite 240
City, State Zip :	Las Vegas, NV 89128
Office Phone :	
License Number :	2510
License Date :	03/22/1989
Status :	Active
Expiration Date :	06/30/2025
Graduated From :	Massachusetts-Tufts University School of Dental Medicine
Graduation Date :	06/01/1981

Permits :

Permit	Permit Number	Issue Date	Exp Date

Board Action / Malpractice :

Action Type	Date	Document Link
Board Action	05/26/2005	
Board Action	06/27/2008	
Board Action	06/01/2000	
Board Action	10/15/2010	

← Close detail

Copyright © 2018 | Nevada State Board of Dental Examiners (http://dental.nv.gov/) | All Rights Reserved

STATE OF NEVADA

BEFORE THE BOARD OF DENTAL EXAMINERS OF NEVADA

NEVADA STATE BOARD OF DENTAL EXAMINERS, Complainant, vs. JOHN H. VENNOCHI, D.M.D., Respondent.	CASE NO.: 05-1160 **STIPULATION**

IT IS HEREBY STIPULATED AND AGREED by and between JOHN H. VENNOCHI, D.D.S. (Hereinafter "Respondent"), by and through his counsel, JOHN R. LUSK, ESQ., and THE NEVADA STATE BOARD OF DENTAL EXAMINERS (hereinafter "Board") by and through Disciplinary Screening Officer, J. PAUL ANDERSON, D.M.D., D.S.O., and Board's counsel, JOHN A. HUNT, ESQ., of the law firm of RALEIGH, HUNT & McGARRY, P.C. as follows:

1. On December 13, 2002, Respondent entered into a memorandum of understanding with Zinovi Ladizhensky, a/k/a Zori Ladin, a/k/a Zori Ladizhensky, d/b/a Paradise Village Dental Center ("Zori"), wherein Zori would provide administrative/support services to Respondent.

2. On October 28, 2003, the Board notified Respondent of a verified complaint received from John Flood. On November 10, 2003, Respondent filed an answer to the complaint with the Board.

3. Based upon the limited investigation conducted to date, Disciplinary Screening Officer, J. Paul Anderson, D.M.D., applying the administrative burden of proof of substantial evidence as set forth in *State, Emp. Security v. Hilton Hotels*, 102 Nev. 606, 608, 729 P.2d 497, 498 (1986); *and see Minton v. Board of Medical Examiners*, 110 Nev. 1060, 881 P.2d 1339 (1994), see also NRS 233B.135(3)(e), but not for any other purpose, finds there is substantial evidence that Respondent rendered treatment below the standard of care to John Flood in violation of NRS

JRL JHV

RALEIGH, HUNT & McGARRY, P.C.
Law Offices
112 GARCES DRIVE
SUITE 200
LAS VEGAS, NEVADA 89101
(702) 386-4841

631.3475(1) &(4).

4. Based upon the limited investigation conducted to date, Disciplinary Screening Officer, J. Paul Anderson, D.S.O., under the administrative standard of proof as set forth in *State, Emp. Security v. Hilton Hotels*, 102 Nev. 606, 608, 729 P.2d 497, 498 (1986);, *and see Minton v. Board of Medical Examiners*, 110 Nev. 1060, 881 P.2d 1339 (1994), but not for any other purpose, finds there is substantial evidence Respondent, on more than one occasion, allowed Zori, to perform dental treatments beyond the scope of practice set forth in NAC 631.220 in violation of NRS 631.3475(1) & (4).

5. Based upon the limited investigation conducted to date, Disciplinary Screening Officer, J. Paul Anderson, D.M.D., applying the administrative burden of proof of substantial evidence as set forth in *State, Emp. Security v. Hilton Hotels*, 102 Nev. 606, 608, 729 P.2d 497, 498 (1986); *and see Minton v. Board of Medical Examiners*, 110 Nev. 1060, 881 P.2d 1339 (1994), see also NRS 233B.135(3)(e), but not for any other purpose, finds there is substantial evidence that Respondent did not report to the Board the civil malpractice lawsuit, *John J. Flood v. Mohamad Malaki, D.D.S., John H. Vennochi, D.M.D. et al*, filed on September 21, 2004, in the Eighth Judicial District Court, Case No. A492330, in violation of NAC 631.155(5).

6. The pertinent part of the statutes and regulations cited are as follows:

NRS 631.3475 The following acts among others, constitute unprofessional conduct:

1. Malpractice;

* * *

4. More than one act by the dentist or dental hygienist constituting substandard care in the practice of dentistry or dental hygiene.

NAC 631.220

A dentist who is licensed in the state of Nevada may authorize a dental assistant in his employ and under his supervision only to do one or more of the following:

1. Expose radiographs.

JRL JHV

2. Retract a patient's cheek, tongue or other tissue during a dental operation.

3. Remove the debris which normally accumulates during or after a cleaning or operation by the dentist by using mouthwash, water, compressed air or suction.

4. Place or remove a rubber dam and accessories used for its placement.

5. Place and secure an orthodontic ligature.

6. Remove sutures.

7. Place and remove a periodontal pack.

8. Remove excess cement from cemented restorations and orthodontic appliances. A dental assistant may not use a rotary cutting instrument to remove excess cement from restorations or orthodontic appliances.

9. Administer a topical anesthetic in any form except aerosol.

10. Train and instruct persons in the techniques of oral hygiene and preventive procedures.

11. Take the following types of impressions:

(a) Those used for the preparation of diagnostic models;
(b) Those used for the preparation of counter or opposing models;
(c) Those used for the fabrication of temporary crowns or bridges; and
(d) Those used for the fabrication of temporary removable appliances, provided no missing teeth are replaced by those appliances.

12. Fabricate and place temporary crowns\ and bridges. This procedure must be checked and approved by the supervising dentist before dismissal of the patient from the office of the dentist.

13. Retract gingival tissue if the retraction cord contains no medicaments that have potential systemic side effects.

14. Remove soft plaque and stain from exposed tooth surfaces, utilizing an appropriate rotary instrument with a rubber cup or brush and a suitable polishing agent. A licensed dentist or dental hygienist shall determine that the teeth to be polished are free of calculus or other extraneous material.

15. Administer a topical fluoride.

JRL JHV

16. Apply pit and fissure sealant to the dentition for the prevention of decay. This procedure must be checked and approved by the supervising dentist before dismissal of the patient from the office of the dentist.

17. Fit orthodontic bands and prepare teeth for orthodontic bands if the bands are cemented or bonded, or both, into the patient's mouth by the dentist who authorized the dental assistant to perform this procedure.

NAC 631.155
Each licensee shall, within 30 days after the occurrence of the event, notify the Board in writing by certified mail of:

*****

5. The filing and service upon him of any claim or complaint of malpractice.

7. Applying the administrative burden of proof of substantial evidence as set forth in *State, Emp. Security v. Hilton Hotels*, 102 Nev. 606, 608, 729 P.2d 497, 498 (1986);see also NRS 233B.135, *and see Minton v. Board of Medical Examiners*, 110 Nev. 1060, 881 P.2d 1339 (1994), see also NRS 233B.135(3)(e), but not for any other purpose, Respondent stipulates the rendered treatment to John Flood was below the standard of care in violation of NRS 631.3475(1) and (4).

8. Applying the administrative burden of proof of substantial evidence as set forth in *State, Emp. Security v. Hilton Hotels*, 102 Nev. 606, 608, 729 P.2d 497, 498 (1986);see also NRS 233B.135. *and see Minton v. Board of Medical Examiners*, 110 Nev. 1060, 881 P.2d 1339 (1994), see also NRS 233B.135(3)(e), but not for any other purpose, Respondent stipulates that on more than one occasion Respondent allowed Zori to perform procedures beyond the permissible scope set forth in NAC 631.220 in violation of NRS 631.3475(1) and (4).

9. Applying the administrative burden of proof of substantial evidence as set forth in *State, Emp. Security v. Hilton Hotels*, 102 Nev. 606, 608, 729 P.2d 497, 498 (1986);see also NRS 233B.135, *and see Minton v. Board of Medical Examiners*, 110 Nev. 1060, 881 P.2d 1339 (1994), see also NRS 233B.135(3)(e), but not for any other purpose, Respondent stipulates that he failed to report to the Board the filing of the civil malpractice complaint, *John J. Flood v. Mohamad Malaki, D.D.S., John H. Vennochi et al*, filed in the Eighth Judicial District Court, Case No. A492330, in

JRL JHV

violation of NRS 631.155.

10. Based upon the stipulations contained in paragraphs 7, 8 and 9, the parties have agreed to resolve the pending disciplinary action pursuant to the following terms:

a. Pursuant to NRS 631.350(h), Respondent's dental practice shall be supervised for a period of two (2) years from the adoption of this Stipulation. During the two (2) year period, Respondent shall allow either the Executive Director of the Board and/or the agent appointed by the Executive Director of the Board to inspect Respondent's records and observe the daily operation of Respondent's dental practice during normal business hours without notice to insure compliance of this Stipulation. The supervision shall include, but will not be limited to, personally observing the treatment rendered to patient(s) as well as contacting patients who have received treatment. In the event the Board's Executive Director finds there is substantial evidence Respondent has refused to either allow the copying of patient records or observation of Respondent's practice during the supervisory period, the Executive Director, shall automatically without any further action by the Board, issue an order suspending Respondent's license to practice dentistry in the State of Nevada. Thereafter, Respondent may request a hearing before the Board. Respondent agrees to waive any right to seek injunctive relief from either the Nevada Federal District Court or the Nevada State District Court to reinstate his license prior to the Board having a hearing and issuing a final order determining whether there was substantial evidence to justify the Executive Director's suspension of Respondent's license to practice dentistry in Nevada. In the event Respondent does not actively practice dentistry in the State of Nevada, the supervisory period shall be tolled for the period of inactive practice.

b. Pursuant to NRS 631.350(h), during the two (2) year supervisory period, Respondent agrees to the following conditions:

i. Patient(s) may not receive treatment(s) or be seated in an operatory unless there is a dentist licensed in the State of Nevada physically present or unless a hygienist licensed in the State of Nevada is performing hygiene treatments in compliance with NRS and NAC 631;

ii. Respondent shall obtain a written acknowledgment from present and future employees and/or independent contractors that they have received and read a copy of this Stipulation. Respondent shall maintain the written acknowledgment(s) in Respondent's office for inspection.

iii. In the event the Board's Executive Director finds there is substantial evidence Respondent has violated any of the provisions contained in either paragraph 10(b)(i) or 10(b)(ii) during the supervised period the Executive Director shall, automatically without any further action by the Board, issue an order suspending Respondent's license to practice dentistry in the State of Nevada. Thereafter, Respondent may request a hearing before the Board. Respondent agrees to waive any right to seek injunctive relief from either the Nevada Federal District Court or the Nevada State District Court to reinstate his license prior to the Board having a hearing and issuing a final order determining whether there was substantial evidence to justify the Executive Director's suspension of Respondent's license to practice dentistry in Nevada.

JRL JHV

c. Based upon the stipulation set forth in paragraph 8, and the anticipated continuing relationship between Respondent and Zori, Respondent agrees as long as Zori performs any services in any capacity to Respondent, Respondent agrees to the following conditions:

i. Zori, shall not at any time perform dental assisting duties as set forth in either NRS or NAC 631 while associated with Respondent or any other licensed dentist in Nevada;

ii. Zori is prohibited from being physically present at any time in the operatory(s) when patient(s) are seated in a dental chair;

iii. Zori is prohibited from participating in the negotiation of any disputes between Respondent and/or dentist or hygienist employed by Respondent regarding the treatment(s) of patient(s). Resolution of any disputes with patients must be contained in a patient's chart and sign off by Respondent; and

iv. In the event the Board's Executive Director finds there is substantial evidence Respondent has violated any of the provisions contained in either paragraph 10(c)(i) or 10(c)(ii) or 10(c)(iii), the Executive Director shall, automatically without any further action by the Board, issue an order suspending Respondent's license to practice dentistry in the State of Nevada. Thereafter, Respondent may request a hearing before the Board. Respondent agrees to waive any right to seek injunctive relief from either the Nevada Federal District Court or the Nevada State District Court to reinstate her license prior to the Board having a hearing and issuing a final order determining whether there was substantial evidence to justify the Executive Director's suspension of Respondent's license to practice dentistry in Nevada.

d. Pursuant to NRS 631.350(k), in addition to completing the required continuing education, Respondent shall obtain a total of twenty-four (24) additional hours of supplemental education. Twelve hours (12) hours of supplemental education must be received in the area of diagnosis and treatment planning and twelve (12) hours of supplemental education must be received in the area of fixed prosthetics. All supplemental education must be completed within two (2) years of the approval of this Stipulation by the Board. The supplemental education must be submitted in writing to the Executive Director of the Board for approval prior to attendance. Upon receipt of a written request to attend supplemental education the Executive Director of the Board shall notify Respondent in writing whether the requested supplemental education is approved for attendance. All costs associated with this supplemental education shall be paid by Respondent. In the event Respondent fails to complete all of the supplemental education within two (2) years, Respondent agrees his license to practice dentistry in the State of Nevada shall automatically be suspended without any further action of the Board other than the issuance of an order by the Executive Director. Upon submitting written proof of completion of the supplemental education, Respondent's license to practice dentistry in the State of Nevada will be automatically reinstated. Respondent agrees to waive any right to seek injunctive relief from any Federal or State of Nevada District Court to prevent the automatic suspension of Respondent's license to practice dentistry in the State of Nevada due to Respondent's failure to comply with Paragraph 10(d). Respondent shall also be responsible for any costs or attorney's fees incurred in the event the Board has to seek

JRL JHV

injunctive relief to prevent Respondent from practicing dentistry during the period Respondent's license is automatically suspended.

e. Respondent agrees to reimburse the Board for costs of the investigation and to monitor this Stipulation in the amount of Seven Thousand Five Hundred Dollars ($7,500.00), pursuant to the following payment schedule:

i Prior to the adoption of this Stipulation, Respondent shall deliver the initial sum of Three Thousand Dollars ($3,000.00) to the Board. If the Board does not adopt this Stipulation the Three Thousand Dollars ($3,000.00) will be returned in full to Respondent.

ii. Thereafter, for the next twenty-four (24) months, on the first business day of each month, Respondent shall deliver to the Board's office located at 6010 S. Rainbow Blvd. Bldg. A, Suite 1, Las Vegas, Nevada, the sum of One Hundred Eighty-Seven and 50/100 Dollars ($187.50) to satisfy the remaining balance due of Four Thousand Five Hundred Dollars ($4,500.00) for costs of this investigation and to monitor this Stipulation.

f. Pursuant to NRS 631.350(1), Respondent agrees to reimburse, Mr. John Flood the amount of Ten Thousand Dollars ($10,000.00) pursuant to the following payment schedule:

i Prior to the adoption of this Stipulation, Respondent shall deliver the initial sum of One Thousand Dollars ($1,000.00) to the Board. If the Board does not adopt this Stipulation the One Thousand Dollars ($1,000.00) will be returned in full to Respondent.

ii. Thereafter, for the next twenty-four (24) months, on the first business day of each month, Respondent shall deliver to the Board's office located at 6010 S. Rainbow Blvd. Bldg. A, Suite 1, Las Vegas, Nevada, the sum of Three Hundred Seventy-Five Dollars ($375.00) to satisfy the remaining balance due of Nine Thousand Dollars ($9,000.00) to reimburse Mr. John Flood.

g. In the event Respondent fails to deliver any of the payments required pursuant to Paragraph 10(e) or 10 (f), Respondent agrees his license to practice dentistry in the State of Nevada shall automatically be suspended without any further action of the Board other than issuance of an order by the Executive Director. Failure to deliver payment would include any checks returned for insufficient funds. Respondent agrees to the payment of twenty-five dollars ($25.00) for each day Respondent fails to deliver any of the payments required by Paragraph(s) 10(e) or 10(f). Respondent may cure any default regarding the payments set forth in Paragraph 10(e) or 10(f), by delivering to the Board's Executive Director the total amount in default, plus the twenty-five dollar ($25.00) per day assessment. Upon receipt of payment in full of any amount in default, plus the twenty-five dollar ($25.00) per day assessment, the Executive Director shall without any further action of the Board reinstated Respondent's license to practice dentistry in the State of Nevada, assuming there are no other violations of any of the provisions contained in this Stipulation. Respondent agrees to waive any right to seek injunctive relief from either the Nevada Federal District Court or the Nevada State District Court to reinstate his license prior to curing any default on the amounts due and owing.

JRL JHV

h. In the event Respondent fails to cure any default in payment within forty-five (45) days of the default, Respondent agrees the amount may be reduced to judgment.

i. Respondent waives any right to have the amounts owed pursuant Paragraph 10(e) or 10(f) discharged in bankruptcy.

j. Respondent, pursuant to NRS 631.350(1)(j), shall retake the jurisprudence test as required by NRS 631.240(2) on the contents and interpretation of NRS 631 and the regulations of the Board. Respondent shall have ninety (90) days assuming adoption of the Stipulation to complete the re-examination. The jurisprudence examination is administered on the first Monday of each month at 10:00 a.m. and 2:00 p.m. at the Board's office. Respondent shall contact the Board to schedule a time to submit to the re-examination. In the event Respondent fails to successfully complete the re-examination within ninety (90) days of adoption of this Stipulation, Respondent agrees his license to practice dentistry in the State of Nevada shall be automatically suspended without any further action of the Board other than issuance of an order by the Executive Director. Upon successful completion of the re-examination, Respondent's license to practice dentistry in the State of Nevada will be automatically reinstated. Respondent agrees to waive any right to seek injunctive relief from any Federal or State of Nevada District Court to prevent the automatic suspension of Respondent's license to practice dentistry in the State of Nevada due to Respondent failure to comply with Paragraph 10(j). Respondent shall also be responsible for any costs or attorney's fees incurred in the event the Board has to seek injunctive relief to prevent Respondent from practicing dentistry during the period Respondent's license is automatically suspended.

k. Respondent agrees a representative of the Board shall make a presentation to Respondent's staff regarding the scope of practice of dental assistants and those procedures which the staff may perform in compliance with NRS 631 and NAC 631.

CONSENT

11. Respondent has read all of the provisions contained in this Stipulation and agrees with them in their entirety.

12. Respondent is aware by entering into this Stipulation he is waiving certain valuable due process rights contained in, but not limited to, NRS 631, NAC 631, NRS 233B and NAC 233B.

13. Respondent expressly waives any right to challenge the Board for bias in deciding whether or not to adopt this Stipulation in the event this matter was to proceed to a full Board hearing.

14. Respondent has reviewed the Stipulation with his attorney, John R. Lusk, Esq., who has explained each and every provision contained in this Stipulation to the Respondent.

15. Respondent acknowledges he is consenting to this Stipulation voluntarily, without

JRL JHV

coercion or duress and in the exercise of his own free will.

16. Respondent acknowledges no other promises in reference to the provisions contained in this Stipulation have been made by any agent, employee, counsel or any person affiliated with the Nevada State Board of Dental Examiners.

17. Respondent acknowledges the provisions in this Stipulation contain the entire agreement between Respondent and the Board and the provisions of this Stipulation can only be modified, in writing, with Board approval.

18. Respondent agrees in the event the Board adopts this Stipulation he hereby waives any and all rights to seek judicial review or otherwise to challenge or contest the validity of the provisions contained in the Stipulation.

19. This Stipulation will be considered by the Board in an open meeting. It is understood and stipulated the Board is free to accept or reject the Stipulation and, if the Stipulation is rejected by the Board, further disciplinary action may be implemented. This Stipulation will only become effective when the Board has approved the same in an open meeting. Should the Board adopt this Stipulation, such adoption shall be considered a final disposition of a contested case. Respondent acknowledges and agrees of this Stipulation shall be made available to the public inspection and copying. Respondent acknowledges and agrees copies of this Stipulation may be disseminated by the Board to the public, or any licensing board or any agency which is investigating Respondent, including but not limited to any law enforcement agency. Respondent agrees and acknowledges this Stipulation shall be reported to the National Practitioners Data Bank.

DATED this 17th day of March, 2005.

JOHN H. VENNOCHI, D.M.D.
Respondent

///

///

///

JRL

JHV

SUBSCRIBED and SWORN to before me this 17th day of March, 2005.

NOTARY PUBLIC

GENELLE L. PRESCOTT
Notary Public State of Nevada
No. 96-1450-1
My appt. exp. Dec. 16, 2006

APPROVED AS TO FORM & CONTENT

JOHN A. HUNT, ESQUIRE
Raleigh, Hunt & McGarry, P.C.
Board Counsel

APPROVED AS TO FORM & CONTENT

J. PAUL ANDERSON, D.M.D., D.S.O.
Disciplinary Screening Office/Informal
Hearing Officer

APPROVED AS TO FORM & CONTENT

JOHN R. LUSK, ESQ.
Attorney for Respondent

The foregoing Stipulation was approved/disapproved by a vote of the Nevada State Board of Dental Examiners at a properly noticed meeting.

DATED this 6 day of June, 2005.

NEVADA STATE BOARD OF DENTAL EXAMINERS

TONY GUILLEN, D.D.S.
President

S:\Eileen.Hwp5]\DENTAL\VENNOCHAINP.STIP Dis\stipulation.wpd

JRL

JHV

BEFORE THE NEVADA STATE BOARD OF DENTAL EXAMINERS

NEVADA STATE BOARD OF DENTAL EXAMINERS, Complainant, vs. JOHN VENNOCHI, DMD Respondent.	CASE NO: 07-1519

NOTICE OF ENTRY OF FINDINGS AND RECOMMENDATIONS OF THE INFORMAL HEARING HELD PURSUANT TO NRS 631 AND NAC 631 & CONSENT OF JOHN VENNOCHI, DMD TO THE FINDINGS AND RECOMMENDATIONS PURSUANT TO N.R.S. § 631.363(5)

TO: Respondent, JOHN VENNOCHI, DMD; and

TO: JOHN R. LUSK, ESQ., Respondent's attorney:

YOU, AND EACH OF YOU WILL PLEASE TAKE NOTICE that the Findings and Recommendations of the Informal Hearing Held Pursuant to NRS 631 and NAC 631 & Consent of John Vennochi, DMD To The Findings and Recommendations Pursuant to N.R.S. 631.363(5) was entered in the above-entitled matter on June 27, 2008, a copy of which is attached hereto.

RESPECTFULLY SUBMITTED this 21 day of July, 2008.

FOX ROTHSCHILD, LLP

John A. Hunt, Esq.
Nevada Bar No. 1888
3800 Howard Hughes Pkwy., Suite 500
Las Vegas, Nevada
Attorneys for Complainant

: Rothschild LLP
) Howard Hughes Parkway
e 500
Vegas, Nevada 89169

CERTIFICATE OF MAILING

I HEREBY CERTIFY that on the 21 day of July, 2008, I served a true copy of the above and foregoing **NOTICE OF ENTRY OF FINDINGS AND RECOMMENDATIONS OF THE INFORMAL HEARING HELD PURSUANT TO NRS 631 AND NAC 631 & CONSENT OF JOHN VENNOCHI, DMD TO THE FINDINGS AND RECOMMENDATIONS PURSUANT TO N.R.S. § 631.363(5)** by causing same to be deposited in the United States Mail, at Las Vegas, Nevada, in a sealed envelope, first class postage thereon fully prepaid, addressed as follows:

John R. Lusk, Esq.
517 South Third Street
Las Vegas, NV 89101
Attorney for Respondent

Employee of Fox Rothschild, LLP

BEFORE THE NEVADA STATE BOARD OF DENTAL EXAMINERS

NEVADA STATE BOARD OF DENTAL EXAMINERS, Complainant, vs. JOHN VENNOCHI, DMD Respondent.	CASE NO: 07-1519

FINDINGS AND RECOMMENDATIONS OF THE INFORMAL HEARING HELD PURSUANT TO NRS 631 AND NAC 631
&
CONSENT OF JOHN VENNOCHI, DMD TO THE FINDINGS AND RECOMMENDATIONS PURSUANT TO N.R.S. § 631.363(5)

I.

INTRODUCTION

1. On December 10, 2007, an informal hearing was held in Las Vegas, Nevada, regarding alleged violations of chapter 631 of the Nevada Revised Statutes ("NRS") and chapter 631 of the Nevada Administrative Code ("NAC") by licensee, JOHN VENNOCHI, DMD. The informal hearing was held pursuant to NRS § 631.363 and NAC §§ 631.250 and 631.255.

2. In attendance at the informal hearing was J. GORDON KINARD, D.D.S., Informal Hearing Officer assigned to this matter; Debra Shaffer, Deputy Executive Director of the Board and Board attorney, JOHN A. HUNT, ESQ., licensee, JOHN VENNOCHI, D.M.D. (hereinafter referred to as "Respondent" or "Dr. Vennochi"), and his attorney, JOHN R. LUSK, ESQ.

Fox Rothschild LLP
3800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169

3. Discussed at length during the informal hearing was the following matters:

A. Whether Respondent had administered, dispensed or prescribed any controlled substance or any dangerous drugs drug as defined in Chapter 454 of NRS to Patients "A", "B" , "C", "D", "E" or "F" that were not required for a dental treatment in violation of NRS 631.3475(5).

B. Whether Respondent issued any controlled substances on more than one occasion as defined in Chapter 454 to Patients "A", "B" , "C", "D", "E" or "F" while Respondent did not possess a valid license to prescribe control substances from the Nevada State Board Pharmacy in violation of NRS 631.3485(2) or NAC 631.230(1)(d) and/or NRS 631.349.

C. Whether Respondent failed to provide the records for Patients "A", "B" , "C", "D", "E" or "F" in violation of NRS 631.3485(4) or NAC 631.230(1)(q) and/or NAC 631.240(1)(c).

D. Whether Respondent's record keeping for Patients "A", "B" , "C", "D", "E" or "F", was in violation of NRS 631.3475(4) and/or NAC 631.230(1)(c).

E. Whether Respondent issued prescriptions for controlled substances for Patients "A", "B" , "C", "D", "E" or "F" in such excessive amounts to constitute a departure from prevailing standards of acceptable dental practice in violation of NAC 631.230(1)(b).

Fox Rothschild LLP
3800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169

F. Pursuant to NRS 629.061(4) the identity of Patients "A", "B" , "C", "D", "E" or "F" must remain anonymous. Respondent has been provided with the identity of Patients "A", "B" , "C", "D", "E" and "F" and each were discussed during the course of the Informal Hearing held on December 10, 2007.

II.

FINDINGS OF FACT

4. Based upon the investigation conducted to date; the information presently available for review, including Dr. Vennochi's response to questions posed during the informal hearing, Dr. J. Gordon Kinard, as the Informal Hearing Officer assigned, issues for following findings of fact:

A. According to the testimony of Respondent, prior to 1993 a patient of Respondent acquired Respondent's prescription pad and issued numerous unauthorized prescriptions. As a result the Massachusetts Dental Board conducted an investigation. On March 27, 1997 an Order to Show Cause was made by the Massachusetts Dental Board charging that Respondent had issued eleven (11) prescriptions for controlled substances to different patients which were not issued for a legitimate medical purposed in the usual course of Respondent's dental practice and Respondent's conduct in issuing the eleven (11) prescriptions did not meet the generally accepted standards of the practice of dentistry. As a result of the Order to Show Cause, Respondent entered into a Consent Agreement with the Massachusetts Dental Board dated September 3, 1997. Pursuant to the terms of the Consent Agreement Respondent, without admitting guilt, consented to the findings that sufficient facts existed from which the Board

could conclude that regarding four of the eleven prescriptions were not issued for a legitimate medical purposed in the usual course of Respondent's dental practice and did not meet the generally accepted standards of the practice of dentistry in violation of G. .L. c . 94C, s. 19(a) and G. L. C. 112, s. 61. As a result Respondent was placed on probation for a minimum of two (2) years and Respondent was required to attend drug and alcohol counseling and submit to random drug testing.

B. On June 1, 2000, Respondent entered into a Stipulation with the Board consenting and agreeing to the following pertinent terms and conditions:

> (1). Respondent did not contest and consented to a finding that Respondent violated NRS 631.3475(5), which states the following acts, among other, constitute unprofessional conduct:
>
> ". . . .5. Administering, dispensing or prescribing any controlled substance or any dangerous drug as defined in chapter 454 of NRS, if it is not required to treat the dentist's patient;. . . ."
>
> (2). Respondent did not contest and consented to a finding that Respondent violated NAC 631.230(1)(b) which states the following acts, among other, constitute unprofessional conduct:
>
> " . . . .(b) Writing prescriptions for controlled substances in such excessive amounts as to constitute a departure from prevailing standards of acceptable dental practice.. . . ."
>
> (3). Respondent did not contest and consented to a finding that his charting and record keeping practices violated NRS 631.075, NRS 631.095, NRS 631.3475(4), and NAC 631.230(1)(c).
>
> (4). Respondent did not contest and consented to a finding that Respondent tested positive for illegal drugs on July 6, 1999.
>
> (5). Respondent agreed to suspension of his license to practice dentistry in the

State of Nevada for a period of six (6) months, effective from the date the Board approves this Stipulated Settlement.

(6). Respondent agreed to attend sixteen (16) hours of supplemental education in the field of pharmacology and pain management prior to completion of the six (6) month suspension period.. . . .

(7). Respondent agreed to submit to random sampling of urine and/or bodily fluids for a period of five (5) years when so ordered by the Executive Director of the Board. In addition to the random drug tests which may be ordered during the five (5) year period, for one (1) year subsequent to the Board's adoption of this Stipulated Settlement, Respondent agreed to submit to urinalysis testing on the first day of the each month at Associated Pathology Laboratories (APL). . . .

. . . . .

(8). Respondent agreed to surrender his license No. CS7855 with the Nevada State Board of Pharmacy, to prescribe controlled substances for Class II, Class II-N, Class III, Class III-N, Class IV and Class V for a period of five (5) years commencing from the time the Respondent originally entered into a Stipulation with the Board on July 6, 1999. . . . .

(9). Respondent agrees to surrender his Registration Certificate No. BV3942477 with the United States Department of Justice, D.E.A., to prescribe controlled substances for Class II, Class II-N, Class III, Class III-N, Class IV and Class V for a period of five (5) years commencing from the time the Respondent originally entered into a Stipulation with the Board on July 6, 1999. . . . .

(10). Respondent's agreed his practice would be supervised for a period of five (5) years to review patient records to assure Respondent's prescription practice are in compliance with NRS 631 and NAC 631. . . . . Respondent was required to maintain, for a period of five (5) years, a list of any prescriptions issued to any of Respondent's patients by any other licensed dentist in the State of Nevada. The list of prescriptions to Respondent's patients written by any other license dentist in the State of Nevada had to include patient's name, date of issuance, licensed dentist who issued the prescription, units and amount of prescription narcotics issued.. . . . .

(11). Respondent agreed to a fine in the amount of $2,000.00 for violations of NRS 631 and NAC 631, . . .

. . . .

(12). Respondent agreed to reimburse the Board the sum of $9500.00 for the cost of this investigation and subsequent monitoring. . . . .

Respondent successfully completed the terms and conditions of the Stipulation entered with the Board on May 31, 2005.

C. On June 13, 2005, Respondent entered into a Second Stipulation with the Board consenting and agreeing to the following pertinent terms and conditions:

(1). Respondent agreed his dental practice would be supervised for a period of two (2) years from the adoption of this Stipulation. . . . .

(2). During the two (2) year supervisory period, Respondent agreed to the following conditions:

i. Patient(s) may not receive treatment(s) or be seated in an operatory unless there is a dentist licensed in the State of Nevada physically present or unless a hygienist licensed in the State of Nevada is performing hygiene treatments in compliance with NRS and NAC 631;

ii. Respondent shall obtain a written acknowledgment from present and future employees and/or independent contractors that they have received and read a copy of this Stipulation. Respondent shall maintain the written acknowledgment(s) in Respondent's office for inspection.

. . .

(3). Based upon the anticipated continuing relationship between Respondent and Zori, Respondent agreed as long as Zori performs any services in any capacity to Respondent, Respondent agreed to the following conditions:

i. Zori, shall not at any time perform dental assisting duties as set forth in either NRS or NAC 631 while associated with Respondent or any other licensed dentist in Nevada;

ii. Zori is prohibited from being physically present at any time in the operatory(s) when patient(s) are seated in a dental chair;

iii. Zori is prohibited from participating in the negotiation of any disputes between Respondent and/or dentist or hygienist employed by Respondent regarding the treatment(s) of patient(s). Resolution of any disputes with patients must be contained in a patient's chart and sign off by Respondent; and

. . . .

(4). Respondent agreed to obtain a total of twenty-four (24) additional hours

Fox Rothschild LLP
3800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169

of supplemental education. Twelve hours (12) hours of supplemental education must be received in the area of diagnosis and treatment planning and twelve (12) hours of supplemental education must be received in the area of fixed prosthetics. . . . .

(5). Respondent agreed to reimburse the Board for costs of the investigation and to monitor this Stipulation in the amount of Seven Thousand Five Hundred Dollars ($7,500.00) . . . .

(6). Respondent agreed to reimburse, Mr. John Flood the amount of Ten Thousand Dollars ($10,000.00) . . . .

. . . .

(7). Respondent, agreed to retake the jurisprudence test as required by NRS 631.240(2) on the contents and interpretation of NRS 631 and the regulations of the Board.. . . .

(8). Respondent agreed a representative of the Board would make a presentation to Respondent's staff regarding the scope of practice of dental assistants and those procedures which the staff may perform in compliance with NRS 631 and NAC 631.

Respondent successfully completed the terms and conditions of the Stipulation entered with the Board on June 12, 2007.

D. Respondent failed to renew his controlled substances registration (CS07588) with the Nevada State Board of Pharmacy prior to the renewal dead line of October 31, 2006.

E. On May 30, 2007, Respondent attempted to reinstate his controlled substances registration (CS07588) by submitting a license renewal application with the Nevada State Board of Pharmacy . Upon submission of the application of renewal from May 30, 2007 until October 17. 2007, Respondent did not receive any correspondence from the Nevada State Board of Pharmacy reinstating Respondent's controlled substances registration (CS07588). During the

Fox Rothschild LLP
3800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169

period of October 31, 2006 until submission of his application for renewal on May 30, 2007, Respondent issued a number of prescriptions for controlled substances while not possessing a valid license to issued controlled substances in the State of Nevada. From May 30, 2007 when Respondent submitted his application to reinstate his controlled substance registration (CS07588) through October 17, 2007, Respondent issued a number of prescriptions for controlled substances while not possessing a valid license to issued controlled substances in the State of Nevada.

F. On June 21, 2007 at a properly noticed meeting the Board approved and authorized an investigation whether Respondent had possibly violated NRS 631.3475(5) regarding patients "A" and "B". On July 17, 2007, Respondent was given notice of the authorized investigation complaint. On July 30, 2007, Respondent submitted answer to the authorized investigation complaint which included but was not limited to Respondents contention that Patient "A" has forged Respondent signature on the prescriptions in question for Patients "A", "B" and "C". On October 16, 2007, Respondent was given supplemental information and documentation obtained by the Board during the course of the investigation regarding Patients "A" and "B". On October 24, 2007, Respondent submitted a supplemental response to the authorized investigation complaint stating the prescriptions issued to Patients "A", "B" , and "C", on October 17, 2006, December 4, 2006, December 11, 2006, January 12, 2007, February 26, 2007 and April 17, 2007 were forgeries.

G. On October 17, 2007 the Board received a copy of correspondence from Louis Ling, General Counsel for the Nevada State Board of Pharmacy to Respondent regarding Respondent's status with the Pharmacy Board. General Counsel Louis Ling stated the

Fox Rothschild LLP
3800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169

following:

(1). Respondent did not timely renew his controlled substances registration (CS07588) by October 31, 2006. Therefore Respondent's registration lapsed as of November 1, 2006 which meant Respondent could not lawfully prescribe, possess, administer or dispense, controlled substances in Nevada effective November 1, 2006.

(2). On May 30, 2007, Respondent submitted a late renewal application along with a check. The check was not deposited by the Pharmacy Board. That Respondent did not receive any indication from the Pharmacy Board that Respondent's registration was renewed.

(3). Respondent's renewal was not processed and would not be possessed until the pending investigation with the Nevada State Board of Dental Examiners was resolved

H. On October 23, 2007, Respondent was served with a Notice of Inspection of Patient Records for Patients "D", "E" and "F".

I. On October 24, 2007, Respondent sent correspondence to the Culinary Free Pharmacy indicating a generic Rx pad had been stolen from his practice in October 2006. Subsequently there had been numerous Rx written for Lortab 10. Those Rx's were all made out to Patients "A", "B" , and "C", and that all were forgeries. Respondent further instructed the Culinary Free Pharmacy not to fill any prescriptions written on Paradise Village Dental Center Rx paper and to contact Respondent immediately.

J. On October 31, 2007, Respondent was served with the Notice of Informal Hearing and a Subpoena Duces Tecum regarding Patients "A", "B", "D", "E" and "F".

K. On December 10, 2007 an Informal Hearing was held at Respondent's attorney's office located at 517 South Third Street , Las Vegas, Nevada. Those individuals present were Respondent, his attorney John R. Lusk, Esq., Disciplinary Screening Officer James G. Kinard,

Debra A. Shaffer, Board Deputy Executive Director and Board Counsel John A. Hunt, Esq.

L. The Massachusetts Consent Order dated September 3, 1997; the Stipulation with the Board date June 1, 2000; and the present authorized investigation complaint dated July 17, 2007; all involved whether Respondent issued of controlled substances that were either not related to dental treatments or involved. The Massachusetts Consent Order and the present authorized complaint both involve the issuance of forged prescription using of Respondent's prescription pads.

M. At the Informal Hearing held on December 10, 2007, Respondent gave the following testimony:

i. Respondent did not have any records for Patients "A". "B" or "C" related to the prescriptions issued and discussed to these patients. Respondent believes these prescriptions to be forgeries.

ii. Respondent has been aware since 1998 he could do a self profile with the Nevada State Board of Pharmacy, but Respondent has never done a self profile.

iii. Respondent acknowledges since November 1, 2006, Respondent has issued on more than one occasion prescriptions for controlled substances while not possessing a valid license with the Nevada State Board of Pharmacy.

iv. Respondent did not report on his attempted license renewal of May 30, 2007 the Consent Order with the Massachusetts Dental Board or the Second Stipulation entered into with the Nevada State Board of Dental Examiners to the Nevada State Pharmacy Board .

v. Since receiving the authorized investigation complaint of July 17, 2007, Respondent never reported to the Nevada State Board of Pharmacy, but did report in writing to the Disciplinary Screening Officer on July 30, 2007, Respondent's contention that ~~his~~ the prescription pad at his prior practice had been stolen by Patient "A" who was also an employee of Respondent who he believes wrote other forged prescriptions to for Patient "A", "B" and "C". October 24, 2007 three months after Respondent's belief his prescription pad had be stolen by Patient "A", Respondent wrote

Fox Rothschild LLP
1800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169

to the Culinary Free Pharmacy regarding his suspicions regarding Patient "A" and not to fill any prescriptions made to Patient "A", "B" or "C" and to contact Respondent.

vi. Respondent does not have any dental records or treatment plan regarding a prescription for a controlled substance written to Patient "D" on September 22, 2007 while Respondent did not possess a valid license to issue controlled substances with the Nevada State Board of Pharmacy. It is Respondent's contention that the treatments received by Patient "D" subsequently on January 11, 14 and 22 2008 related to the prescription issued to Patient "D" on September 22, 2007.

vii. Respondent does not have any dental records or treatment plan regarding a prescription for a controlled substance written to Patient "E" on January 11, 2007 while Respondent did not possess a valid license to issue controlled substances with the Nevada State Board of Pharmacy.

viii. Respondent while he did not possess a license with the Nevada State Board of Pharmacy issued three (3) prescriptions to Patient "F" on April, 20, 2007, April 24, 2007 and April 28, 2007; each prescription was written for 20 units of Hydrocodone Bitartrate and Acetaminophen, 500 mg; 7.5 mg tablet. The April 28, 2007 prescription did not appear in the dental records of Patient "F".

II.

CONCLUSIONS OF LAW

5. Based upon the findings of facts cited above; the investigation conducted to date; the limited information presently available for review and Respondent's responses to questions posed during the informal hearing, Dr. J. Gordon Kinard, as the Informal Hearing Officer assigned, issues for following conclusions of law:

A. It is the finding of the Informal Hearing Officer, based upon the limited information presently available, that there is substantial evidence Respondent had administered,

Fox Rothschild LLP
3800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169

dispensed or prescribed controlled substances or dangerous drugs drug as defined in Chapter 454 of NRS to Patient "E" that were not required for a dental treatment in violation NRS 631.3475(5).

B. It is the finding of the Informal Hearing Officer, based upon the limited information presently available, that there is substantial evidence that Respondent issued controlled substances on more than one occasion as defined in Chapter 454 to Patients "D", "E" or "F" while Respondent did not possess a valid license to prescribe control substances from the Nevada State Board Pharmacy in violation of NRS 631.3485(2) or NAC 631.230(1)(d) and/or NRS 631.349.

C. It is the finding of the Informal Hearing Officer, based upon the limited information presently available, that there is substantial evidence that Respondent failed to provide the records for Patients "D", "E" or "F" in violation of NRS 631.3485(4) or NAC 631.230(1)(q) and/or NAC 631.240(1)(c).

D. It is the finding of the Informal Hearing Officer, based upon the limited information presently available, that there is substantial evidence that Respondent's record keeping for Patients "D", "E" or "F", was in violation of NRS 631.3475(4) and/or NAC 631.230(1)(c).

E. It is the finding of the Informal Hearing Officer, based upon the limited

Fox Rothschild LLP
3800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169

information presently available, that there is substantial evidence that Respondent issued prescriptions for controlled substances for Patients "D", "E" or "F" in excessive amounts to constitute a departure from prevailing standards of acceptable dental practice in violation of NAC 631.230(1)(b).

III.

RECOMMENDATIONS

6. Based upon the findings of fact and conclusions of law as more fully addressed above and taking into consideration present violations are similar to the prior administrative actions taken by the Dental Board Of Massachusetts and the Nevada State Board of Dental Examiner this Informal Hearing Officer makes the following Recommendations:

A. Pursuant to N.R.S. § 631.350(b), Respondent's license to practice dentistry in the State of Nevada should be suspended for a period of four (4) months in the event Respondent consents and the Board adopts these Findings and Recommendations. TO be effective July 26, 2008 IF adopted by Board.

B. Pursuant to NRS 631.350(1)(d) s after completing the four (4) month suspension period this Informal Hearing Officer recommends Respondent be placed probation for a period of five (5) years pursuant to the following terms and conditions:

i. Respondent should surrender his license No. CS7855 with the Nevada State Board of Pharmacy, to prescribe controlled substances for Class II, Class II-N, Class III, Class III-N, Class IV and Class V for a period of five (5) years. At the end of the five (5) year probationary period Respondent should be allowed apply to have his prescription writing privileges with the Nevada State Board of Pharmacy reinstated.

Fox Rothschild LLP
3800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169

ii. Respondent should surrender his Registration Certificate No. BV9085033 with the United States Department of Justice, D.E.A., to prescribe controlled substances for Class II, Class II-N, Class III, Class III-N, Class IV and Class V for a period of five (5) years. In the event Respondent complies with all the terms of this Stipulation, at the end of the five (5) year period Respondent may apply to the D.E.A. to have his prescription privileges reinstated.

iii. The terms and conditions of the probation should be reported to the National Practitioners Data Bank. In the event Respondent does not actively practice dentistry in the State of Nevada the probationary period should be tolled for the period on inactive practice.

iv. Respondent should allow either the Executive Director of the Board and/or agent(s) appointed by the Board's Executive Director to inspect Respondent's records to ensure compliance during the probationary period. Such inspections should be performed, without notice, during normal business hours. During the probationary period Respondent may issue prescriptions for non-narcotic controlled substances pursuant to the terms set forth below. During the probationary period Respondent will prohibited from issuing any prescriptions for Class II, Class IIN, Class III, Class IIIN, Class IV, V or Class VI controlled substances. In the event a patient of Respondent requires a prescription for a Class II, Class IIN, Class III, Class IIIN, Class IV, V or Class VI controlled substance during the probationary period, Respondent will be allowed to authorized a dentist licensed in Nevada to issue such a prescription on his behalf. The prescribing dentist must physically examine the patient. The examination, prescription, and quantity must be entered into the patient's record by the prescribing dentist in his/her own handwriting unless Respondent owns or is employed in a dental practice where the dental charts of a patient are on a computerize system and where the entries can not be altered,. Respondent will be responsible for making sure these entries are in the patient's records. Respondent is prohibited from receiving any pre-signed prescription(s) from a dentist who is issuing a prescription on behalf of any of Respondent's patient(s). All prescriptions issued by Respondent during the probationary period for non-narcotic controlled substances must be in Respondent's handwriting and must have an original signature of Respondent. Respondent must maintain a copy of any prescriptions issued by Respondent for non-narcotic controlled substances. Such copies shall be attached to reports submitted on the first day on each month. During the probationary period Respondent should be allowed to place telephone prescriptions for ~~antibiotics~~. All prescriptions issued by a dentist on behalf of Respondent during the probationary period for Class II, Class IIN, Class III, Class IIIN, Class IV, V or Class VI controlled substances should be required to be in that dentist's own handwriting and must have an original signature of that dentist. Respondent should be required to maintain a copy of any prescriptions issued by a

Fox Rothschild LLP
3800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169

dentist on Respondent's behalf for Class II, Class IIN, Class III, Class IIIN, Class IV, or Class V controlled substances. Such copies shall be attached to reports submitted on the first day on each month. On the first day of each month during the probation period Respondent should be required to prepare a report listing the controlled substance prescriptions issued by any Nevada license dentist who has issued a prescription on Respondent's behalf. Attached to the report should be copies of any prescriptions issued by any Nevada licensed dentist was has issued a prescription on Respondent's behalf. The report should require the following information and shall be submitted to the Executive Director of the Board:

(a) patient's name;
(b) date of issuance;
(c) name of dentist who issued prescription;
(d) units and amount of controlled substance issued; and
(e) reason for issuing the controlled substance.

v. In the event the Board's Executive Director has substantial evidence to believe Respondent has failed to comply with any of the recommended provisions contained in Section III, 6B (iv) the Executive Director, should without further hearing or action by the Board, should issue an Order of Revocation of Respondent's license to practice dentistry in the State of Nevada. Thereafter Respondent should be allowed to petition the Board to reinstate Respondent's revoked license.

vi. Respondent should be required to physically surrender his License with the United States Department of Justice, D.E.A. to prescribe Class II, Class IIN, Class III, Class IIIN, Class IV, V and Class VI during the five (5) year probationary period. In the event the Board's Executive Director has substantial evidence to believe Respondent has either failed to physically surrender his DEA License or has prescribed any Class II, Class IIN, Class III, Class IIIN, Class IV, Vor Class VI controlled substances, the Executive Director, should without further hearing or action by the Board, issue an Order of Revocation of Respondent's license to practice dentistry in the State of Nevada. Thereafter Respondent should be allowed to petition the Board to reinstate Respondent's revoked license.

vii. Respondent should be required to physically surrender his License No. CS7855 with the with the Nevada State Board of Pharmacy to prescribed Class II, Class IIN, Class III, Class IIIN, Class IV, V and Class VI during the five (5) year probationary period. In the event the Board's Executive Director has substantial evidence to believe Respondent has either failed to physically surrender his Nevada State Board of Pharmacy License or has prescribed Class II, Class IIN, Class III, Class IIIN, Class IV, V or Class VI controlled substance, the Executive Director should without further hearing or action by the Board, shall issue an Order of Revocation of Respondent's license to practice dentistry in the State of

Fox Rothschild LLP
3800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169

Nevada. Thereafter Respondent should be allowed to petition the Board to reinstate Respondent's revoked license.

viii. During the five (5) year probationary all chart entries on patients seen or treated by Respondent should be required to be in Respondent's own hand writing unless Respondent owns or is employed in a dental practice where the dental charts of a patient are on a computerize system and where the entries can not be altered. The patient records whether entry by hand or by computer must contain the following minimum information:

1. Date of the treatment;
2. A diagnosis for every treatment performed;
3. A description of the treatment performed;
4. Amount, concentration and types of medications given;

5. Each antibiotic prescription should be in triplicate, serially numbered prescription form which have been inspected and pre-approved by the Executive Director. A copy of each antibiotic prescription should be mailed to the Board on a monthly basis. Respondent should maintain one copy in the patients dental records.

6. For emergency or problem focused evaluations, Respondent must provide a statement in the patient's words of the problem, an observation of the patient's condition, a diagnosis, and a statement of the proposed treatment.

With the exception of viii(5)above in the event Respondent owns or is employed in a dental practice where the dental charts of a patient are on a computerize system and where the entries can not be altered, Respondent will be relieved of his obligation to hand write the such notations require by viii(1) and (2) and (3) and (4) and (6).

In the event the Board's Executive Director has substantial evidence to believe Respondent has failed to comply with any of the provisions contained in Section III, 6B (viii) the Executive Director, should without further hearing or action by the Board, shall issue an Order of Revocation of Respondent's license to practice dentistry in the State of Nevada. Thereafter Respondent should be allowed to petition the Board to reinstate Respondent's revoked license.

ix. Pursuant to NRS 631.350(1)(i), Respondent should be required to perform One Hundred (100) hours of approved community service at a dental public health facility. The One Hundred (100) hours of community service should be completed within four (4) years of commencement of the

Fox Rothschild LLP
1800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169

recommended five (5) year probationary period. Respondent should be required to receive prior written approval from the Board's Executive Director before administering the community service. To receive credit for any of the community service rendered Respondent should be required to have an individual who is responsible for the community service facility attest to the amount of time Respondent has rendered treatment In the event Respondent fails to complete the One Hundred (100) hours of community service within four (4) years of commencement of the recommended five (5) year probationary period Executive Director should without any further action of the Board shall issue an Order suspending Respondent's license to practice dentistry in the State of Nevada. Upon submitting written proof to the Executive Director that Respondent has completed the One Hundred (100) hours of community service the Executive Director should be required without any further action of the Board issue an Order reinstating Respondent's license to practice dentistry in the State of Nevada.

x. Respondent should be required to reimburse the Board for costs of the investigation including but not limited to attorneys fees in the amount of $10,000.00 in event Respondent consents to these Findings and Recommendation and the Board adopts same. Assuming Respondent consents to these Findings and Recommendation and the Board adopts same, Respondent be allowed to make equal monthly payments in the amount of $166.66. The first monthly payment should be made payable to the Board, thirty (30) days from the adoption of these consented to Findings and Recommendations by the Board.

xi. Pursuant to NRS 631.350(c) the Board should impose an appropriate fine upon Respondent in the amount of $2000.00 to be delivered to the Board ~~within ninety (90) days~~ from the adoption of these consented to Findings and Recommendations by the Board . 30 days $500, remaining balance due 5th months from adoption

xii In the event Respondent fails to deliver any of the payments required pursuant to Paragraph 6(B)(xi), and/or Paragraph 6(B)(xi) Respondent license to practice dentistry in the State of Nevada should be automatically be suspended without any further action of the Board other than issuance of an order by the Executive Director. Failure to deliver payment would include any checks returned for insufficient funds. Respondent should be required to pay twenty-five dollars ($25.00) for each day Respondent fails to deliver any of the payments required by Paragraph 6(B)(xi), and/or Paragraph 6(B)(xi) Respondent should be allowed cure any default regarding the payments set forth in Paragraph 6(B)(xi), and/or Paragraph 6(B)(xi) by delivering to the Board's Executive Director the total amount in default, plus the twenty-five dollar ($25.00) per day assessment. Upon receipt of payment in full of any amount in default, plus the twenty-five dollar ($25.00) per day assessment, the Executive Director shall without any further action of the Board reinstated Respondent's license to practice dentistry in the State of Nevada, assuming there are no other violations of any of the provisions

Fox Rothschild LLP
3800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169

contained in these consented to Findings and Recommendations adopted by Board, Respondent should be required to waive any right to seek injunctive relief from either the Nevada Federal District Court or the Nevada State District Court to reinstate his license prior to curing any default on the amounts due and owing. Respondent should also be responsible for any costs or attorney's fees incurred in the event the Board has to seek injunctive relief to prevent Respondent from practicing dentistry during the period Respondent's license is automatically suspended.

xii Pursuant to NRS 631.350(1)(k), within ninety (90) days adoption of these consented to Findings and Recommendations by the Board , Respondent should be required to retake the jurisprudence test as required by N.R.S. § 631.240(2) on the contents and interpretation of chapter 631 of the Nevada Revised Statutes and the regulations of the Board. The jurisprudence examination is administered on the first Monday of each month at 10:00 a.m. and 2:00 p.m. at the Board's office. Respondent should be required to contact the Board to schedule a time to submit to the re-examination.

two years (2) from adoption of Findings/Recom

xiv. Pursuant to NRS 631.350(k), in addition to completing the required continuing education, ~~during the four (4) month suspension period~~ Respondent shall be required to obtain forty (40) additional hours in supplemental education. Twenty (20) hours should be obtained in the area of -ethics, and the remaining twenty(20) hours of supplemental education should be received in the area of record keeping. F The Respondent should be required to submit in writing to the Executive Director of the Board for approval prior to attendance. Upon receipt of a written request to attend supplemental education the Executive Director of the Board should be required to notify Respondent in writing whether the requested supplemental education is approved for attendance. Respondent agrees seventy (70%) per cent of the supplemental education shall be completed through attendance at live lecture. The remaining thirty (30%) per cent of the supplemental education may be completed through online/home study. Respondent should be required to pay all costs associated with this supplemental education. Respondent should not be allowed to commence the practice of dentistry until Respondent has completed the four (4) month suspension period and has submitted written proof of completion of the recommended supplemental education.

_____ this 27 day of June, 2008.
J. GORDON KINARD, D.D.S.
Informal Hearing Officer

Fox Rothschild LLP
3800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169

IV.

CONSENT TO FINDINGS AND RECOMMENDATIONS

N.R.S. § 631.363(5) states:

"5. If the person who was investigated agrees in writing to the findings and conclusions of the investigator, the Board may adopt that report as its final order and take such action as is necessary without conducting its own hearing on this matter."

7. I, JOHN VENNOCHI, DMD, hereby acknowledge that I have read N.R.S. § 631.363 (5). I am aware that if I decide not to consent to the Findings and Recommendations of the Informal Hearing Officer, a formal complaint may be filed against me. In the event a formal complaint is filed, I am aware I have the right to a full disciplinary hearing before the Nevada State Board of Dental Examiners.

8. I have read all of the Findings and Recommendations of Informal Hearing Officer, J. GORDON KINARD, DDS, and upon advice of my counsel, I consent to all of the Informal Hearing Officer's Findings and Recommendations.

9. I have reviewed the Findings and Recommendations of Informal Hearing Officer with my attorney, John R. Lusk, Esquire, who has explained each and every provision contained in all of the Informal Hearing Officer's Findings and Recommendations.

10. I further agree this consent in no way prohibits the Nevada State Board of Dental Examiners from using the findings, recommendations and information obtained from this investigation in future disciplinary actions.

Fox Rothschild LLP
3800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169

11. I further acknowledge that I am consenting to the Findings and Recommendations of the Informal Hearing Officer voluntarily, without coercion or duress, and in the exercise of my own free will.

12. I am aware by consenting to the Findings and Recommendations, I am admitting to all of the Findings and Recommendations as stated by the Informal Hearing Officer.

13. I am aware by consenting to the Findings and Recommendations, I am waiving all rights to seek judicial review or otherwise to challenge or contest the validity of the Findings and Recommendations contained herein.

14. I am aware that the Nevada State Board of Dental Examiners may choose not to adopt my consent to the Findings and Recommendations of the Informal Hearing Officer. The Findings and Recommendations and consent will be presented to the Board for ratification at its next properly noticed meeting. If the Board ratifies the Findings, Recommendations and Consent, such ratification will be considered a final disposition of a contested case and shall become a public record. Further copies of the ratified Findings and Recommendations shall be provided/reported to the public, appropriate agencies/entities, including but not necessarily limited to, the National Practitioners Data Bank.

15. I hereby specifically recognize, acknowledge and agree that failure on my part to fully

Fox Rothschild LLP
3800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169

satisfy all of the terms and conditions of the Findings and Recommendations of the Informal Hearing Officer, shall constitute unprofessional conduct; I further agree in the event I fail to satisfy all of the Findings and Recommendations of the Informal Hearing Officer, the Board may impose additional disciplinary penalties, upon the convening of a full Board hearing to determine solely whether I have breached any of the consented to Findings and Recommendations of Informal Hearing Officer, J. GORDON KINARD, DDS.

_____ this 27th day of June, 2008.
JOHN VENNOCHI, DMD

APPROVED AS TO FORM AND CONTENT

_____ this 27th day of June, 2008.
JOHN R. LUSK, ESQ.
Respondent's attorney

V.

ACTION BY THE BOARD

The foregoing Findings and Recommendations and Consent thereto was (circle the appropriate action):

X Approved

Disapproved

by a vote of the Nevada State Board of Dental Examiners at a properly noticed meeting.

DATED this 27th day of JUNE, 2008.

NEVADA STATE BOARD OF DENTAL EXAMINERS

_____
WILLIAM G. PAPPAS, President

Fox Rothschild LLP
3800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169

STATE OF NEVADA

BEFORE THE BOARD OF DENTAL EXAMINERS OF NEVADA

NEVADA STATE BOARD OF DENTAL EXAMINERS, Complainant, vs. JOHN H. VENNOCHI, D. M. D., Respondent.	Case No. 00-526 **STIPULATION**

IT IS HEREBY STIPULATED AND AGREED by and between JOHN H. VENNOCHI, D.M.D. (hereinafter "Respondent"), and his counsel, JOHN R. LUSK, ESQ. and THE NEVADA STATE BOARD OF DENTAL EXAMINERS (hereinafter "Board") by and through its counsel JOHN A. HUNT, ESQ., of the law firm RALEIGH, HUNT & McGARRY, P.C. as follows:

1. On March 9, 1998, the Nevada State Board of Dental Examiners notified Respondent of a verified complaint received from patient Barbara Fuchs regarding the care and treatment received by Barbara Fuchs.

2. On April 8, 1998, the Respondent filed an answer to the complaint.

3. On March 30, 1998, pursuant to a properly noticed meeting, the Board authorized an investigation of Respondent regarding his failure to report a consent decree which was entered into with the Dental Board of the State of Massachusetts, pursuant to NAC 631.155(3).

4. On May 5, 1999, Dr. Susan Jancar, the Disciplinary Screening Officer/Informal Hearing Officer assigned, notified Respondent that an Informal Hearing would be held on June 7, 1999 to discuss the care and treatment of patient Barbara Fuchs and Respondent's license renewal application.

JRL

JHV

RALEIGH, HUNT & McGARRY, P.C.
Law Offices
302 E. CARSON AVENUE
SUITE 1102
LAS VEGAS, NEVADA 89101
(702) 386-4842

5. On June 7, 1999, an Informal Hearing was held to discuss the items contained in the Notice of Informal Hearing. During the course of the Informal Hearing, pursuant to NAC 631.250, a preliminary discussion was had regarding Respondent's prescription practices as identified by the Nevada State Board of Pharmacy. Thereafter, the Informal Hearing was re-noticed for April 7, 2000.

6. On June 10, 1999, the Nevada State Board of Dental Examiners received an updated prescription profile from Keith McDonald, Executive Secretary of the Nevada State Board of Pharmacy, regarding the prescription practices of Respondent.

7. Subsequent to receiving the prescription profile from the Nevada State Board of Pharmacy, the Disciplinary Screening Officer/Informal Hearing Officer subpoenaed patient records for those individuals identified on the prescription profile from the Respondent and previous employers of Respondent.

8. Thereafter, Respondent's attorney, John Lusk, Esq., and the Board's attorney, John A. Hunt, Esq., entered into negotiations in order to protect the citizens of the State of Nevada and Respondent's due process rights. As a result of these negotiations a Stipulation was submitted and adopted by the Board on July 6, 1999 wherein Respondent voluntarily agreed not to prescribe any controlled substances for Class II, Class II-N, Class III, Class III-N, Class IV and Class V until such time as a written agreement was entered into between the Respondent and the Board allowing Respondent to resume his privilege to prescribed controlled substances.

9. Subsequent to entering into the Stipulation with the Board, Disciplinary Screening Officer/Informal Hearing Officer, Dr. Susan Jancar, continued her investigation and reviewed the subpoena documents of patients identified on the prescription profile submitted by the Nevada State Board of Pharmacy. Respondent was notified of the intention of the Disciplinary Screening Officer/Informal Hearing Officer to renotice the informal hearing and/or file a formal complaint with

LAW OFFICES OF RALEIGH, HUNT & GARRY, P.C.
302 E. CARSON AVENUE
SUITE 1102
LAS VEGAS, NEVADA 89101
(702) 386-4842

JRL

JHV

the Nevada State Board of Dental Examiners. As a result of further negotiations, the parties have agreed to resolve the pending matters pursuant to the following consents and conditions:

a. Respondent does not contest and consents to a finding that Respondent violated NRS 631.3475(5), which states the following acts, among other, constitute unprofessional conduct:

> "....
> 5. Administering, dispensing or prescribing any controlled substance or any dangerous drug as defined in chapter 454 of NRS, if it is not required to treat the dentist's patient;
>
> ...."

b. Respondent does not contest and consents to a finding that Respondent violated NAC 631.230(1)(b) which states the following acts, among other, constitute unprofessional conduct:

> "....
>
> (b) Writing prescriptions for controlled substances in such excessive amounts as to constitute a departure from prevailing standards of acceptable dental practice.
>
> ...."

c. Respondent does not contest and consents to a finding that his charting and record keeping practices violated NRS 631.075, NRS 631.095, NRS 631.3475(4), and NAC 631.230(1)(c).

d. Respondent does not contest and consents to a finding that Respondent testing positive for illegal drugs on July 6, 1999.

10. In light of Respondent's consent to a finding of violations of the provisions of NRS Chapter 631 and NAC Chapter 631, pursuant to NRS 631.350(1)(b), Respondent agrees to suspension of his license to practice dentistry in the State of Nevada for a period of six (6) months, effective from the date the Board approves this Stipulated Settlement. Respondent shall physically deliver his license to the Board's Executive Director, located at 2295-B Renaissance Drive, Las Vegas, Nevada 89119, upon approval of the Stipulation by the Board. Provided Respondent is in

RALEIGH, HUNT & GARRY, P.C.
302 E. CARSON AVENUE
SUITE 1102
LAS VEGAS, NEVADA 89101
(702) 386-4942

JRL

JHV

compliance with the conditions specified herein, the Executive Director shall return Respondent's license to him on the day that represents six (6) months from the date the Board approves this Stipulation.

11. In addition to complying with the six (6) month suspension agreed upon in Paragraph 10, Respondent also agrees to abide by the following conditions:

a. In addition to complying with the continuing education requirements of NAC 631.173, pursuant to NRS 631.350(k), Respondent agrees to attend sixteen (16) hours of supplemental education in the field of pharmacology and pain management prior to completion of the six (6) month suspensionary period. The additional sixteen (16) hours must receive the approval of the Board's Executive Director prior to attendance. All costs relating to continuing education will be borne by the Respondent.

b. Pursuant to NRS 631.350(g), Respondent agrees to submit to random sampling of urine and/or bodily fluids for a period of five (5) years when so ordered by the Executive Director of the Board. In addition to the random drug tests which may be ordered during the five (5) year period, for one (1) year subsequent to the Board's adoption of this Stipulated Settlement, Respondent will submit to urinalysis testing on the first day of the each month at Associated Pathology Laboratories (APL). Should the first day of the month fall on a Saturday or Sunday, Respondent will submit the monthly sample on the first business day of the month. Any test or analysis of bodily fluids taken shall be conducted in such a manner that the testing agency shall preserve enough of the sample to allow for subsequent independent confirmatory tests. The results of any tests or analysis of bodily fluids shall be reported to the Board. Respondent shall be responsible for all costs incurred for the analysis of urine and/or bodily fluids.

c. In the event any test or analysis of bodily fluids taken from Respondent, pursuant to the terms of this Stipulation, is positive, indicating the presence of controlled substances (not pursuant to a valid prescription), Respondent will be notified and allowed to arrange for a subsequent independent confirmatory test. Should the Respondent test positive, Respondent shall voluntarily cease practicing dentistry in the State of Nevada until such time as a full Board hearing is held to evaluate the positive findings and subsequent independent confirmatory tests.

d. Should Respondent fail to present himself for random drug testing, when directed by the Executive Director of the Board, within twenty-four (24) hours of said direction by the Executive Director, Respondent's license to practice dentistry in the State of Nevada will be revoked indefinitely

RALEIGH, HUNT & GARRY, P.C.
302 E. CARSON AVENUE
SUITE 1102
LAS VEGAS, NEVADA 89101
(702) 386-4842

JRL

JHV

without any other action by the Board other than the entry of an appropriate Order of Revocation.

e. Respondent authorizes reports generated by the urinalysis and/or bodily fluids testing, and any substance abuse evaluation reports, and any status reports rendered by individuals treating Respondent to be furnished to the Executive Director of the Board. All reports submitted to the Executive Director of the Board shall remain confidential and for use by the Board's Executive Director only. In the event of a violation in the form of a confirmed, positive test result, all reports previously submitted to the Executive Director of the Board will be available for use by the Board in connection with any subsequent disciplinary action of the Board.

f. Respondent shall notify, in writing, each of his active patients that he will not be practicing dentistry for six (6) months subsequent to the Board's adoption of this Stipulation and will inform his patients that their records will be made available so they can procure alternate dental services, if they so desire.

g. Due to Respondent's consent to a finding of violations of NRS 631 and NAC 631 contained in Paragraph 9, Respondent agrees to surrender his license No. CS7588 with the Nevada State Board of Pharmacy, to prescribe controlled substances for Class II, Class II-N, Class III, Class III-N, Class IV and Class V for a period of five (5) years commencing from the time the Respondent originally entered into a Stipulation with the Board on July 6, 1999 . In the event Respondent complies with all the terms of this Stipulation, at the end of the five (5) year period Respondent may apply to have his prescription writing privileges with the Nevada State Board of Pharmacy reinstated.

h. Due to Respondent's consent to a finding of violations of NRS 631 and NAC 631 contained in Paragraph 9, Respondent agrees to surrender his Registration Certificate No. BV3942477 with the United States Department of Justice, D.E.A., to prescribe controlled substances for Class II, Class II-N, Class III, Class III-N, Class IV and Class V for a period of five (5) years commencing from the time the Respondent originally entered into a Stipulation with the Board on July 6, 1999. In the event Respondent complies with all the terms of this Stipulation, at the end of the five (5) year period Respondent may apply to the D.E.A. to have his prescription privileges reinstated.

i. Pursuant to NRS 631.350(h), Respondent's practice shall be supervised for a period of five (5) years to review patient records to assure Respondent's prescription practice are in compliance with NRS 631 and NAC 631. During the five (5) years of supervision, Respondent shall allow either the Informal Hearing Officer and/or the Executive Director of the

RALEIGH, HUNT & GARRY, P.C.
Law Offices
302 E. CARSON AVENUE
SUITE 1102
LAS VEGAS, NEVADA 89101
(702) 386-4842

JRL

JHV

Board and/or an agent appointed by the Board to inspect Respondent's records to assure compliance with this Stipulated Agreement. Such inspection shall be performed, without notice, during normal business hours. Respondent shall maintain, for a period of five (5) years, a list of any prescriptions issued to any of Respondent's patients by any other licensed dentist in the State of Nevada. The list of prescriptions to Respondent's patients written by any other license dentist in the State of Nevada shall include patient's name, date of issuance, licensed dentist who issued the prescription, units and amount of prescription narcotics issued. Respondent's failure to accurately maintain the list of prescriptions issued to his patients by any other licensed dentist in the State of Nevada shall be deem unprofessional conduct and in violation of this Stipulation and shall be considered by the Board in determining whether or not to revoke Respondent's license to practice dentistry in the State of Nevada.

j. Pursuant to NRS 631.350(c), Respondent agrees to be fined in the amount of $2,000.00 for violations of NRS 631 and NAC 631, as cited above.

k. Respondent agrees, until such time as the fine of $2,000.00 is paid, Respondent shall not practice dentistry in the State of Nevada until such time as the fine is paid in full. Respondent further agrees, in the event the Board has to initiate any legal proceedings to enforce the fine or in the event the Board has to seek injunctive relief if Respondent fails to voluntarily cease practicing dentistry in the State of Nevada, Respondent shall be responsible for legal fees and costs incurred by the Board in any such proceedings.

l. Upon approval of this Stipulation by the Board, Respondent agrees to pay the Board the sum of $9500.00 to reimburse the Board for the cost of this investigation and subsequent monitoring to enforce this Stipulation. Respondent shall pay the reimburse amount pursuant to the following schedule:

i. Upon approval of this Stipulation by the Board, Respondent shall pay the Board the sum of $1,583.35;
ii. Nine (9) months from date of the first payment, Respondent shall pay the Board the sum of $1,583.33;
iii. Six (6) months from date of the second payment, Respondent shall pay the Board the sum of $1,583.33;
iv. Six (6) months from date of the third payment, Respondent shall pay the Board the sum of $1,583.33;
v. Six (6) months from date of the fourth payment, Respondent shall pay the Board the sum of $1,583.33;
vi. Six (6) months from date of the fifth payment, Respondent shall pay the Board the sum of $1,583.33.

In the event Respondent fails to reimburse the Board for the cost of the

RALEIGH, HUNT & GARRY, P.C.
302 E. CARSON AVENUE
SUITE 1102
LAS VEGAS, NEVADA 89101
(702) 386-4842

investigation pursuant to the schedule cited above, Respondent shall cease practicing dentistry in the State of Nevada until such time as the payment schedule is brought current. Respondent further agrees, in the event the Board has to initiate any legal proceedings to enforce the payment schedule identified above or to seek injunctive relief if Respondent fails to voluntarily cease practicing dentistry in the State of Nevada until such time as the payments are made current, Respondent shall be responsible for legal fees and costs incurred by the Board in any such proceedings.

CONSENT

12. Respondent has read all of the provisions contained in this Stipulation and agrees with them in their entirety.

13. Respondent is aware by entering into this Stipulation he is waiving certain valuable due process rights contained in, but not limited to, NRS 631, NAC 631, NRS 233B and NAC 233B.

14. Respondent expressly waives any right to challenge the Board for bias in deciding whether or not to adopt this Stipulation in the event this matter was to proceed to a full Board hearing.

15. Respondent has reviewed the Stipulation with his attorney, John R. Lusk, Esq., who has explained each and every provision contained in this Stipulation to the Respondent.

16. Respondent acknowledges he is consenting to this Stipulation voluntarily, without coercion or duress and in the exercise of his own free will.

17. Respondent agrees in the event the Board adopts this Stipulation he hereby waives any and all rights to seek judicial review or otherwise to challenge or contest the validity of the provisions contained in the Stipulation.

18. This Stipulation will be considered by the Board in an open meeting. It is understood and stipulated the Board is free to accept or reject the Stipulation and, if the Stipulation is rejected by the Board, further disciplinary action may be implemented. This Stipulation will only become effective when the Board has approved the same in an open meeting. Should the Board adopt this

RALEIGH, HUNT & GARRY, P.C.
Law Offices
302 E. CARSON AVENUE
SUITE 1102
LAS VEGAS, NEVADA 89101
(702) 386-4842

JRL

JHV

Stipulation, such adoption shall be considered a final disposition of a contested case.

DATED this 14th day of MARCH, 2000.

JOHN H. VENNOCHI, D. M. D.
Respondent

SUBSCRIBED and SWORN to before me this 14th day of March, 2000.

DEBRA K. CAROSELLI
Notary Public - Nevada
No. 93-0213-1
My appt. exp. Oct. 27, 2001

NOTARY PUBLIC in and for said County and State

APPROVED AS TO FORM & CONTENT

JOHN A. HUNT, ESQUIRE
Complainant's attorney

APPROVED AS TO FORM & CONTENT

SUSAN S. JANCAR, D.D.S.
Disciplinary Screening Office/Informal Hearing Officer

APPROVED AS TO FORM & CONTENT

JOHN R. LUSK, ESQUIRE
Attorney for Respondent

The foregoing Stipulation was approved/disapproved by a vote of the Nevada State Board of Dental Examiners at a properly noticed meeting.

DATED this 1st day of JUNE, 2000.

NEVADA STATE BOARD OF DENTAL EXAMINERS

A. TED TWESME, D.D.S.
President

RALEIGH, HUNT & McGARRY, P.C.
302 E. CARSON AVENUE
SUITE 1102
LAS VEGAS, NEVADA 89101
(702) 386-4842

JRL

JHV

Case No. 99-526

STATE OF NEVADA

BEFORE THE BOARD OF DENTAL EXAMINERS OF NEVADA

NEVADA STATE BOARD OF DENTAL EXAMINERS, Complainant, vs. JOHN H. VENNOCHI, D. M. D., Respondent.	**STIPULATION**

IT IS HEREBY STIPULATED AND AGREED by and between JOHN H. VENNOCHI, D.M.D. (hereinafter "Respondent"), and his counsel, JOHN R. LUSK, ESQ. and THE NEVADA STATE BOARD OF DENTAL EXAMINERS (hereinafter "Board") by and through its counsel JOHN A. HUNT, ESQ., of the law firm of RALEIGH, HUNT & McGARRY, P.C. as follows:

1. Currently the Board is conducting an investigating into the dental practice of Respondent.

2. On June 7, 1999 an Informal Hearing was held regarding the dental practice of the Respondent.

3. On June 10, 1999, the Nevada State Board of Dental Examiners received a

JRL JHV

RALEIGH, HUNT & McGARRY, P.C.
3012 E. CARSON AVENUE
SUITE 1102
LAS VEGAS, NEVADA 89101
(702-386-4842

prescription inquiry from Keith W. McDonald, Executive Secretary of the Nevada State Board of Pharmacy regarding the prescription practices of Respondent.

4. At this time, without admitting to the patients or the number of times, Respondent hereby admits there is probable cause to believe Respondent has violated NRS 631.3475(5), which states the following acts, among others, constitute unprofessional conduct;

> "5. Administering, dispensing or prescribing of any controlled substance or any dangerous drug as defined in chapter 454 of NRS, if it is not required to treat the dentist's patients; ...."

5. At this time, without admitting to the patients or the number of times, Respondent admits there is probable cause to believe Respondent has violated NAC 631:230(b) which states the following acts, among others, constitutes unprofessional conduct;

> "(b) Writing prescriptions for controlled substances in an excessive amount as to constitute a departure from the prevailing standards of acceptable dentistry practice."

6. At this time, without admitting to patients or the number of times, Respondent admits there is probable cause to believe Respondent has violated NAC 631.230(1)(d) which states the following acts, among others, constitute unprofessional conduct.

> "(1)(d) The acquisition of any controlled substances from any pharmacy or other sources, by misrepresentation, fraud, deception or subterfuge."

7. Based upon the information contained in Paragraphs 1 through 6 above, Respondent hereby voluntarily agrees he will not prescribe any controlled substances for Class II, Class II-N, Class III, Class III-N, Class IV and Class V until such time as a written agreement is entered into between the Respondent and the Board allowing Respondent to resume his privilege to prescribed controlled substances.

JRL

JHV

RALEIGH, JUNDT & McGARRY, P.C.
302 E. CARSON AVENUE
SUITE 1102
LAS VEGAS, NEVADA 89101
(702-386-4842

8. In the event Respondent prescribes any controlled substances as defined in V prior to the Board reinstating Respondent privilege to prescribe controlled substances for Class II, Class II-N, Class III, Class III-N, Class IV and Class V, Respondent hereby stipulates and agrees the Board shall revoke Respondent's license to practice dentistry in the State of Nevada without any further action by the Board, other than appropriate order of revocation executed by the Board's Executive Director.

9. Respondent agrees, until such time as the Board completes its present investigation, Respondent's practice shall be monitored to assure Respondent does not issue any prescriptions for controlled substances, as defined in Class II, Class II-N, Class III, Class III-N, Class IV and Class V. Until the Board's present investigation is completed, Respondent shall allow either the Informal Hearing Officer, assigned to this matter and/or the Executive Director of the Board and/or any agent appointed by the Board, to inspect Respondent's office and records to insure compliance with this stipulation. Such inspection shall be performed, without notice, during normal business hours. Respondent further agrees, pursuant to the Consent Order entered into with the Commonwealth of Massachusetts, paragraphs 4B & C, Respondent shall forward to the Board's Executive Director copies of all random and supervised urine screening tests. Respondent shall also forward copies of all quarterly therapists' reports, submitted to the Commonwealth of Massachusetts.

10. Upon approval of this Stipulation by the Board, Respondent agrees to pay the Board the sum of $1,000 to reimburse the Board for the preparation of this stipulation.

RALEIGH, HUNT & McGARRY, P.C.
302 E. CARSON AVENUE
SUITE 1102
LAS VEGAS, NEVADA 89101
(702-386-4842

JRL

JHV

CONSENT

11. Respondent has read all of the provisions contained in this Stipulation and agrees with them in their entirety.

12. Respondent is aware that by entering into this Stipulation he is waiving certain valuable due process rights contained in, but not limited to, NRS 631, NAC 631, NRS 233B and NAC 233B.

13. Respondent expressly waives any right to challenge the Board for bias should the Board reject this Stipulation and this matter proceed to a full Board hearing.

14. Respondent has reviewed every provision of this Stipulation with his attorney, JOHN R. LUSK, ESQ. and has been advised of the ramifications of each provision of the Stipulation.

15. Respondent acknowledges that he is consenting to this Stipulation voluntarily, without coercion or duress and in the exercise of his own free will.

16. Respondent agrees that in the event the Board adopts this Stipulation he hereby waives any and all rights to seek judicial review or otherwise to challenge or contest the validity of the provisions contained in the Stipulation.

17. This Stipulation will be considered by the Board in an open meeting. It is understood and stipulated the Board is free to accept or reject the Stipulation. This Stipulation will only become effective when the Board has approved the same in an open meeting. Should the Board adopt this

JRL

JHV

RALEIGH, HUNT & McGARRY, P.C.
302 E. CARSON AVENUE
SUITE 1102
LAS VEGAS, NEVADA 89101
(702-366-4842

Stipulation, such adoption shall be considered a final disposition of a contested case.

DATED this 6th day of July, 1999.

SUSAN S. JANCAR, D.D.S.
Disciplinary Screening Officer/Informal Hearing Officer

JOHN A. HUNT, ESQUIRE
Attorney for Complainant

JOHN H. VENNOCHI, D.M.D.
Respondent

JOHN R. LUSK, ESQUIRE
Attorney for Respondent

STATE OF NEVADA)
) ss
COUNTY OF CLARK)

ACKNOWLEDGMENT

On this 6th day of July, 1999, personally appeared before me, a Notary Public in and for said County and State, JOHN H. VENNOCHI, D.M.D. known to me to be the person described in and who executed the foregoing instrument, who acknowledged to me that he executed the same freely and voluntarily.

DEBRA K. CAROSELLI
Notary Public - Nevada
No. 93-0213-1
My Appt. exp. Oct. 27, 2001

NOTARY PUBLIC in and for said County and State

JRL

JHV

Law Offices
RALEIGH, HUNT & McGARRY, P.C.
307 E. CARSON AVENUE
SUITE 1102
LAS VEGAS, NEVADA 89101
(702) 366-1702

The foregoing Stipulation was approved/disapproved by a vote of the Nevada State Board of Dental Examiners at a properly noticed meeting.

DATED this 6th day of July, 1999.

NEVADA STATE BOARD OF DENTAL EXAMINERS

A. TED TWESME, D.D.S.
President

Law Offices
RALEIGH, HUNT & McGARRY, P.C.
302 E. CARSON AVENUE
SUITE 1102
LAS VEGAS, NEVADA 89101
(702) 386-4812

JRL

JHV

*

BEFORE THE NEVADA STATE BOARD OF DENTAL EXAMINERS

NEVADA STATE BOARD OF DENTAL EXAMINERS, Complainant, vs. JOHN VENNOCHI, DMD Respondent.	CASE NO: 07-1519

ORDER

Whereas, the above-captioned matter came on for hearing before the Nevada State Board of Dental Examiners (the "Board"), on Friday, October 1, 2010, at that offices of the Board at 6010 South Rainbow Boulevard, Suite A-1, Las Vegas, Nevada 89118, pursuant to a *Notice of Hearing* dated September 10, 2010.

1. The Board appeared by and through the following members who comprised a quorum: William G. Pappas, DDS, President; Donna J. Hellwinkel, DDS, Board Member; James Kinard, DDS, Board Member; J. Stephen Sill, DMD, Board Member; Lisa M. Wark, Public Board Member; Leslea R. Villigan, RDH, Board Member; Masih Soltani, DDS, Board Member; James (Tuko) McKernan, RDH, Board Member (via teleconferencing from Reno, NV); Tony Guillen, DDS, Secretary-Treasurer (via teleconference from Reno, NV), and Rosanne (Missy) Matthews, RDH Board Member (via teleconference from Reno, NV).

2. The Board was represented by Cameron Vandenberg, Deputy Attorney General. John A. Hunt, Esq. appeared for the Complainant. Respondent, John Vennochi, DMD ("Respondent" or

Fox Rothschild LLP
3800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169

"Dr. Vennochi"), appeared in person and was represented by and through his attorney, John R. Lusk, Esq. Also present were Kathleen J. Kelly, the Board's Executive Director, and Debra A. Shaffer, the Board's Deputy Executive Director.

3. In pertinent part, the above-referenced *Notice of Hearing* dated September 10, 2010, provides:

> 8. With regards to the above-captioned matter (i.e., Case No. 07-1519), on June 27, 2008, Respondent agreed to and executed *Findings and Recommendations of the Informal Hearing Held Pursuant to NRS 631 and NAC 631 & Consent of John Vennochi, DMD to the Findings and Recommendations Pursuant to N.R.S. § 631.363(5)* (Case No. 07-1519 – approved by the Board on or about June 27, 2008) (hereinafter "June 2008 Order").
>
> 9. In pertinent part, the June 2008 Order provides:
>
> > xiv. Pursuant to NRS 631.350(k), in addition to completing the required continuing education, ~~during the four (4) month suspension period~~ Respondent shall be required to obtain forty (40) additional hours in supplemental education [*two years (2) from adoption of Finding & Recom*]. Twenty (20) hours should be obtained in the area of ethics, and the remaining twenty(20) hours of supplemental education should be received in the area of record keeping. F The Respondent should be required to submit in writing to the Executive Director of the Board for approval prior to attendance. Upon receipt of a written request to attend supplemental education the Executive Director of the Board should be required to notify Respondent in writing whether the requested supplemental education is approved for attendance. Respondent agrees seventy (70%) per cent of the supplemental education shall be completed through attendance at live lecture. The remaining thirty (30%) per cent of the supplemental education may be completed through online/home study. Respondent should be required to pay all costs associated with this supplemental education. Respondent should not be allowed to commence the practice of dentistry until Respondent has completed the four (4) month suspension period and has submitted written proof of completion of the recommended supplemental education.
>
> Id., ¶ 6.B.xiv. at 18:12-22 (the italic language is annotated language in the original document).

Fox Rothschild LLP
3800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169

///

10. Further, the June 2008 Order also provides, in pertinent part, at the "Consent to Findings and Recommendations" section:

> 15. I hereby specifically recognize, acknowledge and agree that failure on my part to fully satisfy all of the terms and conditions of the Findings and Recommendations of the Informal Hearing Officer, shall constitute unprofessional conduct; I further agree in the event I fail to satisfy all of the Findings and Recommendations of the Informal Hearing Officer, the Board may impose additional disciplinary penalties, upon the convening of a full Board hearing to determine solely whether I have breached any of the consented to Findings and Recommendations of Informal Hearing Officer, J. GORDON KINARD, DDS.

Id., ¶ 15, at 20:26 to 21:7.

11. Respondent has failed to fully satisfy all of the terms and conditions of the June 2008 Order. Specifically, Respondent has failed to provide the Board with evidence/documentation that he has complied with the requirements of the above-referenced language from paragraph 6.B.xiv. at page 18, lines 12-22 of the June 2008 Order.

12. **WHEREFORE, YOU ARE HEREBY GIVEN NOTICE** that the Board has scheduled a public hearing to consider Respondent's failure to fully satisfy all of the terms and conditions of the June 2008 Order in that Respondent has failed to provide the Board with evidence/documentation that he has complied with the requirements of the above-referenced language from paragraph 6.B.xiv. at page 18, lines 12-22 of the June 2008 Order. The public hearing is scheduled for **Friday, October 1, 2010,** at **10:00 a.m.** at the offices of the Nevada State Board of Dental Examiners, 6010 South Rainbow Boulevard, Suite A-1, Las Vegas, Nevada 89118.

13. **YOU ARE FURTHER ADVISED** that pursuant to the "Consent to Findings and Recommendations" portion of the July 2008 Order at ¶ 15, 20:26 to 21:7 ("..., the Board may impose additional disciplinary penalties, upon the convening of a full Board hearing to determine solely whether I have breached any of the consented to Findings and Recommendations..."), the purpose of the hearing is to consider Respondent's failure to provide the Board with evidence/documentation that he has complied with the requirements of the above-referenced language from paragraph 6.B.xiv. at page 18, lines 12-22 of the June 2008 Order and to determine whether Respondent should be subject to discipline

///

pursuant to NRS 631.350 and/or other relevant and applicable provisions of the Nevada Revised Statutes ("NRS") and/or Nevada Administrative Code ("NAC"), chapters 631 for his failure to comply with said terms/conditions of the June 2008 Order.

Id., at 2:17 to 4:25, at ¶¶ 8-13.

4. The Complainant's Exhibits A-F were offered and admitted. Respondent's Exhibits 1-8 were offered and admitted. Kathleen Kelly and Respondent answered questions under oath. Opening statements and closing arguments were made by the Complainant and Respondent.

5. Respondent, by counsel, stipulated on the record at the October 1, 2010, hearing that he had not completed the required 40 hours of supplemental education requirements of the above-referenced language from paragraph 6.B.xiv. at page 18, lines 12-22 of the June 2008 Order; as a consequence, IT IS HEREBY ORDERED that in light of Respondent's stipulation, Respondent is deemed/found to have violated the June 2008 Order.

6. IT IS HEREBY ORDERED that following a motion, the motion being seconded, allowing time for discussion, and by a majority vote that Dr. Vennochi shall be and is hereby granted two (2) additional years to complete the supplemental education requirements referenced at paragraph 6.B.xiv. at page 18, lines 12-22 of the June 2008 Order. The additional two (2) years shall be deemed to begin on June 27, 2010.

///

///

///

///

///

7. IT IS FURTHER ORDERED that, pursuant to NRS 622.400, Dr. Vennochi shall pay the Board's attorney's fees and costs relative to this matter, due to his violation of the June 2008 Order.

DATED & DONE this 15th day of OCTOBER, 2010.

NEVADA STATE BOARD OF DENTAL EXAMINERS

WILLIAM G. PAPPAS, DDS, PRESIDENT

Fox Rothschild LLP
3800 Howard Hughes Parkway
Suite 500
Las Vegas, Nevada 89169

11C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

(This application cannot be used by PA's or APRN's)

Y

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☐ Schedule I ☑ Schedule II ☑ Schedule III ☑ Schedule IV ☑ Schedule V

Section 1: Personal Information

First: Shannon Middle: — Last: Washington

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Home Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Degree: MD Practitioner License #: 15168 Specialty: Emergency Medicine

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled substance registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Revenge MD

Practice Address: 2610 W Horizon Ridge Pkwy Suite #: 105

City: Henderson State: NV Zip: 89052

Telephone: 702-335-7033 Fax: _____ Email: www.revengemd.com

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?	✓	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # 3 & 4 **Provide all the following *<u>where applicable</u>*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

#. 3. In around 2021 I was cited for Aiding and Abetting a non licened Provider. In this case I was the Supervising MD of a Physician Assistant who did not have an Active Nevada licence. The Facility hired her and I did not do my due diligence to make sure she was licensed in Las Vegas. She ended up doing unathorized lipo suction. The case was performed without my knowledge. My licences was placed on probation for 2yrs and I was fined as well as had to take a course.

4. In 2021 - or 2022 multiple prescriptions weire made of my signitwie. Multiple copies were made for the drug "phentermine" This was done in an office unknow to me. I then lost my controlled licensing ability for 2yrs.

Original Signature (electronic, copies or stamps not accepted)

9/03/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sherman Washington IV MD — 9/3/2024

Print Name (First, Last) — Date

[redacted] — 9/3/2024

Original Signature (electronic, copies or stamps not accepted) — Date

Board Use Only: Date Processed: 9/9/24	Amount: $700 CC

Summary	Attachments
COMPLAINT Case No.: 21-41427-1 August 31, 2021 The Investigative Committee of the Nevada State Board of Medical Examiners filed a formal Complaint against Sherman Washington, M.D., alleging five (5) violations of Nevada Revised Statues of (NRS), Chapter 630. Count I: Alleges a violation NRS 630.301(4) Malpractice; Count II: Alleges a violation of NRS 630.305(1)(e) Aiding the Unlicensed Practice of Medicine; Count III: Alleges a violation of NRS 630.306(1)(b)(3) Engaging in Conduct that Violated Pharmacy Board Regulations; Count IV: Alleges a violation of NRS 630.3062(1)(h) Fraudulent, Illegal, Unauthorized and Otherwise Inappropriate Prescribing of Controlled Substances; and Count V: Alleges a violation of NRS 630.306(1)(p) Unsafe or Unprofessional Conduct. Complaint: Twenty-nine (29) pages.	Complaint - 21-41427-1.pdf (/rest/public/data/downloadannotation/index.php?id=6138f259fee73402bc497b20&entity=$2y$10$Q4AHS7pzVTWnvn7gz1e5hOO4xi2GlUcbR3HKIXEY.xJl5g2/
COMPLIANCE Case No. 21-41427-1 December 4, 2023 Completed all terms of the settlement agreement for the above case as of December 3, 2023. ********** **SETTLEMENT AGREEMENT AND ORDER Case No. 21-41427-1 December 3, 2021** On December 3, 2021, the Nevada State Board of Medical Examiners accepted and approved a Settlement Agreement which allowed for an order to be entered finding Dr. Washington violated NRS 630.301(4), NRS 630.305(1)(e), NRS 630.306(1)(b)(3), NRS 630.3062(1)(h) and NRS 630.306(1)(p), as set forth in the Complaint, and ordering that he receive a public reprimand; pay a fine of $5,000.00; complete 22 hours of continuing medical education (CME) related to medical ethics and professionalism, in addition to his statutory CME requirements for licensure; a 24 month probationary period on his license; and to reimburse the Board's fees and costs incurred in the investigation and prosecution of the case against him. Settlement Agreement and Order: nine (9) pages.	Settlement Agreement and Order - 21-41427-1.pdf (/rest/public/data/downloadannotation/index.php?id=61b9291681edb569d72d5a92&entity=$2y$10$8hgss07B03GE/rej6HdsKePK1qbUZElhvUlsi9uXX7FVo9WS

Current Employment Status / Conditions / Restrictions on License / Prior Malpractice Claims

Summary	Attachments
12/3/21 Sherman Washington, M.D. Dr. Washington's license is placed on probation for a period of 24 months from the date of the Board's acceptance, adoption and approval of this Agreement. During the probation period, should Dr. Washington commit any new violations of the Medical Practice Act or fail to comply with any term or condition of this Agreement, the IC shall be authorized to immediately suspend Dr. Washington's license to practice medicine in Nevada pending an Order to Show Cause Hearing maintaining the suspension pending final adjudication by the Board of the alleged violation. Dr. Washington shall pay a find in the amount of five thousand dollars within sixty days. Dr. Washington shall pay the costs and expenses incurred in the investigation and prosecution of the above-referenced matter within sixty days in the amount of $2,142.48. Dr. Washington shall complete twenty-two hours of CME regarding medical ethics and professionalism within six months. This is a disciplinary action and is reportable to the appropriate entities and parties as required by law, including, but not limited to, the National Practitioner Data Bank.	N/A

Malpractice Information

Summary	Attachments
None.	

Supervisor To

Licensee	Relationship	Date of Association
GRANDE, Megan Colleen	Primary Supervisor	Aug-02-2023
JOHNSON, Logan Daniel	Primary Supervisor	Jan-12-2023
BRISSON, Holly Nicole	Additional Supervisor	Jan-25-2024

Powered by Thentia Cloud (https://www.thentia.com)

Sherman WASHINGTON Jr.

License Number:
15168

License Type:
Medical Doctor

License Status:
Active

Initial License Date:
Feb-07-2014

Expiration Date:
Jun-30-2025

Public Address:
Complete Medical Center 1820 E Lake Mead Blvd Ste M

Public City:
North Las Vegas

Public State:
Nevada

Public ZIP Code:
89030

Public Country:
United States

Public Phone Number:
[redacted]

Credential:
M.D.

Specialties

Specialty
Emergency Medicine

Education History

Institution	Degree/Certificate	Date Enrolled	Date To
Howard Univ College of Medicine / Washington DC	Medical Doctor Degree	N/A	May-11-1985

Postgraduate Training

Institution	Program Type	Specialty Type	Start Date	End Date
Howard University Hospital / Washington DC	Internship	Emergency Medicine	Jul-01-1985	Jun-30-1986
Howard University Hospital / Washington DC	Residency	Emergency Medicine	Jul-01-1986	Jun-30-1988

Board Actions

FILED
APR 26 2022
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. LAS VEGAS SCRIPTS RX, Pharmacy License No. PH03930, NATHAN EDOUARD, RPH, Certificate of Registration No. 19462, and SHERMAN WASHINGTON, MD, Certificate of Registration No. CS24310, Respondents.	CASE NOS. 19-243-PH-S 19-243-RPH-S 19-243-CS-S NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because at the time of the events alleged herein, Respondent Las Vegas Scripts Rx ("LV Scripts") held a Nevada Pharmacy License No. PH03930, Respondent Nathan Edouard, RPh, ("Edouard") held a Nevada Pharmacist Certificate of Registration No. 19462, and Respondent Sherman Washington, MD, ("Washington") held a Controlled Substance Registration No. CS24310, all issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent LV Scripts is a pharmacy located at 2920 N. Green Valley Parkway, #814, in Henderson, Nevada.

3. Respondent Edouard was/is the owner of LV Scripts and was/is employed as the managing pharmacist during the alleged and relevant timeframes.

4. Respondent Washington was/is a physician who wrote prescriptions with copied signatures filled by LV Scripts during the relevant timeframes.

5. On or about June 10, 2019, LV Scripts received a prescription written by Dr. M.B. for patient M.W. for "Cold Cough & Chest rub 240 grams". The prescription was designated prescription #4000099 and was compounded with Dimethyl Sulfoxide Liquid and Promethazine-Codeine Syrup, which were not written on the prescription. The ingredients and percentages of each drug were not identified on the prescription label.

6. On or about September 25, 2019, Board inspectors completed their annual inspection at LV Scripts. At the inspection, the following violations were discovered:

a. LV Scripts was shipping prescriptions to California and Arizona where LV Scripts is not licensed.

b. LV Scripts appeared to be filling faxed prescriptions that were not signed by practitioners, but contained copied signatures.

c. LV Scripts did not include the required documentation on prescriptions received by telephone from practitioners. The prescriptions also lacked the name(s) of the person(s) who telephoned the prescription, the date(s) the prescription(s) were received and/or the name(s) of the pharmacist(s) who received the order(s).

d. LV Scripts is providing pre-printed prescription forms for marketing purposes in efforts to promote sales to patients and/or practitioners.

e. Respondent Eduoard was improperly documenting prescriptions received by telephone orders on transferred prescriptions.

APPLICABLE LAW

7. A pharmacy must be managed by a registered pharmacist who is responsible for compliance by the pharmacy and personnel with all state, and federal laws and regulations regarding the operation of the pharmacy. NRS 639.220(1).

8. Unprofessional conduct includes a licensee failing strictly to follow the instructions of the prescribing practitioner in filling of and/or placing contents on the label of the prescription. NRS 585.485(2)(b)(1); NAC 639.6703(1)(a); NAC 639.945(1)(c), (d).

9. Unprofessional conduct includes a licensee performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

10. Unprofessional conduct includes a licensee performing any act, task, or operation for which licensure, certification, or registration is required without the required licensure, certification, or registration. NAC 639.945(1)(k).

11. Unprofessional conduct includes the use of secret formulas and failure to strictly follow the instructions of the person writing, making, or ordering a prescription, and to specify the content on the label of the prescription. NAC 639.6703(1)(a); NAC 639.945(1)(c), (d).

12. No pharmacist or owner of a pharmacy may offer an unearned rebate. The furnishing to a practitioner by a pharmacist or pharmacy of prescription blanks bearing the name and address of the pharmacy is an unearned rebate. NRS 639.264.

13. A pharmacy owner is responsible for violations committed by the pharmacy's employees. NRS 639.230; NAC 639.702; NAC 639.945.

14. Respondents are subject to discipline for violations pursuant to NRS 453.236, NRS 453.241, NRS 639.210 and/or NRS 639.255.

COUNT ONE

Unprofessional Conduct – Failure to Strictly Follow Instructions of Prescribing Practitioner (Respondent Edouard)

15. Respondent Edouard engaged in unprofessional conduct when he failed to strictly follow the directions of the prescribing practitioner when compounding prescription #4000099 for patient M.W., which were compounded with Dimethyl Sulfoxide Liquid, a substance not to be used for medicinal purposes on humans, and Promethazine-Codeine Syrup; the ingredients were not written on the prescription in violation of NRS 585.485(2)(b)(1), NAC 639.6703(1)(a), and NAC 639.945(1)(c)(d), and (i), and Respondent Edouard is therefore subject to discipline pursuant to NRS 639.210(4), (12), and/or NRS 639.255.

COUNT TWO

Unprofessional Conduct – Incompetent, Unskillful and Negligent Conduct (Respondents Edouard and Washington)

16. Respondent Edouard engaged in unprofessional conduct and conduct contrary to the public interest, and performed his duties in an incompetent, unskillful or negligent manner when he processed copied signatures on prescriptions for Respondent Washington in violation of NAC 453.440(2), NAC 454.060, and is therefore subject to discipline pursuant to NRS 453.236, NRS 453.241, NRS 639.210, and/or NRS 639.255.

17. Respondent Washington engaged in unprofessional conduct and conduct contrary to the public interest, and performed his duties in an incompetent, unskillful or negligent manner when he allowed his copied signature to be used on prescriptions in violation of NAC 453.440(2), NAC 454.060, and is therefore subject to discipline pursuant to NRS 453.236, NRS 453.241, NRS 639.210, and/or NRS 639.255.

COUNT THREE

Failure to Properly Document Prescriptions on Telephoned Orders (Respondent Edouard)

18. Respondent Edouard failed to provide proper documentation of telephoned orders in violation of NAC 639.707(1), (2), and (6)(b), and is therefore subject to discipline pursuant to NRS 639.210(12), (15), and/or NRS 639.255.

COUNT FOUR

Unprofessional Conduct – Utilization of Pre-printed Forms as Unearned Rebate (Respondent Edouard)

19. As a pharmacy owner/pharmacist registered with the Board, Respondent Edouard engaged in unprofessional conduct and conduct contrary to the public interest when he utilized pre-printed forms as unearned rebates in marketing his business in violation of NRS 639.264, NAC 639.945(1)(i), and is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

COUNT FIVE

Unprofessional Conduct – Unlicensed Activity (Respondent Edouard)

20. As a pharmacy owner/pharmacist registered with the Board, Respondent Edouard engaged in unprofessional conduct and conduct contrary to the public interest when he shipped prescriptions to California and Arizona without valid licenses in those jurisdictions in violation of NAC 639.945(1)(k), and is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

COUNT SIX

Pharmacy/Pharmacy Owner Responsibility (Respondent LV Scripts)

21. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, LV Scripts is responsible for those violations, including those of the pharmacy's employees, pursuant to NAC 639.702, NAC 639.945(2) and is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of license(s)/registration(s) of these Respondents.

Signed this 26th day of APRIL 2022.

J. David Wiest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENTS

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SHERMAN WASHINGTON, MD,** **Certificate of Registration No. CS24310,** **Respondent.**	**CASE NO. 19-243-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, June 1, 2022, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 26th day of April, 2022.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. SHERMAN WASHINGTON, MD, Certificate of Registration No. CS24310, Respondent.	CASE NO. 19-243-CS-S ANSWER AND NOTICE OF DEFENSE

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2022.

_____

SHERMAN WASHINGTON, MD,

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of April 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Sherman Washington, MD
[redacted]
Las Vegas, NV 89118

Sherman Washington, MD
Transforming Arts
2906 N. Green Valley Pkwy., Suite 114
Henderson, NV 89014

Sherman Washington, MD
[redacted]
North Las Vegas, NV 89030

Nathan Edouard, RPH
[redacted]
Henderson, NV 89014

Las Vegas Scripts Rx
2920 N. Green Valley Pkwy #814
Henderson, NV 89014

SHIRLEY HUNTING

FILED
SEP 08 2022
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SHERMAN WASHINGTON, MD,** **Certificate of Registration No. CS24310,** **Respondent.**	**Case Nos. 19-243-CS-S** **21-104-CS-N** **STIPULATION AND ORDER**

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Sherman Washington, MD, Certificate of Registration No. CS24310, by and through counsel, Michael Mee, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. The Board has jurisdiction over Respondent and this matter.

2. On or about April 7, 2022, Respondent was served with the Notice of Intended Action and Accusation on file in in Case No. 21-104-CS-N together with the Statement to Respondent and Notice of Hearing.

3. On or about April 26, 2022, Respondent was served with the Notice of Intended Action and Accusation on file in in Case No. 19-243-CS-S together with the Statement to Respondent and Notice of Hearing.

4. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

5. Respondent is aware of the right to a hearing on the matters alleged herein, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives his rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

7. Respondent does not contest the allegations plead with particularity in each accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit,* that:

A. Respondent violated 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR § 1306.03(a)(1) , 21 CFR § 1306.04(a), NRS 453.226(1), NRS 453.321(1)(a), NRS 453.331(1) (f) and (i), NRS 453.381(1), NRS 453.401(l)(a), NRS 639.100(1), NRS 639.235(1) and/or NAC 454.060, by permitting persons not licensed as practitioners in Nevada to fraudulently issue prescriptions for controlled substances and/or dangerous drugs under Respondent's credentials;

B. Respondent violated NRS 453.164(7) and NRS 639.23507 by failing to query the Prescription Monitoring Program (PMP) database;

C. Respondent violated NRS 453.331(1)(e) by failing to disclose administrative actions to the Board on his 2020 biennial renewal application and on his applications for two additional controlled substance registrations;

D. Respondent violated 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR § 1306.03(a)(1), 21 CFR § 1306.04(a), CFR § 1301.71, NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 453.377, NRS

453.381(1), NRS 454.213(1), NRS 454.215(3); NRS 454.221, NRS 454.316, NRS 454.321, NRS 454.356, NRS 454.480, NRS 454.510, NRS 454.530, NRS 639.100(1), NRS 639.235(1), NRS 639.23505, NAC 639.742, NAC 453.400 and/or NAC 453.410(1)(d), in the course of operating Vida Spa as detailed in the Nevada State Board of Medical Examiners' order in Case No. 21-41427-1; and

E. Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), (i), (j), (k), (n) and/or (o); and committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1).

8. In order to resolve Case Nos. 19-243-CS-S and 21-104-CS-N without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties:

A. The certificate of registration of Respondent Sherman Washington, MD, Certificate of Registration No. CS24310, is hereby revoked pursuant to NRS 453.241(l)(b):

1) Respondent may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense a controlled substance until he has petitioned the Board for reinstatement pursuant to NRS 639.257 and the Board reinstates his certificate of registration.;

2) Pursuant to NRS 622A.410(1) and 639.257(1), Respondent may not petition for reinstatement of his certificate of registration for a period of two (2) years from the effective date of this Order; and

3) In the event Respondent applies for reinstatement of his certificate of registration, or applies for any other certificate, license or permit with the Board, he shall appear before the Board to answer questions and give testimony regarding his application, his compliance with this Order, and the facts and circumstances underlying this matter.

B. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of Five Thousand Dollars ($5,000.00) for the violations, through monthly payments pursuant to the following schedule:

Due Date	Amount
10/1/2022	400.00
11/1/2022	400.00
12/1/2022	400.00
1/1/2023	400.00
2/1/2023	400.00
3/1/2023	400.00
4/1/2023	400.00
5/1/2023	400.00
6/1/2023	400.00
7/1/2023	400.00
8/1/2023	400.00
9/1/2023	600.00
Total	**$5,000.00**

Respondent shall make the monthly payments of the fine amount by personal, business, certified or cashier's check or money order made payable to **"State of Nevada, Office of the Treasurer,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Respondent has the right to pre-pay any or all of the payments.

C. Pursuant to NRS 622.400, Respondent shall pay:

1) Six Hundred Dollars ($600.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting Case No. 19-243-CS-S; and

2) Four Thousand Dollars ($4,000.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting Case No. 21-104-CS-N.

Respondent shall pay the attorney's fees and costs through monthly payments pursuant to the following schedule:

Due Date	Amount
10/1/2022	400.00
11/1/2022	400.00
12/1/2022	400.00
1/1/2023	400.00
2/1/2023	400.00
3/1/2023	400.00
4/1/2023	400.00
5/1/2023	400.00
6/1/2023	400.00
7/1/2023	400.00
8/1/2023	400.00
9/1/2023	200.00
Total	**$4,600.00**

Respondent shall make the monthly payments of the attorney's fees and costs by personal, business, certified or cashier's check or money order made payable to the **"Nevada State Board of Pharmacy"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Respondent has the right to pre-pay any or all of the payments.

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 8, 2022. Respondent or his counsel will appear at the meeting to answer questions from the Board

Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 2 day of September, 2022

SHERMAN WASHINGTON, MD,
Certificate of Registration No. CS24310

Signed this 2 day of September, 2022

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT this 2nd day of September, 2022

MICHAEL MEE, ESQ.
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Sherman Washington, MD, Certificate of Registration No. CS24310, in Case Nos. 19-243-CS-S and 21-104-CS-N and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this 8th day of September, 2022.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of September 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Michael Mee, Esq.
3175 E. Warm Springs Rd. Suite #134
Las Vegas, NV 89120

9171 9690 0935 0265 0825 41

KRISTOPHER MANGOSING

FILED
OCT 10 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SHERMAN WASHINGTON, MD,** **Certificate of Registration No. CS24310,** **Respondent.**	**Case Nos. 19-243-CS-S** **21-104-CS-N** **ORDER TO SHOW CAUSE**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), makes the following that will serve both a notice of intended action under NRS 233B.127(3) and as an order to show cause under NAC 639.965:

1. Sherman Washington, MD, revoked Certificate of Registration No. CS24310, is hereby directed to appear before the Board for a hearing to show cause scheduled on **January 15, 2025, at 9:00AM at the following location:**

Hilton Garden Inn South
7830 S Las Vegas Blvd
Las Vegas, NV 89123

2. On September 8, 2022, the Board approved and entered a Stipulation and Order revoking Certificate of Registration No. CS24310 and imposing discipline on Respondent pursuant to NRS 453.241(1)(b) and NRS 639.255.

3. Respondent has failed to make payment of a fine of Five Thousand Dollars ($5,000) pursuant to the Stipulation and Order payment schedule.

4. Respondent has failed to make payment of Four Thousand Six Hundred Dollars ($4,600.00) for recoverable attorney's fees and costs pursuant to the Stipulation Order payment schedule.

5. Respondent is therefore directed to show cause why he should not be subject to further discipline pursuant to NRS Chapters 453 and 639, or otherwise demonstrate that his conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3).

IT IS SO ORDERED.

Entered this 10th day of October 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 11th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Sherman Washington, MD
[redacted]
Las Vegas, NV 89030

Sherman Washington, MD
[redacted]
Las Vegas, NV 89135

Sherman Washington, MD
[redacted]
Las Vegas, NV 89118

Sherman Washington, MD
[redacted]
North Las Vegas, NV 89030

Michael Mee, Esq.
400 S 4th St. #500
Las Vegas, NV 89101

ERIN MILLER
ADMINISTRIVE ASSISTANT –
BOARD COORDINATOR II

11D

FILED
OCT 21 2024
NEVADA STATE BOARD
OF PHARMACY

Shouping LI, MD
[redacted]

8/05/2024

Nevada State Board of Pharmacy

RE: request the board appearance to remove the restriction on schedule II-
Through V a max 4-day supply on my NV CS 35340 license.

Medical license # 22911 (good standing)

Dear Members of Nevada State Board of Pharmacy

I am writing to formally request to have the board appearance for removal of the restriction (a max 4 day supply) on my CS 35340 license which was granted on March , 2023 . As a licensed medical professional, my primary commitment is to provide the best possible care to my patients, and having the ability to prescribe these medications is essential to fulfilling this duty.

I have adhered strictly to the conditions set forth by the DEA and the Nevada State Board of Pharmacy since my new pharmacy license (CS 35340) was granted. I have participated in continuing education programs focused on the responsible prescription of controlled substances, ensuring that my knowledge and practices are current and aligned with the highest standards of medical care.

Restoring my full prescribing privileges will allow me to better address the needs of my patients and improve their quality of life. And participate in the care of patients whose medical insurance stipulates I hold licensure through the DEA and State board of pharmacy.

Enclosed with this letter are copies of my continuing education certificates, MyRx history of Nevada PMP) and my DEA registration, I respectfully request that you review my case and consider lifting the restriction. I am confident that my actions over the past 18 months demonstrate my dedication to compliance and patient care.

Thank you for your time and consideration. I look forward to your positive response.

Sincerely,

Shouping Li, MD
NV medical lic # 22911
[redacted]
NV CS35340

Shouping Li, MD

[redacted] [redacted]

To: Nv Pharm **Date:** 10/21/2024

Fax: 7758501444 **Pages:** 2

Subject: (no subject)

Pls add it with my request letter to the attorney. Thanks

This fax may contain privileged or confidential information and is intended for the exclusive use of the addressee(s).
If you are not an intended recipient, please notify sender and destroy all copies. Failure to do so may result in legal sanction.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	03-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	PRACTITIONER	01-10-2024

LI, SHOUPING
[redacted]

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	03-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	PRACTITIONER	01-10-2024

LI, SHOUPING
[redacted]

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

Form DEA-223 (9/2016)

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Shouping Li, MD
[redacted]

Dave Wuest, PharmD
Executive Secretary
985 Damonte Ranch Pkwy, STE 206
Reno, NV 89521

3/13/2023

Re: Update Dr. Shouping Li's NV medical license documents

Dear Mr. Wuest:

It's nice to see you at March 9th BOP Vegas meeting . I'd like to thank you very much for your moderating my appearance board for my CS application.

Please review Encl a copy of my new NV medical license documents.

Thank you for your support and help.

Sincerely,

Shouping Li, MD
[redacted]

Shouping Li

License Number:	22911
License Type:	Medical Doctor
License Status:	Active-Conditions
Initial License Date:	Sep-29-2022
Expiration Date:	Jun-30-2023
Public Address:	[redacted]
Public City:	Reno
Public State:	Nevada
Public ZIP Code:	89511
Public Country:	United States
Public Phone Number:	[redacted]
Credential:	M.D.

Specialties

Specialty
Cardiovascular Diseases
Family Medicine
Family Medicine
Cardiovascular Diseases
Cardiovascular Diseases
Family Medicine

Education History

Institution	Degree/Certificate	Date Enrolled	Date To
Xuzhou Medical College	Medical Doctor Degree	Sep-01-1979	Aug-01-1984
Peking Union Medical College	Doctor of Philosophy	Sep-01-1988	Oct-30-1992

Postgraduate Training

Powered by Thentia Cloud (https://www.thentia.com)

Institution	Program Type	Specialty Type	Start Date	End Date
LINCOLN MEDICAL EDUCATION PARTERNSHIP PROGRAM	Residency	Family Medicine	Jul-01-2004	Jun-30-2007
LINCOLN MEDICAL EDUCATION PARTNERSHIP PROGRAM	Residency	Family Medicine	Jul-01-2004	Jun-30-2007
Lincoln Family Medicine / Lincoln , Nebraska	Residency	Family Medicine	Jul-01-2004	Jun-30-2007

Board Actions

Summary	Attachments
None.	

Current Employment Status / Conditions / Restrictions on License / Prior Malpractice Claims

Summary	Attachments
9/16/22 Dr. Li is issued a conditional license, subject to the requirements that both preceptors provide bi-monthly reports, with 100% chart review for the first six months, 50% chart review for the following six months, and 25% chart review for the following six months, and that every six months Dr. Li provide to the Board an evaluation by a neurologist documenting his fit health.	N/A

Malpractice Information

Summary	Attachments
None.	

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NEVADA

* * * * *

In the Matter of the License to Practice Medicine of:	**License No. 22911**
SHOUPING LI, M.D.,	
Applicant.	

FILED
APR - 5 2023
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

ORDER GRANTING LICENSE WITH CONDITIONS

Shouping Li, M.D. (Dr. Li), appeared before the Nevada State Board of Medical Examiners (Board) in Reno, Nevada, at its regularly scheduled meeting on September 16, 2022, regarding his application for licensure as a medical doctor in the State of Nevada. Dr. Li was present and represented by his counsel Lyn E. Beggs, Esq. Board members Victor M. Muro, M.D., President, Aury Nag, M.D., Vice President, Ms. Maggie Arias-Petrel, Secretary-Treasurer, Bret W. Frey, M.D., Chowdhury H. Ahsan, M.D., Ph.D., FACC, Ms. Pamela J. Beal, Col. Eric D. Wade, USAF, (Ret.), Nicola (Nick) M. Spirtos, M.D., F.A.C.O.G., and Carl N. Williams, Jr., M.D., FACS were present. After considering Dr. Li's application, the Board enters the following Order:

IT IS HEREBY ORDERED that the Board grants Dr. Li's application for license subject to the conditions that he comply with a preceptorship plan as follows:

1. Dr. Charles Stringham shall be the primary preceptor. The primary preceptorship shall be eighteen (18) months and will take place at Dr. Stringham's private family practice located at 50 E. Haskell Street, #A, Winnemucca, NV 89445.

2. Dr. Stringham will directly observe Dr. Li's patient encounters during the first month of the preceptorship.

3. Dr. Li will see patients for primary/family care services Tuesday through Friday, every other week, for the first six (6) months of the preceptorship.

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

4. Dr. Stringham will provide a report to the Board two (2) times per month regarding Dr. Li's provision of patient care. Additionally, Dr. Stringham will advise the Board of any concerns related to Dr. Li's mental health and cognition.

5. After the first month of the preceptorship, if Dr. Stringham will be out of the office during anytime that Dr. Li is seeing patients, Dr. Stringham will be available for consultation to Dr. Li by telephone.

6. Dr. Stringham and Dr. Li shall discuss clinical care at least two (2) times per month for the first six (6) months of the preceptorship, and as frequently as Dr. Stringham deems appropriate thereafter.

7. Dr. Christopher Vlasek, a board-certified family practice physician with Carson Tahoe Medical Group, shall be the secondary preceptor.

8. During the first six (6) months of the preceptorship, Dr. Li will observe Dr. Vlasek's patient care for two (2) to three (3) days per week.

9. Dr. Vlasek will provide a report to the Board two (2) times per month regarding his review of Dr. Li's patient charts and Dr. Li's program of observation.

10. Dr. Stringham and Dr. Vlasek shall between the two of them (divided as agreed upon between them) review Dr. Li's charts on the following schedule:

a. 100% of Dr. Li's charts during the first six months of the preceptorship;

b. 50% of Dr. Li's charts during months 7-12 of the preceptorship; and

c. 25% of Dr. Li's charts during months 13-18 of the preceptorship.

IT IS HEREBY FURTHER ORDERED that every six (6) months, Dr. Li shall provide to the Board an evaluation by a neurologist documenting his fitness to practice medicine, with the first evaluation to be completed as soon as possible.

///

///

///

///

///

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

IT IS HEREBY FURTHER ORDERED that if Dr. Li does not comply with these requirements, then this conduct may be grounds for disciplinary action and/or immediate suspension of his license pursuant to NRS 630.3065(2)(a) and/or NRS 630.326.

DATED this 16th day of September, 2022.

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: V M Muro MD

VICTOR M. MURO, M.D.
President of the Board

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

FILED
JUN 13 2019
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 19-087-CS-S**
Petitioner,	)	
v.	)	
	)	**NOTICE OF INTENDED ACTION**
SHOUPING LI, MD,	)	**AND ACCUSATION**
Certificate of Registration No. CS15391,	)	
Respondent.	)	

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because at the time of the alleged events, Respondent Shouping Li, MD (Li), held a Nevada Controlled Substance Registration, Certificate No. CS15391, issued by the Pharmacy Board.

FACTUAL ALLEGATIONS

II.

On February 5, 2019, Li executed a plea agreement under Fed. R. Crim. P. 11(c)(1)(A) and (B) (Plea Agreement) with the United States Attorney's Office for the District of Nevada, and entered in United States District Court for the District of Nevada, in D. Nev. case no. 3:19-cr-00009-MMD-CBC.

III.

In Section II(A) of the Plea Agreement, Li pled guilty to one count of distribution of a controlled substance in violation of 21 U.S.C. § 841(a)(1) and (b)(1)(c).

IV.

In Section III of the Plea Agreement, the elements of Li's criminal violation are specified as:

First, beginning on a date unknown but in no event later that October 2017 and continuing through on or about February 2018, the defendant knowingly distributed Schedule II substances, to wit: Oxycodone and Hydrocodone;

Second, the defendant knew that the controlled substances were Oxycodone and Hydrocodone or some other prohibited drug;

Third, the defendant distributed the controlled substances outside the usual course of professional practice and not for a legitimate medical purpose; and

Fourth, the defendant intended to distribute the controlled substances outside the course of his professional practice.

V.

In Section IV(E) of the Plea Agreement, Li admits to the following facts:

1. The defendant, SHOUPING LI (LI), was a licensed physician who, since 2007, practiced medicine in Nevada under Nevada License Number 12382, specializing in family medicine with a concentration in cardiovascular diseases. LI held the position of Vice Chief of Staff for the Humboldt County General Hospital IN Winnemucca, Nevada.

2. As part of his medical practice, he prescribed Schedule II Controlled Substances, including Oxycodone and Hydrocodone, under Drug Enforcement Administration ("DEA") license number BL8898770.

3. Defendant know that under the Controlled Substances Act, Title 21, United States Code, Section 841(a) et seq., and Title 21, Code of Federal Regulations, Section 1306.04, a prescription for a Schedule II controlled

substances was lawful only when written for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice.

4. Between approximately August 2015 and February 2018, defendant prescribed dosages and amounts of Oxycodone and Hydrocodone, to patients outside the usual course of his professional practice and without a legitimate medical purpose.

5. Defendant did so with intent to prescribe Oxycodone and Hydrocodone, to patients outside the usual course of his professional practice and without a legitimate medical purpose.

6. Several patients who were actively being seen as patients by the Defendant passed away.

7. All of the foregoing occurred in the State and Federal District of Nevada and elsewhere.

APPLICABLE LAW

VI.

A practitioner may prescribe controlled substances only for a legitimate medical purpose and in the usual course of his professional practice. NRS 453.381(1); 21 CFR § 1306.04.

VII.

Performing any duties as the holder of a license or registration issued by the Board in an incompetent, unskillful or negligent manner constitutes unprofessional conduct and conduct contrary to the public interest. NAC 639.945(1)(i).

VIII.

Prescribing a drug as a prescribing practitioner to a patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct and conduct contrary to the public interest. NAC 639.945(1)(o).

IX.

The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(d) and NRS 453.241(1).

X.

Engaging in conduct that constitutes unprofessional conduct or that is contrary to the public interest is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

XI.

Conviction of a violation of any law or regulation of the Federal Government related to controlled substances is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(6).

XII.

Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(11).

XIII.

Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(12).

FIRST CAUSE OF ACTION

XIV.

By prescribing controlled substances to patients outside the usual course of his professional practice and without a legitimate medical purpose, Li performed his duties as the holder of a Nevada Controlled Substance Registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 639.210(4) and NRS 639.255.

SECOND CAUSE OF ACTION

XV.

By prescribing controlled substances to patients with whom he did not have a bona fide therapeutic relationship, Li engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(o), and is subject to discipline pursuant to NRS 639.210(4) and NRS 639.255.

THIRD CAUSE OF ACTION

XVI.

By prescribing controlled substances to patients outside the usual course of his professional practice and without a legitimate medical purpose in violation of 21 U.S.C. § 841(a)(1) and (b)(1)(c), and by his conviction thereof, Li committed an act that would render his Nevada Controlled Substance Registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1)(d) and NRS 453.241(1).

FORTH CAUSE OF ACTION

XVII.

By prescribing controlled substances to patients outside the usual course of his professional practice and without a legitimate medical purpose in violation of 21 U.S.C. § 841(a)(1) and (b)(1)(c), and by his conviction thereof, Li is subject to discipline pursuant to NRS 639.210(6), (11) and/or (12), and NRS 639.255.

FIFTH CAUSE OF ACTION

XVIII.

By prescribing controlled substances to patients outside the usual course of his professional practice and without a legitimate medical purpose, Li violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.381(1) and 21 CFR § 1306.04, and is subject to discipline pursuant to NRS 639.210(12) and NRS 639.255.

XIX.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this 13th day of June, 2019.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file of two copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 639.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 19-087-CS-S**
	)	
Petitioner,	)	
v.	)	**STATEMENT TO THE**
	)	**RESPONDENT**
SHOUPING LI, MD,	)	**NOTICE OF INTENDED ACTION**
Certificate of Registration No. CS15391,	)	**AND ACCUSATION**
	)	**RIGHT TO HEARING**
Respondent.	/	

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, July 17, 2019, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada.

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 13th day of June, 2019.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 19-087-CS-S**
	)	
Petitioner,	)	
v.	)	**ANSWER AND NOTICE**
	)	**OF DEFENSE**
SHOUPING LI, MD,	)	
Certificate of Registration No. CS15391,	)	
	)	
Respondent.	/	

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this ___ day of June, 2019.

SHOUPING LI, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 13th day of June, 2019, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

SHOUPING LI, MD
[redacted]
Winnemucca, NV. 89445

SHIRLEY HUNTING

FILED
JUL 17 2019
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 19-087-CS-S**
Petitioner,	)	
v.	)	**VOLUNTARY SURRENDER OF REGISTRATION IN LIEU OF HEARING AND OTHER DISCIPLINARY ACTION**
SHOUPING LI, MD,	)	
Certificate of Registration No. CS15391,	)	
Respondent.	)	

I, SHOUPING LI, MD, Certificate of Registration No. CS15391, wish to voluntarily surrender my Nevada Certificate of Registration No. CS15391 in lieu of appearing before the Nevada State Board of Pharmacy (Board) at a formal disciplinary hearing in July 2019. To that end, I voluntarily and knowingly admit as follows:

1. I was registered with the Board at the time of the conduct described in the *Notice of Intended Action and Accusation* (Accusation) on file in this matter and as referenced herein. I am therefore subject to the Board's jurisdiction.

2. On February 5, 2019, I executed a plea agreement under Fed. R. Crim. P. 11(c)(1)(A) and (B) (Plea Agreement) with the United States Attorney's Office for the District of Nevada, and entered in United States District Court for the District of Nevada, in D. Nev. case no. 3:19-cr-00009-MMD-CBC.

3. On or about June 13, 2019, the Board filed the Accusation pursuant to NRS 639.233B.127(3), NRS 622A.300(1) and NRS 639.241, alleging five (5) causes of action against me, each relating to unprofessional and illegal conduct in prescribing dosages and amounts of Oxycodone and Hydrocodone to patients outside the usual course of my professional practice and without a legitimate medical purpose, as detailed in the Plea Agreement.

4. If this matter proceeded to a hearing, I admit that sufficient admissible evidence exists that the prosecutor could present to the Board in the form of testimony from witnesses and through documentary evidence to prove the facts alleged in the Accusation.

5. Based on those facts, the Board could conclude that the violations alleged in the Accusation occurred.

6. In lieu of appearing at a hearing where the prosecutor could prove the State's case against me and where the Board may take other and/or additional disciplinary actions against me, I hereby voluntarily surrender my Nevada Certificate of Registration No. CS15391.

7. In addition to this Voluntary Surrender, I agree to pay Five-Hundred Dollars ($500.00) to partially reimburse the Board for reasonable attorney's fees and costs incurred in investigating and prosecuting this matter. I agree to pay these reasonable attorney's fees and costs by *cashier's check* or *certified check* or *money order* made payable to "Nevada State Board of Pharmacy," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Voluntary Surrender.

8. The factual allegations in the Accusation, if proven at a hearing, would constitute unprofessional conduct pursuant to NAC 639.945(1)(i) and NAC 639.945(1)(o), and subject me to disciplinary action pursuant to NRS 639.210(4) and NRS 639.255, as alleged in the First and Second Causes of Action.

9. Additionally, the factual allegations in the Accusation, if proven at a hearing, would constitute violations of 21 U.S.C. § 841(a)(1) and (b)(1)(c), and subject me to disciplinary action pursuant to NRS 453.236(1)(d) and NRS 453.241(1), as alleged in the Third Cause of Action.

10. Additionally, the factual allegations in the Accusation, if proven at a hearing, would constitute violations of 21 U.S.C. § 841(a)(1) and (b)(1)(c), and subject me to disciplinary

action pursuant to NRS 639.210(6), (11) and/or (12), and NRS 639.255, as alleged in the Fourth Cause of Action.

11. Additionally, the factual allegations in the Accusation, if proven at a hearing, would constitute violations of, or attempts to violate, assist or abet in the violation of or conspiracy to violate NRS 453.381(1) and/or 21 CFR § 1306.04, and subject me to disciplinary action pursuant to NRS 639.210(12) and NRS 639.255, as alleged in the Fifth Cause of Action.

12. I have read this Voluntary Surrender and I fully understand and acknowledge its facts and terms.

13. I am aware of, understand, and have been advised of the effect of this Voluntary Surrender.

14. I am aware that I have certain constitutional rights, including:

a. I have the right to hire an attorney to represent me in this proceeding;

b. I have the right to demand a hearing on the charges against me, and I can require the Board Staff to prove the allegations;

c. I have the right to cross-examine the witnesses against me;

d. I have the right to call witnesses to provide evidence in my own behalf; and

e. I have other rights accorded to me under NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), NRS Chapter 639 (Nevada Pharmacy Act), and Chapter 639 of the Nevada Administrative Code.

15. I am aware of the foregoing rights, and I voluntarily, knowingly, and intelligently waive these rights in return for the Board accepting this Voluntary Surrender of my Nevada Certificate of Registration No. CS15391 in lieu of a hearing and other and/or additional disciplinary action.

16. I understand this Voluntary Surrender is considered a disciplinary action pursuant to NRS 233B.121(6), and as such will become part of my permanent record.

17. I understand that as a disciplinary action this this Voluntary Surrender is a public record in accordance with NRS 639.255(5).

18. I understand that as a disciplinary action this Voluntary Stipulation is reportable to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60, and to other national repositories that record disciplinary action taken against licensees or certificate holders, or to any agency of another state which regulates the practice of pharmacy.

19. I understand this Voluntary Surrender may be used in any subsequent hearings by the Board as evidence against me to establish a pattern of behavior and for the purpose of proving additional acts of misconduct.

20. This Voluntary Surrender shall not be construed as excluding or reducing any criminal or civil penalties or sanction or other remedies that may be applicable under federal, state or local laws.

21. I understand that this Voluntary Surrender is effective the day it is accepted by the Board, however, I agree to immediately cease and desist from prescribing any controlled substance in the State of Nevada.

22. I will immediately return my Nevada Certificate of Registration, No. CS15391, with this signed Voluntary Surrender of License In Lieu of Other Disciplinary Action, to the extent I have that certificate/registration in my possession.

23. If at any time I seek to obtain a new license or registration with the Board, I may be required to appear before the Board, which may ask me questions regarding my application, the allegations in this action, and/or any other circumstances surrounding the voluntary surrender of my registration.

I, SHOUPING LI, MD, Certificate of Registration No. CS15391, by affixing my signature below, agree with the foregoing facts and representations, and therefore choose to voluntarily surrender my Nevada Certificate of Registration No. CS15391.

SIGNED this ___ day of July 2019.

SHOUPING LI, MD,
Certificate of Registration No. CS15391

*****FOR NOTARY USE ONLY*****

State of Nevada

County of Washoe

On this 15th **day of** July **20** 19

Shouping Li
personally appeared before me and proved to me through satisfactory evidence of identification to be the person whose name is signed on the preceding document in my presence.

JAIME SANTOS
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 05-15-2022
Certificate No: 18-2776-2

Notary Public

05/15/2022
My Commission Expires

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby accepts the voluntary surrender of SHOUPING LI, MD, Certificate of Registration No. CS15391, in Case No. 19-087-CS-S, in lieu of a hearing and other or additional discipline. The Board hereby orders that the terms of the foregoing voluntary surrender be made effective upon execution below.

17 July 2019
Dated

Jason Penrod, President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 26th day of July, 2019, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

SHOUPING LI, MD
[redacted]
Winnemucca, NV, 89445

SHIRLEY HUNTING

11E

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

(This application cannot be used by PA's or APRN's)

4

CS26115

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☑ Schedule I ☑ Schedule II ☑ Schedule III ☑ Schedule IV ☐ Schedule V

Section 1: Personal Information

First: Victor Middle: Jimenez Last: Bonuel

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Home Address: [redacted]

City: [redacted] State: NV Zip: 89012

Telephone: [redacted] Email: [redacted]

Degree: MD Practitioner License #: 7208 Specialty: [redacted]

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled sub[redacted]

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Dr. Dara Forte Family Practice

Practice Address: 9010 West Cheyenne Ave Suite #:

City: Las Vegas State: NV Zip: 89129

Telephone: 7022408646 Fax: 702 240 0206 Email: dforte@forte family practice .com

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Victor Samuel [redacted] — 8-22-2024

Print Name (First, Last) — Date

Original Signature (electronic, copies or stamps not accepted) — 8-22-2024

Date

Board Use Only: Date Processed: 9/17/24 Amount: ~~$600.00~~

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Oct 2023 / Pending		AL	Montgomery	
Case # 5		Governing, licensing, Arresting Presiding Body/Agency/Court: Pending review attached documents		
Reason/Charge: Suspension of AL Board of Pharmacy License				
Plaintiff/Defendant/Claimant/Respondent: AL Medical Boards			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity: American Family Care				

Provide explanation below:

#3. Ive to give up my Controlled Substance license in Alabama in Jan. 2024 due to. Infractions e.g. Not doing urine drug screens on patients, Not checking the PDMP profiles on all patients, etc Subsequently the DEA in Alabama told me to surrender my DEA license (# BB3732371). Over 2000 Alabama Doctors have to Surrender their Controlled Substances DEA licenses due to multiple reasons including above statements. Sometime in February, I decided not to fight the Alabama Medical Board case + not attend their hearing. I decided to voluntarily Surrender my AL Board of Pharmacy License as well as my DEA license.

Original Signature (electronic, copies or stamps not accepted) — Date: Aug 22, 2024 / Sept 30, 2024

BEFORE THE ALABAMA STATE BOARD OF MEDICAL EXAMINERS

ALABAMA STATE BOARD OF MEDICAL EXAMINERS,	)	
Complainant,	)	
-vs-	)	**CASE NO. 2023 - 22**
VICTOR JIMENEZ BONUEL, M.D.,	)	
Respondent.	)	

ORDER DISMISSING PROCEEEDING

The Alabama State Board of Medical Examiners dismisses the order to show cause previously set for hearing on February 22, 2024, for the reasons stated below.

On February 14, 2024, Victor Jimenez Bonuel, M.D., voluntarily surrendered his Alabama Controlled Substances Certificate. See Motion to Dismiss, Exhibit A.

Done and Ordered in Montgomery, Alabama, on March 4, 2024.

Mark H. LeQuire, M.D.
Chairman, Alabama State Board of Medical Examiners

CC: BY ELECTRONIC MAIL ONLY
E. Wilson Hunter, Esq.
Alicia Harrison, Esq.

By FedEx Commercial Carrier
Victor Jimenez Bonuel, M.D.
[redacted]

By Electronic Mail
[redacted]

BEFORE THE ALABAMA STATE BOARD OF MEDICAL EXAMINERS

ALABAMA STATE BOARD OF MEDICAL EXAMINERS,	)	
Complainant,	)	
v.	)	**CASE NO.: 2023-22**
VICTOR JIMENEZ BONUEL, M.D.,	)	
Respondent.	)	

MOTION TO DISMISS

The Alabama State Board of Medical Examiners ("the Board"), by and through its counsel of record, moves to dismiss the Order to Show Cause previously filed in this matter by the Board on November 13, 2023. As grounds for this motion, the Board states that Respondent Victor Jimenez Bonuel, M.D. executed a Voluntary Surrender of Alabama Controlled Substances Certificate on February 14, 2024. *See* **Exhibit A.**

WHEREFORE, the Board requests the hearing officer, Honorable William Gordon, to enter an order dismissing this action.

Respectfully submitted on this the 1st day of March, 2024.

s/ Alicia Harrison
Alicia Harrison
Associate General Counsel
ALABAMA STATE BOARD OF MEDICAL EXAMINERS
PO Box 946
Montgomery AL 36101-0946
[redacted]

CERTIFICATE OF SERVICE

I hereby certify that I have on this 1st day of March, 2024, served a copy of the foregoing pleading upon the following, *via* electronic or U.S. Mail:

Victor Jimenez Bonuel, M.D.
[redacted]

Honorable William R. Gordon
[redacted]

Current address & emails:
[redacted]

s/ Alicia Harrison
OF COUNSEL

[redacted]

From: BME
Sent: Thursday, February 15, 2024 3:24 PM
To: [redacted]
Subject: FW: Dr Bonuel
Attachments: IMG_6854.HEIC; IMG_6853.HEIC

From: [redacted]
Sent: Thursday, February 15, 2024 1:21 PM
To: BME <bme@albme.gov>; [redacted]
Subject: Dr Bonuel

You don't often get email from nldavicmd59@yahoo.com. Learn why this is important

Hello,
I'm voluntarily giving up my ACSC . I'm cancelling our meeting on February 22,2024.

Thank you.

Dr Bonuel
[redacted]

Warning EXTERNAL EMAIL
This message has originated from outside albme.gov. Do not click links or open attachments unless you recognize the sender and never give out your password.

STATE OF ALABAMA)

MONTGOMERY COUNTY)

VOLUNTARY SURRENDER OF ALABAMA CONTROLLED SUBSTANCES CERTIFICATE

After being fully advised of my rights, and understanding that I am not required to surrender my controlled substances privileges, I freely execute this document and choose to take the actions described herein.

I, VICTOR JIMINEZ BONUEL, M.D., hereby knowingly, freely, and voluntarily surrender any authority under my Alabama Controlled Substances Certificate, ACSC number ACSC.38778, to order, manufacture, distribute, possess, dispense, administer or prescribe Schedule II, IIN, III, IIIN, IV and/or V controlled substances. I acknowledge that this action is taken by me while under investigation by the Alabama Board of Medical Examiners relating to my prescribing of controlled substances.

I understand and acknowledge I will have no authority to order, dispense, distribute, administer, or prescribe controlled substances in the state of Alabama.

I further understand and acknowledge that this surrender shall be effective immediately upon execution.

I acknowledge that I sign this document willingly and that I execute it as my free and voluntary act for the purposes herein expressed, and that I am of sound mind and under no constraint or undue influence. I understand that I have a right to a hearing in this matter, and I hereby freely, knowingly, and voluntarily waive such right to a hearing.

I also understand that the Alabama State Board of Medical Examiners shall [illegible] to any investigative file in this matter should I request reinstatement of my ACSC and that the Board has the right to contest my reinstatement. I understand that the Board may summarily deny any petition for reinstatement for two (2) years from the effective date of the surrender of my ACSC. I further understand that upon application for reinstatement, it shall be my burden to prove by sufficient evidence that I meet the criteria for reinstatement as provided for in the Board's rules, which [illegible] not limited to, demonstrating to the satisfaction of the Board that I can practice medicine with reasonable skill and safety to patients.

I further acknowledge that this voluntary surrender constitutes a public record of the Alabama State Board of Medical Examiners and will be reported by the Board to the National Practitioner Data Bank and to the Federation of State Medical Boards. This voluntary surrender may be released by the Alabama State Board of Medical Examiners to any person or entity requesting information concerning the licensure status in Alabama of the physician named herein.

EXECUTED this 14th day of February, 2024.

[redacted]

VICTOR JIMINEZ BONUEL, M.D.

Witnessed by:

(Print) Nida Bonuel (Sign) [redacted]

Victor Jimenez BONUEL

License Number:
7208

License Type:
Medical Doctor

License Status:
Active

Initial License Date:
Jul-28-1994

Expiration Date:
Jun-30-2025

Public Address:
[redacted]

Public City:
Henderson

Public State:
Nevada

Public ZIP Code:
89012

Public Country:
United States

Public Phone Number:
[redacted]

Credential:
M.D.

Specialties

Specialty
Internal Medicine

Education History

Institution	Degree/Certificate	Date Enrolled	Date To
Far Eastern University / Manila, Philippines	Medical Doctor Degree	N/A	Apr-05-1983

Postgraduate Training

Institution	Program Type	Specialty Type	Start Date	End Date
Woodhull Medical & Mental Health Ctr/ Brooklyn, NY	Residency	Internal Medicine	Jul-01-1990	Jun-30-1993

Board Actions

Summary	Attachments
None.	

Current Employment Status / Conditions / Restrictions on License / Prior Malpractice Claims

Summary	Attachments
None.	

Malpractice Information

Summary	Attachments
None.	

Powered by Thentia Cloud (https://www.thentia.com)

11F

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

Y CS18697

(This application cannot be used by PA's or APRN's)

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☐ Schedule I ☑ Schedule II ☑ Schedule III ☑ Schedule IV ☑ Schedule V

Section 1: Personal Information

First: William Middle: Wilbur Last: CLARK

Date of Birth: [redacted] SSN or ITIN [redacted] Sex: ☒ M ☐ F ☐ X

Home Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone [redacted] Email: [redacted]

Degree: DO Practitioner License #: 12419 Specialty: Anesthesia

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled substance registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): North State Medical Clinic

Practice Address: 495 Apple St Suite 125 Suite #: 125

City: Reno State: NV Zip: 89502

Telephone: 775 815 7355 Fax: _____ Email: [redacted]

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	X	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	X	
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		X
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

[redacted]

Original Signature (electronic, copies or stamps not accepted)

September 25, 2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

William W CLARK
Print Name (First, Last)

September 25, 2024
Date

[redacted]
Original Signature (electronic, copies or stamps not accepted)

September 25, 2024
Date

Board Use Only: Date Processed: 9/30/24 Amount: $200.00

Nevada State Board of Pharmacy

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521
(775) 850-1440 • FAX (775) 850-1444
[redacted] Web Page: bop.nv.gov

October 28, 2020

VIA CERTIFIED U.S. MAIL

William Clark, DO
[redacted]

Re: Suspension of Certificate of Registration No. CS18697 (Case No. 21-048-CS-N)

Dear Dr. Clark:

The Nevada State Board of Pharmacy (Board) has been notified by the U.S. Drug Enforcement Administration that you surrendered your DEA Certificate of Registration No. BC8772647 for cause by execution of the enclosed DEA-104 on October 20, 2021.

Please be advised that pursuant to NRS 639.2107 your surrender of your DEA registration operates as an immediate suspension of your Certificate of Registration No. CS18697 with the Board. Furthermore, your access to the Nevada Prescription Monitoring Program (PMP) database is terminated effective immediately since you are no longer authorized to access the PMP pursuant to NRS 453.221.

You may request a hearing before the Board to contest the suspension of your registration by submitting a written request to the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

Please be aware that the foregoing does not preclude a formal investigation or filing of an accusation pursuant to NRS 639.241. If you have any questions, please do not hesitate to contact me at 775-850-1440 or [redacted]

Best regards,

Brett Kandt
General Counsel
Nevada State Board of Pharmacy

Enclosure

U. S. Department of Justice - Drug Enforcement Administration

SURRENDER FOR CAUSE OF DEA CERTIFICATE OF REGISTRATION

DEA USE ONLY
File No.

In view of my alleged failure to comply with the Federal requirements pertaining to controlled substances or list I chemicals, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part, I hereby surrender for cause my Drug Enforcement Administration (DEA) Certificate of Registration.

I understand that submission of this document to DEA, including any employee of DEA, shall result in the immediate termination of my registration.

I understand that I am not entitled to a refund of any payments made by me in connection with my registration.

I understand that, beginning on the date that I sign below, I am not authorized to order, manufacture, distribute, possess, dispense, administer, prescribe, or engage in any other activities with controlled substances or list I chemicals.

With the understanding that I am not required to surrender my DEA Certificate of Registration, I freely and under no duress, implied or expressed, execute this document and choose to take the action described herein.

NAME OF REGISTRANT *(Print)*	ADDRESS OF REGISTRANT
Dr. William W. Clark	975 Roberta Lane Suite 101B Sparks, NV 89431
DEA REGISTRATION NO.	
BC8772647	
SIGNATURE OF REGISTRANT OR AUTHORIZED INDIVIDUAL [redacted]	DATE 10-20-2021

WITNESSES TO REGISTRANT'S SIGNATURE

NAME AND DATE	TITLE
Joshua Leavo [redacted] 10-20-21	Diversion Investigator
NAME AND DATE	TITLE
D. Lucas [redacted] 10/20/21	Special Agent

PRIVACY ACT

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (21 U.S.C 821).
PURPOSE: Permit surrender for cause of DEA Certificate of Registration.
ROUTINE USES: The Controlled Substances Act Registration Records produce special reports as required for statistical analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
C. Persons registered under the Controlled Substances Act (21 U.S.C. 822 and 957) for the purpose of verifying the registration of customers and practitioners.
EFFECT: Submission of this information is voluntary. There is no effect on the individual if not provided

FORM DEA-104 (07/16) *Previous editions obsolete*

21-048 - Clark Surrender of License

Individual Details

Name : Clark William Wilbur
Individual ID : [redacted]
DOB [redacted]
License# : CS18697
Original Issue Date : 07/14/2010
Mailing Address : [redacted] Apple Street Ste [redacted]
Reno,NV, 89502
Practice Phone :
Home Phone : [redacted]
Cell Phone : [redacted]
Email Address : [redacted]

License Details

Controlled Substance - 10/28/2021 - 10/31/2022 - Revoked

Explanatory Answers for BOP Application-Clark

Section 5, question #1

While I do not have a mental illness, substance/alcohol abuse, or physical condition that would currently impair my ability to perform the essential functions of my license, in 2003 and 2012, I went through substance abuse treatment for opioid use. After leaving treatment I completed a five-year contract with the Nevada Physician Health Program (at the time overseen by [redacted]. I remain committed to my recovery and currently see a psychiatrist once per month, participate in NA meetings twice a week, have a sponsor and continue to be seen by an addictionologist. I currently am prescribed medication for pain by my pain management physician and am regularly monitored, including submitting to regular drug screens.

Section 5, question #3

On July 14, 2022, the Nevada State Board of Pharmacy approved a Stipulation and Order resolving an Accusation file done May 11, 2022. Pursuant to the terms of the Stipulation and Order, my Nevada controlled substances registration was revoked, and I was prohibited from petitioning for reinstatement for a period of one year.

Section 5, question #4

My license to practice as a osteopathic physician has never been subjected to discipline, however as noted in my response to question #3, my Nevada controlled substance registration was revoked based on violations of pharmacy law.

[redacted]

FILED
JUL 14 2022
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. WILLIAM CLARK, DO, Certificate of Registration No. CS18697, Respondent.	CASE NO. 21-048-CS-N STIPULATION AND ORDER

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent William Clark, DO, Certificate of Registration No. CS18697, by and through counsel, Lyn E. Beggs, Esq., **HEREBY STIPULATE AND AGREE THAT:**

1. The Board has jurisdiction over Respondent and this matter.

2. On or about May 11, 2022, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

3. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives his rights to a

hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Respondent does not admit or deny the allegations contained in the Accusation, however, Respondent agrees that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the Accusation, *to wit*:

A. By diverting controlled substances, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 841(a); 21 U.S.C. § 843(a)(3), 21 U.S.C. § 844 42 U.S.C. § 12210 21 CFR § 1306.04(a), NRS 453.336(1), NRS 453.381(1), NRS 453.391(1) and/or NRS 453.411(1), and engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(g) and (h);

B. On October 20, 2021, Respondent surrendered his DEA Certificate of Registration No. BC8772647 to the U.S. Drug Enforcement Administration by executing a DEA Form 104, entitled "Surrender for Cause";

C. On or about October 28, 2021, Board staff served Respondent with notice that his surrender of his DEA Certificate of Registration No. BC8772647 for cause operated as an immediate suspension of his Certificate of Registration No. CS18697 with the Board pursuant to NRS 639.2107; and

D. By surrendering his DEA Certificate of Registration No. BC8772647 for cause, Respondent has admitted to failing to comply with the Federal requirements pertaining to controlled substances, has committed an act that would render his registration inconsistent with the public interest, is no longer authorized by Federal law to dispense controlled substances, and

his Certificate of Registration No. CS18697 is subject to revocation pursuant to NRS 453.236(1) and NRS 453.241(1).

7. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties:

A. The certificate of registration of Respondent William Clark, DO, Certificate of Registration No. CS18697, is hereby revoked pursuant to NRS 453.241(l)(b);

B. Respondent may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense a controlled substance until he has petitioned the Board for reinstatement pursuant to NRS 639.257 and the Board reinstates his certificate of registration;

C. Pursuant to NRS 622A.410(1) and 639.257(1), Respondent may not petition for reinstatement of his certificate of registration for a period of one (1) year from the effective date of this Order; and

D. In the event Respondent applies for reinstatement of his certificate of registration, or applies for any other certificate, license or permit with the Board, he shall appear before the Board to answer questions and give testimony regarding his application, his compliance with this Order, and the facts and circumstances underlying this matter.

8. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

9. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on July 13-14, 2022.

Respondent or his counsel will appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

10. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r-2 and 45 CFR Part 60.

11. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 3rd day of July, 2022

WILLIAM CLARK, DO,
Certificate of Registration No. CS18697

Signed this 5th day of June, 2022

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this 5th day of June, 2022

LYN E. BEGGS, ESQ.
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent William Clark, DO, Certificate of Registration No. CS18697, in Case No. 21-048-CS-N and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this 14th day of July, 2022.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 15th day of July 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

William Clark, DO
[redacted]

Lyn Beggs
[redacted]

[redacted]
KRISTOPHER MANGOSING

Nevada State
Board of Osteopathic Medicine

Attention | **Do not contact licensees directly. Please contact the Board to inquire about a licensee.**

William Wilbur Clark

License Number
DO1419

License Status
Active

License Type
Osteopathic Physician and Surgeon

Original Date of Licensure
07/29/2008

License Expiration Date
12/31/2025

Place of Practice

Address line 1
[redacted]Appe St

Address line 2
Suite[redacted]

City
Reno

State
Nevada

Postal Code
89502

Post Graduate Training

None

Historical Residencies

Profile
N/A

Facility
University of Connecticut

Specialty
Anesthesiology

Enrollment Date
07/01/1998

Graduation Date
06/30/2001

Profile
N/A

Facility
Roger Williams Medical Center

Specialty
Internal Medicine

Enrollment Date
07/01/1997

Graduation Date
06/30/1998

Profile
N/A

Facility
University of South Florida

Specialty
Neurology

Enrollment Date
12/01/2005

Graduation Date
06/30/2006

Board Actions

None

Malpractice Claim

None

12

12A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmaceutical Technician IN TRAINING (PTT) Application

Non-Refundable $50 fee

Rev (03/16/2023)

Section 1: General Information

First: NICHOLAS Middle: JASON Last: DIPIRRO

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] LYNBROOK ST

City: HENDERSON State: NV Zip: 89012

Telephone: [redacted] Email: [redacted]

Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you are enrolled in a PT school or training program.) NAC 639.258

Program/School Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Name of Program Director: _____

Signature of Program Director: _____

Section 3: Employment Information

Pharmacy Name: WALGREENS License #: _____

Address: 401 ARROYO GRANDE AVE

City: HENDERSON State: NV Zip: 89014

Section 4: Age and Education Requirements (You do not qualify to be a PT if you answer "NO" in this section.)	**Yes**	**No**
1. Are you 18 years of age or older?	Y	
2. Are you a high school graduate or the equivalent?	Y	

High School Name: RANCHO Graduation Date OR Date GED obtained (mm/yy): 06/97

Address: 1900 SEARLES AVE

City: N. LAS VEGAS State: NV Zip: 89101

Section 5: Military Service (NRS 622.120)	**Yes**	**No**
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	Y	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		Y
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		Y

Section 6: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 7: Personal and Professional History		
Before answering the questions below, please INITIAL to the right to attest you have read and understand the following: WARNING You MUST provide truthful and complete responses to the questions on this application. If you omit information or provide false or misleading responses, including any failure to disclose past arrests or expunged convictions, this may be a basis for denial of your application and may result in disciplinary action against any other license or registration you hold from the Board.	Initials WD	
	Yes	**No**
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		X
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state even if the case or charge has been dismissed, sealed, acquitted, or expunged?	X	
3. Have you been the subject of a board citation or administrative action whether completed or pending in any state?		X
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

7-10-24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician in training who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Nicholas DiPirro

Print Name

Original Signature (electronic, copies or stamps not accepted)

7/10/24

Date

Board Use Only	Date Received: 7/23/24	Amount: $50 cc

SCOPE II - R211 ▸ Dissemination - Citizens

LVMPD CITIZENS REPORT

SCOPE RESPONSE

PERSON BASE RECORD

ID #: [redacted]

NAM: DIPIRRO, NICHOLAS JASON **DOB:** [redacted]

SEX: [redacted] **RAC:** [redacted] **HGT:** [redacted] **WGT:** [redacted] **HAIR:** [redacted] **EYE:** [redacted]

ADR: RS [redacted] BOULDER HWY
LAS VEGAS NV 89122

AKA [3]

NAME	AGY	ENTRY DATE
DIPIRRO, NICHOLAS	LAS VEGAS METRO PD	3/6/2018
DIPERRO, NICHOLAS J	LAS VEGAS METRO PD	9/4/2019
DIPIRRO, NICHOLAS JASON	LAS VEGAS METRO PD	11/19/1996

ADDITIONAL DOB [1]

DOB	AGY	ENTRY DATE
[redacted]	LAS VEGAS METRO PD	11/19/1996

EVENT REPORTS [2]

TYPE:	ASSOCIATION:	AGY:	REPORTED:	ENTERED:	EVENT#:
OTHER	UNKNOWN	LAS VEGAS METRO PD	08/31/2001 00:00:00	08/31/2001 00:00:00	[redacted]

COMMENT [1]

COMMENT: **AGY:** LAS VEGAS METRO PD **COMMENT DATE:** 05/18/2013 15:40:23
T/C MANDALAY BAY (STA RPT PRK GAR)

TYPE:	ASSOCIATION:	AGY:	REPORTED:	ENTERED:	EVENT#:
OTHER	UNKNOWN	LAS VEGAS METRO PD	11/16/1996 00:00:00	11/16/1996 00:00:00	[redacted]

COMMENT [1]

COMMENT: **AGY:** LAS VEGAS METRO PD **COMMENT DATE:** 05/18/2013 15:40:23
T/C EASTERN/RENO

CRIMINAL HISTORY **ARR [4] CIT [1] SUM [0]**

ARREST DATE: 4/23/2022 **AGY: LAS VEGAS METRO PD** **PCN#: DSD1105000C** **BK#: -**

RN#: [redacted] **CHARGE:** 1 **TYPE:** PC **OFF:** 51448 DISCHG GUN/OTHER WEAPON WHERE PERS MIGHT BE ENDANG (G) **COUNTS:** 1 **EVT#:** [redacted]

CCN: [redacted] LAS VEGAS JUSTICE COURT **SEQ#:** 1 **CREATED:** 4/24/2022 **UPDATED:**

JUV/CERT/ADULT: ADULT

FINAL DISPO DATE:	FINAL OFF:	DISPO:	SENTENCED:
5/25/2022	51444 DISCHG GUN W/I STRUCT/VEH NOT W/I PROHIBIT AREA (M)	FOUND GUILTY	5/25/2022

CCN: [redacted] **UPDATED:**

FINE	EXCUSE	RESTITUTION
$	$	$

PER NEVADA REVISED STATUTES, LAS VEGAS METRO PD IS AUTHORIZED TO RELEASE OUR AGENCY'S CRIMINAL HISTORY INFORMATION ONLY. FOR OTHER AGENCY INFORMATION, CONTACT THE AGENCY DIRECTLY – OR – FOR COMPLETE BACKGROUND CHECKS, CONTACT THE STATE OF NEVADA REPOSITORY.

LAS VEGAS METRO PD LORALI WOODS/L19972W 02/12/2024 14:49:27

RELEASE TO: DIPIRRO, NICHOLAS

	MIN	YRS	MOS	DAYS	HRS		MIN	YRS	MOS	DAYS	HRS
TERM OF SENTENCE						COMMUNITY SERVICE					
CREDIT TIME SERVED					NO	PROBATION					

CITE DATE: 8/30/2019 **AGY: LAS VEGAS METRO PD** **PCN#:**

RN#: 0005 **CHARGE:** 1 **TYPE:** CRIM **OFF:** 51453 DRAW DW IN THREATENING MANNER (M) **COUNTS:** 1 **EVT#:** [redacted]
CITE#: 1-05741270A **CREATED:** 9/4/2019 **UPDATED:** **JUV/CERT/ADULT:** ADULT

FINAL DISPO DATE:	FINAL OFF:	DISPO:
10/14/2019	51453 DRAW DW IN THREATENING MANNER (M)	DISMISSED

CCN: [redacted] **UPDATED:**

FINE	EXCUSE	RESTITUTION
$	$	$

	MIN	YRS	MOS	DAYS	HRS		MIN	YRS	MOS	DAYS	HRS
TERM OF SENTENCE						COMMUNITY SERVICE					
CREDIT TIME SERVED					NO	PROBATION					

ARREST DATE: 1/15/2019 **AGY: LAS VEGAS METRO PD** **PCN#:** **BK#: -**

RN#: 0004 **CHARGE:** 1 **TYPE:** WA **OFF:** 51453 DRAW DW IN THREATENING MANNER (M) **COUNTS:** 1 **EVT#:** [redacted]
CCN: [redacted] LAS VEGAS JUSTICE COURT **CREATED:** 1/16/2019 **UPDATED:** **JUV/CERT/ADULT:** ADULT

FINAL DISPO DATE:	FINAL OFF:	DISPO:
2/20/2019	51453 DRAW DW IN THREATENING MANNER (M)	DISMISSED

CCN: [redacted] **UPDATED:** 2/11/2020

FINE	EXCUSE	RESTITUTION
$	$	$

	MIN	YRS	MOS	DAYS	HRS		MIN	YRS	MOS	DAYS	HRS
TERM OF SENTENCE						COMMUNITY SERVICE					
CREDIT TIME SERVED					NO	PROBATION					

ARREST DATE: 3/4/2018 **AGY: LAS VEGAS METRO PD** **PCN#: 25739016** **BK#: -**

RN#: 0002 **CHARGE:** 1 **TYPE:** PC **OFF:** 53815 PEDESTRIAN/ANIMAL RIDER FAIL WALK/RIDE ON SIDEWALK (M) **COUNTS:** 1 **EVT#:** [redacted]
CCN: [redacted] LAS VEGAS JUSTICE COURT **SEQ#:** 1 **CREATED:** 3/6/2018 **UPDATED:** **JUV/CERT/ADULT:** ADULT

RN#: 0003 **CHARGE:** 2 **TYPE:** PC **OFF:** 53819 INTOX PEDESTRIAN/ANIMAL RIDER ON ROAD (M) **COUNTS:** 1 **EVT#:** [redacted]
CCN: [redacted] LAS VEGAS JUSTICE COURT **SEQ#:** 2 **CREATED:** 3/6/2018 **UPDATED:** **JUV/CERT/ADULT:** ADULT

ARREST DATE: 1/15/2016 **AGY: LAS VEGAS METRO PD** **PCN#: 25602452** **BK#: -**

RN#: 0001 **CHARGE:** 1 **TYPE:** PC **OFF:** 50235 DOM BATTERY, (1ST) (M) **COUNTS:** 1 **EVT#:** [redacted]
CCN: [redacted] LAS VEGAS JUSTICE COURT **SEQ#:** 1 **CREATED:** 1/15/2016 **UPDATED:** **JUV/CERT/ADULT:** ADULT

FINAL DISPO DATE:	FINAL OFF:	DISPO:

PER NEVADA REVISED STATUTES, LAS VEGAS METRO PD IS AUTHORIZED TO RELEASE OUR AGENCY'S CRIMINAL HISTORY INFORMATION ONLY. FOR OTHER AGENCY INFORMATION, CONTACT THE AGENCY DIRECTLY – OR – FOR COMPLETE BACKGROUND CHECKS, CONTACT THE STATE OF NEVADA REPOSITORY.

LAS VEGAS METRO PD LORALI WOODS/L19972W 02/12/2024 14:49:27

RELEASE TO: DIPIRRO, NICHOLAS

6/13/2016 50235 DOM BATTERY, (1ST) (M) DISMISSED
CCN: [redacted] **UPDATED:** 1/28/2020

	FINE	EXCUSE	RESTITUTION
	$	$	$

	MIN	YRS	MOS	DAYS	HRS		MIN	YRS	MOS	DAYS	HRS
TERM OF SENTENCE						COMMUNITY SERVICE					
CREDIT TIME SERVED					NO	PROBATION					

WORK CARD/BUSINESS LICENSE - INACTIVE [1]

TYPE: WORKCARD
DESCRIPTION: SEC GRD – UNARMED
JURISDICTION: COUNTY
STATUS: APPROVED
ISSUE DATE: 4/4/2017
EXPIRATION DATE: 4/4/2022

EMPLOYER INFORMATION [1]

EMPLOYER: ALEXIS PARK HOTEL
POSITION: UNARMED SECURITY
NOTIFIED:

COMMENTS:

PER NEVADA REVISED STATUTES, LAS VEGAS METRO PD IS AUTHORIZED TO RELEASE OUR AGENCY'S CRIMINAL HISTORY INFORMATION ONLY. FOR OTHER AGENCY INFORMATION, CONTACT THE AGENCY DIRECTLY – OR – FOR COMPLETE BACKGROUND CHECKS, CONTACT THE STATE OF NEVADA REPOSITORY.

LAS VEGAS METRO PD LORALI WOODS/L19972W 02/12/2024 14:49:27

RELEASE TO: DIPIRRO, NICHOLAS

12B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

4

Pharmaceutical Technician IN TRAINING (PTT) Application

Non-Refundable $50 fee

Rev (03/16/2023)

Section 1: General Information

First: THOMAS Middle: FORBES Last: LYNCH

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] CARSON ST. [redacted]

City: CARSON CITY State: NV Zip: 89701

Telephone: [redacted] Email: [redacted]

Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you are enrolled in a PT school or training program.) NAC 639.258

Program/School Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Name of Program Director: _____

Signature of Program Director: _____

Section 3: Employment Information

Pharmacy Name: CVS Pharmacy #09842 License #: PHD1422

Address: 1980 N. Carson Street

City: Carson City State: NV Zip: 89701

Section 4: Age and Education Requirements (You do not qualify to be a PT if you answer "NO" in this section.)	**Yes**	**No**
1. Are you 18 years of age or older?	✓	
2. Are you a high school graduate or the equivalent?	✓	

High School Name: SAN CARLOS H.S. Graduation Date OR Date GED obtained (mm/yy): 07/82

Address: 2600 MELENDY DR.

City: SAN CARLOS State: CA Zip: 94070

Section 5: Military Service (NRS 622.120)	**Yes**	**No**
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 6: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	✓	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✓	

Section 7: Personal and Professional History		
Before answering the questions below, please INITIAL to the right to attest you have read and understand the following: WARNING You MUST provide truthful and complete responses to the questions on this application. If you omit information or provide false or misleading responses, including any failure to disclose past arrests or expunged convictions, this may be a basis for denial of your application and may result in disciplinary action against any other license or registration you hold from the Board.	**Initials** TV	
	Yes	**No**
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state even if the case or charge has been dismissed, sealed, acquitted, or expunged?	✓	
3. Have you been the subject of a board citation or administrative action whether completed or pending in any state?		✓
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
4/[illegible]/2023	4/28/2023	NV	CARSON CITY	CARSON CITY
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		CARSON CITY JUDICIAL COURT		
Reason/Charge				
453.336, 2A POSSESS CONT SUBSTANCE				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

I AM CURRENTLY ON PROBATION AND HAVE BEEN IN SUBSTANCE COUNSELING AND RECOVERY FOR 18 MONTHS. I HAVE BEEN CLEAN AND SOBER FOR 554 DAYS.

Thomas Lynch
Original Signature (electronic, copies or stamps not accepted)

10/21/24
Date

C%lose

%Open

%Save

%Print

1 Case Maintenance
2 Docket Entries
3 Parties
4 No Notes
5 Ticklers
6 Costs
7 Events
8 Case Disposition
9 Print Docket
10 Other Records
11 Link Case
12 Citation Information

Case Attributes

Case Number [redacted] Filed 04/16/2023 Case Status CLOSED Incmpf CONFIDENTIAL

Prosecutor ATTORNEY CARSON CITY DISTRICT > Judge ARMSTRONG, THOMAS R Department DEPT. I >

Nbr Type > Number Officer Agency CARSON CITY SHERIFF'S OFFICE > Officer BINDLEY, CODY >

Jurisdiction CARSON CITY > Complainant >

Defendant 1 of 1

Full Name LYNCH, THOMAS > Def Status CARSON CITY JAIL Def Status As Of 04/16/2023

DLN/State UNKNOWN Type Defendant Disposition

D.O.B. [redacted] S.S.N Degree of Offense FELONY

S.I.D. Home Address TRANSIENT

Def ID Def Number Bad Address

FBI Number Gender Male

Race WHITE Code Hair GRAY (NCIC) City/ST/Zip >

Height [redacted] Weight [redacted] Eyes [redacted] (NCIC) At Location 323 N STEWART ST

Other Case Nbr Court CARSON CITY JUSTICE COURT Attorney SPENCE, DANIEL J >

Charge(s) 1 of 1

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
1	State	D01190E00NV1C	POSSESS SCHEDULE 1 OR 2 CONTROLLED SUBSTANCE LESS THAN 14 GRAMS, 1ST OR 2ND OFFENSE		FELONY	DISMISSED

On	(to)	Off Tm	PCN Number	Citation Number	DMV	Bail Amount	Payable
04/15/2023	04/15/2023	3:08PM	NVCCSO6016953C	23-2249			1

453.336.2A

Charge	Statute Type	Enhancement Description	Disposition

On	(to)	Off Tm	PCN Number	Citation Number	Bail Amount	Payable

Total Bail Amount 0.00

Next Event	Appearance Date	Judge	Location

CARSON CITY JUSTICE AND MUNICIPAL COURT

JUDGMENT AND ORDER OF THE COURT

DEFENDANT: LYNCH, THOMAS

COURT CASE #: [redacted] ORIGINATING CASE #: [redacted] LANGUAGE SPOKEN: ENGLISH STATUS: CLOSED

PROSECUTING ATTORNEY: CARSON CITY DISTRICT ATTORNEY DEFENSE ATTORNEY: DANIEL SPENCE

CHARGE AND SENTENCE INFORMATION

CHARGES: 453.336.2A - POSSESS SCHEDULE 1 OR 2 CONTROLLED SUBSTANCE LESS THAN 14 GRAMS, 1ST OR 2ND OFFENSE

:

PLEA: NO PLEA

DISPOSITION: 04/28/2023 - DISMISSED JAIL:

FINES AND FEES

	ORIGINAL AMT	AMT PAID	AMT DISMISSED	AMT DUE
ADDITIONAL FEES				

TOTAL OWING AS OF THIS NO FINES OR FEES ARE DUE ON THIS CASE.

CONDITIONS INFORMATION

REQUIREMENTS	DUE DATE	CONDITION(S)	COMPLETED
		NO CONDITIONS ARE CURRENTLY ORDERED ON THIS CASE.	

ARREST/BAIL/BOND INFORMATION

ARREST DATE	STATUS DATE	CURRENT STATUS	AMOUNT	TYPE OF BAIL
04/15/2023	04/17/2023	RELEASED OWN RECOGNIZANCE		

NEXT COURT HEARING INFORMATION

NO FUTURE COURT DATE SCHEDULED AT THIS TIME

ADDITIONAL CASE INFORMATION

NO FURTHER INFORMATION

JUDGE'S SIGNATURE:_____ THOMAS ARMSTRONG,

C%lose

%Open

%Save

%Print

1 Case Maintenance
2 Docket Entries
3 Parties
4 Notes
5 Ticklers
6 Costs
7 Events
8 Case Disposition
9 Print Docket
10 Other Records
11 Link Case
12 Citation Information

Case Attributes

Case [redacted] Filed 03/06/23 Case Status MISDEMEANOR TREATMENT COURT IncmpF 1 Confidentia !_

Prosecutor CARSON CITY DISTRICT ATTORNEY > Judge ARMSTRONG, THOMAS R > Department DEPT. I >

Nbr Type > Number Officer Agency CARSON CITY SHERIFF'S OFFICE > Officer BINDLEY, CODY >

Jurisdiction CARSON CITY > Complainant >

Defendant 1 of 1

Full Name LYNCH, THOMAS > Def Status CARSON CITY JAIL !_ Def Status As Of 03/06/23

DLN/State Lic Type C CLASS LICENSE !_

D.O.B. [redacted] S.S.N

Defendant Disposition
Degree of Offense FELONY
Degree of Offense FELONY
Degree of Offense MISDEMEANOR
Degree of Offense MISDEMEANOR
Degree of Offense MISDEMEANOR
Degree of Offense MISDEMEANOR
Degree of Offense MISDEMEANOR

Home Address 1850 N. Carson St. #131

Def ID Type
Def Number
Bad Address
FBI Number
Gender Male
Race WHITE
Hair GRAY (NCIC)
City/ST/Zip CARSON CITY NV 89706 >
Code
Height [redacted] Weight [redacted] Eyes [redacted] (NCIC)
At Location [redacted]N CARSON ST
Other Case Nbr
Court CARSON CITY JUSTICE COURT !_
Attorney SPENCE, DANIEL J >

Charge(s) 1 of 7

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
1	State	D04004M00NV1C !_	USE OR POSSESS DRUG PARAPHERNALIA	!_	MISDEMEANOR	GUILTY

On	(to)	Off Tm	PCN Number	Citation Number	DMV	Bail Amount	Payable
03/04/2023	03/04/2023	4:16PM	NVCCSO6016656C	23-1370			1 !_

453.566

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
2	State	D01190E00NV1C !_	POSSESS SCHEDULE 1 OR 2 CONTROLLED SUBSTANCE LESS THAN 14 GRAMS, 1ST OR 2ND OFFENSE	!_	FELONY	NO CHARGES FILED

On	(to)	Off Tm	PCN Number	Citation Number	DMV	Bail Amount	Payable
03/04/2023	03/04/2023	4:16PM	NVCCSO6016656C	23-1370			1 !_

453.336.2A

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
3	State	W01009W00NV1C !_	ARREST FOR VIOLATION OF A CONDITION OF RELEASE	!_	MISDEMEANOR	GUILTY

On	(to)	Off Tm	PCN Number	Citation Number	DMV	Bail Amount	Payable
04/15/2023	04/15/2023	3:08PM	NVCCSO6016656C	23-1370			1 !_

178.4851.7A

Charge	Statute	Action/NOC/Statute	Description	Enhancement	Degree of	Disposition

				Description		Off.		
4	State	W01009W00NV1C	ARREST FOR VIOLATION OF A CONDITION OF RELEASE		MISDEMEANOR	GUILTY		

On	(to)	Off Tm	PCN	Number	Citation Number	DMV	Bail Amount	Payable
04/24/2023	04/24/2023		NVCCSO6016	656C	23-1370			1

178.4851.7A

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
5	State	W01009W00NV1C	ARREST FOR VIOLATION OF A CONDITION OF RELEASE		MISDEMEANOR	GUILTY

On	(to)	Off Tm	PCN	Number	Citation Number	DMV	Bail Amount	Payable
05/15/2023	05/15/2023		NVCCSO6016	656C	23-1370			1

178.4851.7A

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
6	State	W01017W00NV	ARREST OF MISDEMEANOR PROBATIONER FOR VIOLATION OF CONDITION OF PROBATION OR RESIDENTIAL CONFINEMENT		MISDEMEANOR	PROBATION EXTENDED

On	(to)	Off Tm	PCN	Number	Citation Number	DMV	Bail Amount	Payable
05/09/2024	05/09/2024		NVCCSO6016	656C	23-1370			1

211A.125

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
7	State	W01017W00NV	ARREST OF MISDEMEANOR PROBATIONER FOR VIOLATION OF CONDITION OF PROBATION OR RESIDENTIAL CONFINEMENT		MISDEMEANOR	PROBATION REINSTATED

On	(to)	Off Tm	PCN	Number	Citation Number	DMV	Bail Amount	Payable
07/11/2024	07/11/2024		NVCCSO6016	656C	23-1370			1

211A.125

Total Bail Amount 0.00

Next Event	MISDEMEANOR TREATMENT COURT	Appearance Date	11/07/2024	Judge	ARMSTRONG, THOMAS R	Location	DEPT. I

CARSON CITY JUSTICE AND MUNICIPAL COURT

JUDGMENT AND ORDER OF THE COURT

DEFENDANT: LYNCH, THOMAS

COURT CASE #: [redacted] ORIGINATING CASE #: [redacted] LANGUAGE SPOKEN: ENGLISH STATUS: MISDEMEANOR TREATMENT COURT

PROSECUTING ATTORNEY: CARSON CITY DISTRICT ATTORNEY DEFENSE ATTORNEY: DANIEL SPENCE

CHARGE AND SENTENCE INFORMATION

CHARGES: 453.336.2A - POSSESS SCHEDULE 1 OR 2 CONTROLLED SUBSTANCE LESS THAN 14 GRAMS, 1ST OR 2ND OFFENSE

:AMENDED TO: 453.566 USE OR POSSESS DRUG PARAPHERNALIA

PLEA: 04/28/2023 - GUILTY
DISPOSITION: 06/28/2023 - GUILTY JAIL: 180 DAYS JAIL SUSPENDED FOR 1 YEAR

CHARGES: 453.336.2A - POSSESS SCHEDULE 1 OR 2 CONTROLLED SUBSTANCE LESS THAN 14 GRAMS, 1ST OR 2ND OFFENSE

:

PLEA: NO PLEA
DISPOSITION: 03/06/2023 - NO CHARGES FILED JAIL:

CHARGES: 178.4851.7A - ARREST FOR VIOLATION OF A CONDITION OF RELEASE

:

PLEA: 04/28/2023 - GUILTY
DISPOSITION: 04/28/2023 - GUILTY JAIL: 4 DAYS, - 4 DAYS CREDIT, = 0 DAYS TO SERVE

CHARGES: 178.4851.7A - ARREST FOR VIOLATION OF A CONDITION OF RELEASE

:

PLEA: 06/28/2023 - GUILTY
DISPOSITION: 06/28/2023 - GUILTY JAIL: 2 DAYS, - 2 DAYS CREDIT, = 0 DAYS TO SERVE,

CHARGES: 178.4851.7A - ARREST FOR VIOLATION OF A CONDITION OF RELEASE

:

PLEA: 06/28/2023 - GUILTY
DISPOSITION: 06/28/2023 - GUILTY JAIL: 2 DAYS, - 2 DAYS CREDIT, = 0 DAYS TO SERVE,

CHARGES: 211A.125 - ARREST OF MISDEMEANOR PROBATIONER FOR VIOLATION OF CONDITION OF PROBATION OR RESIDENTIAL CONFINEMENT

:

PLEA: 05/09/2024 - ADMIT
DISPOSITION: 05/09/2024 - PROBATION EXTENDED JAIL: 1 DAYS REVOKED, - 0 DAYS CREDIT, = 1 DAYS TO SERVE, 179 DAYS REMAIN SUSPENDED MISSING TEST

CHARGES: 211A.125 - ARREST OF MISDEMEANOR PROBATIONER FOR VIOLATION OF CONDITION OF PROBATION OR RESIDENTIAL CONFINEMENT

:

PLEA: 07/11/2024 - ADMIT
DISPOSITION: 07/11/2024 - PROBATION REINSTATED JAIL: 1 DAYS REVOKED, - 0 DAYS CREDIT, = 1 DAYS TO SERVE, 178 DAYS REMAIN SUSPENDED MISSED GROUP

FINES AND FEES

	ORIGINAL AMT	AMT PAID	AMT DISMISSED	AMT DUE
ADDITIONAL FEES	$298.50	$102.50	$0.00	$196.00
	$298.50	$102.50	$0.00	$196.00

TOTAL OWING AS OF THIS $196.00

CONDITIONS INFORMATION

REQUIREMENTS	DUE DATE	CONDITION(S)	COMPLETED
		SPECIALTY COURT ADMISSION GRANTED MTC/PHASE 3	
8.00 HOUR(S)		COMMUNITY SERVICE; REPORT IMMEDIATELY OR UPON RELEASE FROM JAIL, TO THE DEPARTMENT OF ALTERNATIVE SENTENCING. MISSED GROUP	
		COMPLY WITH ALL RECOMMENDATIONS OF SPECIALTY COURT.	
1.00 DAY(S)	05/11/2024	JAIL TIME ORDERED; REPORT TO THE CARSON CITY JAIL ALCOHOL AND DRUG FREE. OK TO DO ON WEEKEND	
		CURFEW 10PM TO 5AM	
		REPORT TO DAS TO HAVE COLOR ASSIGNED (TESTING) ORCHID	06/28/2023
		SUBMIT TO SEARCH & SEIZURE WITH OR WITHOUT CAUSE FOR ALCOHOL, ILLEGAL DRUGS, MARIJUANA AND/OR ANY PRODUCTS CONTAINING THC, ILLEGAL DRUGS(INCLUDING ANY AND ALL SYNTHETIC CANNABINOIDS), DRUG PARAPHERNALIA; ANY NARCOTIC MEDICATIONS, EVEN IF PRESCRIBED BY A PHYSICIAN, MUST BE APPROVED BY DEPT OF ALTERNATIVE SENTENCING PRIOR TO TAKING.	

		NO BARS OR CASINOS SMOKE OR VAPE SHOPS	
8.00 HOUR(S)	07/12/2023	COMMUNITY SERVICE; REPORT IMMEDIATELY OR UPON RELEASE FROM JAIL, TO THE DEPARTMENT OF ALTERNATIVE SENTENCING. ASSOCIATION	07/20/2023
10.00 HOUR(S)	05/22/2024	COMMUNITY SERVICE; REPORT IMMEDIATELY OR UPON RELEASE FROM JAIL, TO THE DEPARTMENT OF ALTERNATIVE SENTENCING. MISSED PEER APPOINTMENT**** DUE DATE EXTENDED AND HOURS ADDED	
		OBEY ALL LAWS	
		NO ASSOC. W/ ANYONE USING DRUGS, ALCH, ON PROB	
	05/09/2025	FORMAL PROBATION; REPORT IMMEDIATELY OR UPON RELEASE FROM JAIL TO THE DEPARTMENT OF ALTERNATIVE SENTENCING.	
		DO NOT POSSESS OR CONSUME ANY ALCOHOL, ILLEGAL DRUGS, MARIJUANA AND/OR ANY PRODUCTS CONTAINING THC, ILLEGAL DRUGS (INCLUDING ANY AND ALL SYNTHETIC CANNABINOIDS), DRUG PARAPHERNALIA, ANY NARCOTIC MEDICATIONS, EVEN IF PRESCRIBED BY A PHYSICIAN, MUST BE APPROVED BY DEPT OF ALTERNATIVE SENTENCING PRIOR TO TAKING.	
		DEFENDANT TO BE SCREENED FOR ADMISSION TO SPECIALTY COURT, IF ACCEPTED MUST COMPLY WITH RECOMMENDATIONS.	06/28/2023

		MTC/APL	
12.00 HOUR(S)	08/02/2023	COMMUNITY SERVICE; REPORT IMMEDIATELY OR UPON RELEASE FROM JAIL, TO THE DEPARTMENT OF ALTERNATIVE SENTENCING. BEING DISRUPTIVE IN GROUP	08/03/2023
		REPORT TO DAS TO HAVE COLOR ASSIGNED (TESTING)	
1.00 DAY(S)	07/18/2024	JAIL TIME ORDERED; REPORT TO THE CARSON CITY JAIL ALCOHOL AND DRUG FREE.	
1.00 REPORT(S)	08/02/2023	MISCELLANEOUS CONDITION WRITE AN APOLOGY LETTER AND READ TO GROUP	07/06/2023

ARREST/BAIL/BOND INFORMATION

ARREST DATE	STATUS DATE	CURRENT STATUS	AMOUNT	TYPE OF BAIL
03/06/2023	03/06/2023	RELEASED OWN RECOGNIZANCE		
04/15/2023	04/17/2023	RELEASED OWN RECOGNIZANCE		

NEXT COURT HEARING INFORMATION

MISDEMEANOR TREATMENT COURT	Thursday, August 1, 2024	10:00 am

ADDITIONAL CASE INFORMATION

NO FURTHER INFORMATION

JUDGE'S SIGNATURE:_____ THOMAS ARMSTRONG, 7/11/2024

C%lose
%Open
%Save
%Print

Case Attributes

Case Number [redacted] Filed 03/12/202 0 Case Status CLOSED Incmpf 1 Confidentia l

Prosecutor ATTORNEY > CARSON CITY DISTRICT > Judge ARMSTRONG, THOMAS R Departmen t DEPT. I >

Nbr Type > Number Officer Agency CARSON CITY SHERIFF'S OFFICE > Officer ESPINO, KYLE >

Jurisdiction CARSON CITY > Complainant >

Defendant 1 of 1

Full Name LYNCH, THOMAS FORBES > Def Status CARSON CITY JAIL Def Status As Of 03/12/20 20

DLN/Stat Lic Type C CLASS LICENSE Defendant Disposition

D.O.B. [redacted] S.S.N

Degree of Offense FELONY
Degree of Offense GROSS MISDEMEANOR
Degree of Offense FELONY
Degree of Offense MISDEMEANOR
Degree of Offense GROSS MISDEMEANOR
Degree of Offense MISDEMEANOR
Degree of Offense MISDEMEANOR

1 Case Maintenance
2 Docket Entries
3 Parties
4 No Notes
5 Ticklers
6 Costs
7 Events
8 Case Disposition
9 Print Docket
10 Other Records
11 Link Case
12 Citation Information

Def ID Type
Def Number
FBI Number
Gender Male
Race WHITE Code
Hair GRAY (NCIC)
Height [redacted] Weight [redacted] Eyes [redacted] (NCIC)
Other Case Nbr
Court
Home Address TRANSIENT
Bad Address
City/ST/Zip >
At Location [redacted] HWY 50 E #308
Attorney WALKER, JOHN S. >

Charge(s) 1 of 7

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
1	State	B06008M00CC1C	PETIT LARCENY		MISDEMEANOR	GUILTY

On	(to)	Off Tm	PCN	Number	Citation Number	DMV	Bail Amount	Payable
03/12/20 20	03/12/2020	2:33AM			20-1582			1

Amend
08.04.121 CS, 205.240

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
2	State	B03004G00NV1C	POSSESS BURGLARY TOOLS		GROSS MISDEMEANOR	DISMISSED

On	(to)	Off Tm	PCN	Number	Citation Number	DMV	Bail Amount	Payable
03/12/20 20	03/12/2020	2:33AM			20-1582			1

205.080

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
3	State	D05023M00CC1C	POSSESS DRUG NOT TO BE INTRODUCED INTO INTERSTATE COMMERCE		MISDEMEANOR	GUILTY

On	(to)	Off Tm	PCN	Number	Citation Number	DMV	Bail Amount	Payable
Amend 03/12/20 20	03/12/2020	2:33AM			20-1582			1

08.04.125 CS, 454.351

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
4	Ordinance	D04004M00CC1C	USE OR POSSESS DRUG PARAPHERNALIA		MISDEMEANOR	NO CHARGES FILED

On	(to)	Off Tm	PCN	Number	Citation Number	DMV	Bail Amount	Payable
03/12/20 20	03/12/2020	2:33AM			20-1582			1

08.04.126 CS, 453.566

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
5	State	D05015G00NV1C	POSSESS DANGEROUS DRUG WITHOUT LEGAL PRESCRIPTION, FIRST OR SECOND OFFENSE		GROSS MISDEMEANOR	NO CHARGES FILED

On	(to)	Off Tm	PCN	Number	Citation Number	DMV	Bail Amount	Payable
03/12/2020	03/12/2020	2:33AM			20-1582			1

454.316.1, 454.316

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
6	State	W01017W00NV1C	ARREST OF MISDEMEANOR PROBATIONER FOR VIOLATION OF CONDITION OF PROBATION OR RESIDENTIAL CONFINEMENT		MISDEMEANOR	SUSPENDED SENTENCE REVOKED

On	(to)	Off Tm	PCN	Number	Citation Number	DMV	Bail Amount	Payable
07/20/2020	07/20/2020	12:25PM			20-1582			1

211A.125

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
7	State	W01017W00NV1C	ARREST OF MISDEMEANOR PROBATIONER FOR VIOLATION OF CONDITION OF PROBATION OR RESIDENTIAL CONFINEMENT		MISDEMEANOR	SUSPENDED SENTENCE REVOKED

On	(to)	Off Tm	PCN	Number	Citation Number	DMV	Bail Amount	Payable
07/22/2020	07/22/2020				20-1582			1

211A.125

Total Bail Amount 0.00

Next Event	Appearance Date	Judge	Location

JUDGMENT AND ORDER OF THE COURT
CARSON CITY JUSTICE AND MUNICIPAL COURT

DEFENDANT: LYNCH, THOMAS FORBES

COURT CASE #: [redacted] ORIGINATING CASE #: [redacted] LANGUAGE SPOKEN: ENGLISH STATUS: CLOSED

PROSECUTING ATTORNEY: CARSON CITY DISTRICT ATTORNEY DEFENSE ATTORNEY: JOHN WALKER

CHARGE AND SENTENCE INFORMATION

CHARGES: 205.060.2 - BURGLARY, FIRST OFFENSE

:AMENDED TO: 8.04.121 CS PETIT LARCENY

PLEA: 03/31/2020 - NO CONTEST
DISPOSITION: 03/31/2020 - GUILTY JAIL: 19 DAYS, - 19 DAYS CREDIT, = 0 DAYS TO SERVE, 161 ADDITIONAL DAYS SUSPENDED FOR 1 YEAR

CHARGES: 205.080 - POSSESS BURGLARY TOOLS

:

PLEA: NO PLEA
DISPOSITION: 03/31/2020 - DISMISSED JAIL:

CHARGES: 453.336.2a - POSSESS SCHEDULE I, II, III OR IV CONTROLLED SUBSTANCE, FIRST OR SECOND OFFENSE

:AMENDED TO: 8.04.125 CS POSSESS DRUG NOT TO BE INTRODUCED INTO INTERSTATE COMMERCE

PLEA: 03/31/2020 - GUILTY
DISPOSITION: 03/31/2020 - GUILTY JAIL: 19 DAYS, -19 DAYS CREDIT, = 0 DAYS TO SERVE, 161 ADDITIONAL DAYS SUSPENDED FOR 1 YEAR

CHARGES: 8.04.126 CCMC - USE OR POSSESS DRUG PARAPHERNALIA

:

PLEA: NO PLEA
DISPOSITION: 03/12/2020 - NO CHARGES FILED JAIL:

CHARGES: 454.316.1 - POSSESS DANGEROUS DRUG WITHOUT LEGAL PRESCRIPTION, FIRST OR SECOND OFFENSE

:

PLEA: NO PLEA
DISPOSITION: 03/12/2020 - NO CHARGES FILED JAIL:

CHARGES: 211A.125 - ARREST OF MISDEMEANOR PROBATIONER FOR VIOLATION OF CONDITION OF PROBATION OR RESIDENTIAL CONFINEMENT

:

PLEA: 08/19/2020 - ADMIT
DISPOSITION: 08/19/2020 - SUSPENDED SENTENCE REVOKED JAIL: 161 DAYS REVOKED, - 30 DAYS CREDIT, = 131 DAYS TO SERVE, CASE CLOSED

CHARGES: 211A.125 - ARREST OF MISDEMEANOR PROBATIONER FOR VIOLATION OF CONDITION OF PROBATION OR RESIDENTIAL CONFINEMENT

:

PLEA: 08/19/2020 - ADMIT
DISPOSITION: 08/19/2020 - SUSPENDED SENTENCE REVOKED JAIL:

FINES AND FEES

	ORIGINAL AMT	AMT PAID	AMT DISMISSED	AMT DUE
ADDITIONAL FEES				

TOTAL OWING AS OF THIS **NO FINES OR FEES ARE DUE ON THIS CASE.**

CONDITIONS INFORMATION

REQUIREMENTS	DUE DATE	CONDITION(S)	COMPLETED

ARREST/BAIL/BOND INFORMATION

ARREST DATE	STATUS DATE	CURRENT STATUS	AMOUNT	TYPE OF BAIL
03/12/2020	03/31/2020	JAIL SENTENCE SERVED; RELEASE FROM CUSTODY TODAY.		
07/20/2020	08/19/2020	ONCE JAIL SENTENCE IS SERVED, RELEASE FROM CUSTODY		

NEXT COURT HEARING INFORMATION

NO FUTURE COURT DATE SCHEDULED AT THIS TIME

ADDITIONAL CASE INFORMATION

NO FURTHER INFORMATION

JUDGE'S SIGNATURE: _____ **THOMAS ARMSTRONG,**

C%lose Case Attributes

%Open

%Save

%Print

1 Case Maintenance
2 Docket Entries
3 Parties
4 No Notes
5 Ticklers
6 Costs
7 Events
8 Case Disposition
9 Print Docket
10 Other Records
11 Link Case
12 Citation Information

Case Number21 [redacted] Filed04/21/202 Case Status CLOSED IncmpF Confidentia l

ProsecutoCARSON CITY DISTRICT ATTORNEY > Judge ARMSTRONG, THOMAS R DepartmenDEPT. I t >

Nbr Type > Number Officer Agency CARSON CITY SHERIFF'S OFFICE > OfficeSIMPSON, r NICK >

JurisdictCARSON CITY ion > Complainan t >

Defendan t 1 of 1

Full NameLYNCH, THOMAS FORBES > Def StatusCARSON CITY JAIL |_Def Status As Of 04/21/20 21

DLN/Sta· Lic Type C CLASS LICENSE |_ Defendant Disposition

D.O.B. [redacted] S.S.N . Degree of Offense FELONY

Degree of Offense MISDEMEANOR

Degree of Offense MISDEMEANOR

Home Address WILL CALL WITH ADDRESS

Def ID Type Def Number Bad Address

FBI Number GenderMale

RaceWHITE Cod e HairGRAY (NCIC) City/ST/Zip >

Height[redacted] Weight [redacted] Eyes [redacted] (NCIC) At Location E LONG ST / MOLLY DR

Other Case Nbr Court |_ Attorney DEFENDER, PUBLIC >

Charge(s) 1 of 3

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
1	State	D04004M00NV1C	_ USE OR POSSESS DRUG PARAPHERNALIA		_ MISDEMEANOR	GUILTY

On	(to)	Off Tm	PCN Number	Citation Number	DMV	Bail Amount	Payable
Amend 04/20/21	04/20/2021	12:40PM	NVCCSO6011679C	21-2600			1

453.566

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
2	Ordinance	D04004M00CC1C	_ USE OR POSSESS DRUG PARAPHERNALIA		_ MISDEMEANOR	NO CHARGES FILED

On	(to)	Off Tm	PCN Number	Citation Number	DMV	Bail Amount	Payable
04/20/21	04/20/2021	12:40PM	NVCCSO6011679C	21-2600			1

08.04.126 CS, 453.566

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
3	State	W01008W00NV1C	_ ARREST FOR VIOLATION OF A CONDITION OF BAIL RELEASE		_ MISDEMEANOR	DISMISSED

On	(to)	Off Tm	PCN Number	Citation Number	DMV	Bail Amount	Payable
07/20/21	07/20/2021	9:30AM		21-4835			1

178.484.12

Total Bail Amount 0.00

Next Event | Appearance Date | Judge | Locatio n

CARSON CITY JUSTICE AND MUNICIPAL COURT

JUDGMENT AND ORDER OF THE COURT

DEFENDANT: LYNCH, THOMAS FORBES

COURT CASE #: [redacted] ORIGINATING CASE #: [redacted] LANGUAGE SPOKEN: ENGLISH STATUS: CLOSED

PROSECUTING ATTORNEY: CARSON CITY DISTRICT ATTORNEY DEFENSE ATTORNEY: PUBLIC DEFENDER

CHARGE AND SENTENCE INFORMATION

CHARGES: 453.336.2A - POSSESS SCHEDULE 1 OR 2 CONTROLLED SUBSTANCE LESS THAN 14 GRAMS, 1ST OR 2ND OFFENSE

:AMENDED TO: 453.566 USE OR POSSESS DRUG PARAPHERNALIA

PLEA: 08/25/2021 - GUILTY
DISPOSITION: 08/25/2021 - GUILTY JAIL: 120 DAYS, - 37 DAYS CREDIT, = 83 DAYS TO SERVE, 0 ADDITIONAL DAYS SUSPENDED FOR 1 YEAR

CHARGES: 8.04.126 CCMC - USE OR POSSESS DRUG PARAPHERNALIA

:

PLEA: NO PLEA
DISPOSITION: 05/25/2021 - NO CHARGES FILED JAIL:

CHARGES: 178.484.12 - ARREST FOR VIOLATION OF A CONDITION OF BAIL RELEASE

:

PLEA: 07/22/2021 - NOT GUILTY
DISPOSITION: 08/25/2021 - DISMISSED JAIL:

FINES AND FEES

	ORIGINAL AMT	AMT PAID	AMT DISMISSED	AMT DUE
ADDITIONAL FEES	$32.00	$0.00	$0.00	$32.00
	$32.00	$0.00	$0.00	$32.00

TOTAL OWING AS OF THIS DATE $32.00

CONDITIONS INFORMATION

REQUIREMENTS	DUE DATE	CONDITION(S)	COMPLETED

ARREST/BAIL/BOND INFORMATION

ARREST DATE	STATUS DATE	CURRENT STATUS	AMOUNT	TYPE OF BAIL
04/20/2021	04/21/2021	RELEASED OWN RECOGNIZANCE NPRA		
07/20/2021	08/25/2021	ONCE JAIL SENTENCE IS SERVED, RELEASE FROM CUSTODY		

NEXT COURT HEARING INFORMATION

NO FUTURE COURT DATE SCHEDULED AT THIS TIME

ADDITIONAL CASE INFORMATION

NO FURTHER INFORMATION

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician in training who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

THOMAS LYNCH

Print Name

Thomas Lynch

Original Signature (electronic, copies or stamps not accepted)

10/21/24

Date

Board Use Only	Date Received: 10/21/24	Amount: 850-MO19-6774355558

13

14

14A

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop – December 5, 2024

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~*omitted material*~~] is language to be omitted, and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 639.070; NRS 639.2177; NRS 639.2327

Amendment of Nevada Administrative Code (NAC) Chapter 639. The proposed amendments set forth the requirements for the licensing and operation of a facility for intermediate care or facility for skilled nursing if the facility is licensed by the State Board of Health pursuant to NRS 449.0303.

Section 1. NAC 639.220 is hereby amended to read as follows:

639.220 1. The Board hereby adopts the following schedule of fees:

For the examination of an applicant for registration as a pharmacist.....Actual cost of the examination

For the investigation or registration of an applicant as a registered pharmacist.....$200

For the investigation, examination or registration of an applicant as a registered pharmacist by reciprocity.....200

For the investigation or issuance of an original license to conduct a retail pharmacy.....500

For the biennial renewal of a license to conduct a retail pharmacy.....500

For the investigation or issuance of an original license to conduct an institutional pharmacy.....500

For the biennial renewal of a license to conduct an institutional pharmacy……..……500

For the investigation or issuance of an original license to conduct a pharmacy in a correctional institution.....500

For the biennial renewal of a license to conduct a pharmacy in a correctional institution.....500

For the investigation or issuance of an original license to conduct a pharmacy in a recovery center or ambulatory surgical center licensed by the State Board of Health pursuant to NRS 449.0303 500

For the biennial renewal of a license to conduct a pharmacy in a recovery center or ambulatory surgical center licensed by the State Board of Health pursuant to NRS 449.0303 500

DRAFT

For the issuance of an original or duplicate certificate of registration as a registered pharmacist.....50

For the biennial renewal of registration as a registered pharmacist.....200

For the reinstatement of a lapsed registration (in addition to the fees for renewal for the period of lapse).....100

For the initial registration of a pharmaceutical technician or pharmaceutical technician in training 40

For the biennial renewal of registration of a pharmaceutical technician or pharmaceutical technician in training.....40

For the investigation or registration of an intern pharmacist.....40

For the biennial renewal of registration as an intern pharmacist.....40

For the investigation or registration of an advanced practice registered nurse or a physician assistant to prescribe drugs that are not controlled substances.....80

For the biennial renewal of registration of an advanced practice registered nurse or a physician assistant to prescribe drugs that are not controlled substances.....80

For authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, facility for treatment with narcotics, researcher, instructional user or any other authorized person to prescribe or possess controlled substances.....200

For the biennial renewal of authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, facility for treatment with narcotics, researcher, instructional user or any other authorized person to prescribe or possess controlled substances.....200

For the investigation or issuance of an original license to engage in business as an authorized warehouse, medical products provider or medical products wholesaler.....500

For the biennial renewal of a license to engage in business as an authorized warehouse, medical products provider or medical products wholesaler.....500

For the investigation or issuance of an original license to a manufacturer or wholesaler.....1,000

For the biennial renewal of a license for a manufacturer or wholesaler.....1,000

DRAFT

For the reissuance of a license issued to a pharmacy, when no change of ownership is involved, but the license must be reissued because of a change in the information required thereon.....50

For authorization of a practitioner, other than a licensed veterinarian, to dispense controlled substances or dangerous drugs, or both, for each location where the practitioner will dispense controlled substances or dangerous drugs, or both.....300

For the biennial renewal of authorization of a practitioner, other than a licensed veterinarian, to dispense controlled substances or dangerous drugs, or both, for each location where the practitioner will dispense controlled substances or dangerous drugs, or both.....300

For authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both, not for human consumption.....150

For the biennial renewal of authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both, not for human consumption.....150

For the investigation or issuance of an original license for an automated drug dispensing system 500

For the biennial renewal of a license for an automated drug dispensing system 500

For the investigation or issuance of an original license to a pharmacy authorizing the use of a mechanical device at a location off the premises of the pharmacy 250

For the biennial renewal of a license to a pharmacy authorizing the use of a mechanical device at a location off the premises of the pharmacy 250

For the investigation or issuance of an original license to a facility for intermediate care or facility for skilled nursing licensed by the State Board of Health pursuant to NRS 449.0303.....500

For the biennial renewal of a license to a facility for intermediate care or facility for skilled nursing licensed by the State Board of Health pursuant to NRS 449.0303.....500

DRAFT

Sec. 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 through 4 of this regulation.

Sec 2.

1. ***Each facility for intermediate care or facility for skilled nursing, licensed by the State Board of Health pursuant to NRS 449.0303, which does not have a licensed pharmacy on the premises and who wishes to maintain a stock of drugs for emergency treatment of inpatients, must:***
    a. ***Apply to the Board for a license to maintain a stock of drugs for emergency treatment of inpatients by submitting an application on a form prescribed by the Board and pay the requisite fee. A license granted pursuant to this section is a revocable privilege, and no holder of such a license acquires any vested right therein or thereunder.***
    b. ***If the stock of drugs includes controlled substances listed in schedule II, III, IV and V, register with the Drug Enforcement Administration of the United States Department of Justice.***
2. ***The director for the facility for intermediate care or facility for skilled nursing must ensure that the facility for intermediate care or facility for skilled nursing adheres to the provisions in NRS 639.2327(2-6) pertaining to the stock of drugs for emergency treatment of inpatients.***

Sec. 3.

1. ***Each facility for intermediate care or facility for skilled nursing, licensed by the State Board of Health pursuant to NRS 449.0303, which does not have a licensed pharmacy on the premises and who wishes to maintain a stock of drugs for emergency treatment of inpatients, or to stock a supply of drugs pursuant to NAC 639.476, to stock a supply of drugs in a mechanical device pursuant to NAC 639.720, or receive a prescription drug filled on the chart order of a practitioner to administer to a patient at the facility for intermediate care or facility for skilled nursing pursuant to NAC 639.478, shall:***
    a. ***Enter into a contract with a licensed pharmacy to provide the stock of drugs for emergency treatment of inpatients, to stock a supply of drugs pursuant to NAC 639.476, to stock a supply of drugs in a mechanical device pursuant to NAC 639.720, or to process and fill a prescription drug on the chart order of a practitioner to administer to a patient at the facility for intermediate care or facility for skilled nursing pursuant to NAC 639.478; and***
    b. ***Employ or enter into a contract with a pharmacist to establish policies and procedures which:***

DRAFT

i. *Are consistent with the policies and procedures developed pursuant to NAC 639.477;*

ii. *Require the maintenance of records in accordance with the provisions of NAC 639.485 and 639.486;*

iii. *Address the purchase, storage, maintenance of records of drugs purchases, administered;*

iv. *Require maintenance of a perpetual inventory of all controlled substances;*

v. *Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;*

vi. *Require the storage of drugs in accordance with specifications of the manufacturer;*

vii. *Require that the stock of drugs for emergency treatment of inpatients is stored pursuant to NRS 639.2327(2), stock of supply of drugs pursuant to NAC 639.476 and prescription drugs filled on the chart order of a practitioner for administration is secured and stored in a locked cabinet or room; and*

viii. *Ensure that the facility for intermediate care or facility for skilled nursing administers drugs pursuant to chart orders and in accordance with applicable state and federal laws; and*

c. *The policies and procedures established pursuant to subsection 1 must be maintained, reviewed at least annually, and dated upon adoption and amendment.*

d. *The pharmacist employed by or contracted with the facility for intermediate care or facility for skilled nursing pursuant to subsection 1b may establish the policies and procedures required pursuant to that subsection with the assistant of the director of the facility for intermediate care or facility for skilled nursing.*

Sec 4.

1. *A pharmacist employed by or contracted with the facility for intermediate care or facility for skilled nursing shall:*

a. *Visit the facility for intermediate care or facility for skilled nursing at least once a month to:*

i. *Evaluate the effectiveness of the policies and procedures established in section 3; and*

ii. *Confirm that the facility for intermediate care or facility for skilled nursing is complying with those policies and procedures, the provisions of this section and Section 3;*

DRAFT

b. Maintain documentation of each visit that the pharmacist makes pursuant to subsection 1;

c. Conduct an audit at least once each month using sufficient number of records of the facility for intermediate care or facility for skilled nursing, including, without limitation, records of patients and records relating to the purchasing, storing, and administration of drugs, which must be randomly selected to determine whether:

i. The records indicate that the drugs are administered in a safe and effective manner in accordance with accepted standards of practice and the specification of the manufacturer;

ii. The records demonstrate:

1. That a discrepancy does not exist in the number or quantity of drug dispensed on the order of a practitioner to the number or quantity of drug remaining;

2. The employees of the facility for intermediate care or facility for skilled nursing maintain accurate records relating to drugs; and

3. The employees of the facility for intermediate care or facility for skilled nursing properly monitor and maintain the perpetual inventory required pursuant to subparagraph 4 of paragraph b of subsection 1 of section 3; and

4. Submit a written report, including, without limitation, a written explanation to the Board not later than 5 business days after the pharmacist determines that:

a. The facility for intermediate care or facility for skilled nursing is violating a state or federal law which affects the care and safety of a patient;

b. There is a discrepancy of 5 percent or more between actual quantity of a controlled substance in the possession of the facility for intermediate care or facility for skilled nursing and the amount of the controlled substance that should be in the possession of the facility for intermediate care or facility for skilled nursing according to the records of the facility, including, without limitation:

i. Purchase orders and invoices for the controlled substance;

ii. Records which indicate the removal of the controlled substance from the storage area;

DRAFT

iii. Patient records;

iv. Records which indicate the return of the controlled substance to the manufacturer;

v. Records which indicate that the controlled substance was destroyed; and

vi. Any other record for the controlled substance;

c. The facility for intermediate care or facility for skilled nursing has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to Section 3.

d. The facility for intermediate care or facility for skilled nursing is administering a drug in violation of accepted standards of practice or the specifications of the manufacturer; or

e. The facility for intermediate care or facility for skilled nursing is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the facility for intermediate care or facility for skilled nursing.

NAC 639.498

1. Except as otherwise provided in subsection 2:

(a) At least once each month, the director or ***the pharmacist employed by or contracted with the facility for intermediate care or facility for skilled nursing*** ~~***a licensed consulting pharmacist***~~ shall destroy, on the premises of the facility, the controlled substances described in subsection 1 of NAC 639.050.

(b) If the director destroys the controlled substances, the ***pharmacist employed by or contracted with the facility for intermediate care or facility for skilled nursing*** ~~***licensed consulting pharmacist***~~ shall witness the destruction of the controlled substances. If the ***pharmacist employed by or contracted with the facility for intermediate care or facility for skilled nursing*** ~~***licensed consulting pharmacist***~~ destroys the controlled substances, the director shall witness the destruction of the controlled substances.

2. The director may designate a nurse licensed pursuant to chapter 632 of NRS to carry out his or her duties pursuant to this section. The ***pharmacist employed by or contracted with the facility for intermediate care or facility for skilled nursing*** ~~***licensed consulting pharmacist***~~ may designate a pharmacist licensed pursuant to chapter 639 of NRS to carry out his or her duties pursuant to this section.

DRAFT

3. The controlled substances must be destroyed in accordance with 21 C.F.R. Parts 1300, 1301, 1304, 1305, 1307 and 1317 and any other provision of federal law governing the destruction or disposal of controlled substances.

Statutes and regulations referenced when drafting this proposed regulation:

NRS 639.004 "Chart order" defined. "Chart order" means an order entered on the chart of a patient in a hospital, recovery center, facility for intermediate care or facility for skilled nursing which is licensed as such by the Division of Public and Behavioral Health of the Department of Health and Human Services or on the chart of a patient under emergency treatment in a hospital by a practitioner or on the written or oral order of a practitioner authorizing the administration of a drug to the patient.

NAC 639.478 Limitations on distribution of drugs. (NRS 639.070**,** 639.071**,** 639.072**)**

1. A drug may be given to a patient in a medical facility or correctional institution only on the order of a practitioner or an agent of the practitioner.
2. A drug may be distributed in a medical facility or correctional institution only from the original or a direct copy of the practitioner's order for medication.
3. A controlled substance listed in schedule II may be distributed to outpatients only pursuant to a written prescription.

(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91)

NRS 639.2327 Maintenance of stocks of drugs by certain facilities. A facility for intermediate care or facility for skilled nursing which is licensed as such by the Division of Public and Behavioral Health of the Department of Health and Human Services and is registered with the Board pursuant to this chapter may maintain a stock of drugs for emergency treatment of inpatients, subject to the following conditions:

1. The Board shall by regulation determine the specific drugs and the quantities thereof which may be maintained.
2. The emergency stock of drugs must be maintained at all times in a solid, sealed container and the seal must remain intact except when the drugs are needed for emergency treatment of a patient in the facility. The sealed container must be stored at all times in a locked compartment on the premises of the facility.
3. All drugs delivered to a facility must be signed for by the nurse or other person in charge. An inventory of the stock of drugs must be appended to the sealed container. Immediately after the drugs are needed, the physician or registered nurse who breaks the seal shall enter on the inventory sheet the following information:
   (a) The date and time the sealed container is opened;
   (b) The name of the patient for whom the drugs are to be used;
   (c) The name of the patient's physician or the physician who directs the administration of the drugs, if different;
   (d) An itemization of the drugs removed; and
   (e) The signature of the person who opened the sealed container.
4. When the drugs have been removed and the information required by subsection 3 has been entered on the inventory, the physician or registered nurse shall immediately replace the container in a locked compartment and shall notify the pharmaceutical consultant, as soon as it is practical to do so, that the container has been opened.

DRAFT

5. The sealed container and its contents at all times remain the responsibility of the pharmaceutical consultant. Upon being notified that the sealed container has been opened, or on the next business day if notification is not received during business hours, but in no event more than 48 hours following receipt of the notification, the pharmaceutical consultant shall:

(a) Examine the inventory sheet;

(b) Replace the drugs removed;

(c) Secure a written prescription for the drugs replaced, if one is required by law;

(d) Enter the name and quantity of the drugs so replaced on the inventory sheet, together with the date and time of replacement;

(e) Reseal the container; and

(f) Sign the inventory sheet.

6. No person other than a licensed physician or registered nurse may open the container or remove any drugs from the container.

7. The Board, its agents and inspectors may at all times have access to the premises of the facility to determine compliance with this section.

NRS 639.23275 Delivery of controlled substance or dangerous drug to hospital, recovery center, facility for intermediate care or facility for skilled nursing which does not have pharmacy on premises.

1. Except as otherwise provided in NRS 453.256, no pharmacy may deliver a controlled substance or dangerous drug for a specific patient to a hospital, recovery center, facility for intermediate care or facility for skilled nursing which is licensed as such by the Division of Public and Behavioral Health of the Department of Health and Human Services which does not have a pharmacy on the premises except pursuant to a prescription given:

(a) Directly from the prescribing practitioner to a pharmacist;

(b) Indirectly by means of an order signed by the prescribing practitioner; or

(c) By an oral order transmitted by an agent of the prescribing practitioner.

2. If an order for entry on a chart is given by a prescribing practitioner, the chart order must be signed by the practitioner who authorized the administration of the drug within 48 hours after the order is given by that practitioner.

NRS 639.2589 Form for prescription required to contain line for practitioner's signature; substitutions in filling prescriptions in certain facilities; substitutions in filling prescriptions ordered on patient's chart in hospital.

1. The form used for any prescription which is issued or intended to be filled in this state must contain a line for the signature of the practitioner.

2. Substitutions may be made in filling prescriptions contained in the orders of a physician, or of an advanced practice registered nurse who is a practitioner, in a facility for skilled nursing or facility for intermediate care.

3. Substitutions may be made in filling prescriptions for drugs ordered on a patient's chart in a hospital if the hospital's medical staff has approved a formulary for specific generic substitutions.

4. Substitutions may be made in filling prescriptions for biological products ordered on a patient's chart in a hospital if the hospital's medical staff has approved a formulary for specific interchangeable biological products.

NRS 639.267 Return, reissuance or transfer of unused drugs: Drugs packaged in unit doses generally; regulations.

1. As used in this section, "unit dose" means that quantity of a drug which is packaged as a single dose.

2. A pharmacist who provides a regimen of drugs in unit doses to a patient in a facility for skilled nursing or facility for intermediate care as defined in chapter 449 of NRS may credit the person or agency

DRAFT

which paid for the drug for any unused doses. The pharmacist may return the drugs to the dispensing pharmacy, which may reissue the drugs to fill other prescriptions or transfer the drugs in accordance with the provisions of NRS 449.2485.

3. Except schedule II drugs specified in or pursuant to chapter 453 of NRS and except as otherwise provided in NRS 433.801, 435.700, 449.2485, 638.200, 639.2675 and 639.2676, unit doses packaged in ampules or vials which do not require refrigeration may be returned to the pharmacy which dispensed them. The Board shall, by regulation, authorize the return of any other type or brand of drug which is packaged in unit doses if the Food and Drug Administration has approved the packaging for that purpose.

NRS 449.0151 "Medical facility" defined. [Effective January 1, 2022.] "Medical facility" includes:

1. A surgical center for ambulatory patients;
2. A freestanding birthing center;
3. An independent center for emergency medical care;
4. An agency to provide nursing in the home;
5. A facility for intermediate care;
6. A facility for skilled nursing;
7. A facility for hospice care;
8. A hospital;
9. A psychiatric hospital;
10. A facility for the treatment of irreversible renal disease;
11. A rural clinic;
12. A nursing pool;
13. A facility for modified medical detoxification;
14. A facility for refractive surgery;
15. A mobile unit; and
16. A community triage center.

NRS 449.0038 "Facility for intermediate care" defined. "Facility for intermediate care" means an establishment operated and maintained to provide 24-hour personal and medical supervision, for a person who does not have illness, disease, injury or other condition that would require the degree of care and treatment which a hospital or facility for skilled nursing is designed to provide.

NRS 449.0039 "Facility for skilled nursing" defined.

1. "Facility for skilled nursing" means an establishment which provides continuous skilled nursing and related care as prescribed by a physician to a patient in the facility who is not in an acute episode of illness and whose primary need is the availability of such care on a continuous basis.
2. "Facility for skilled nursing" does not include a facility which meets the requirements of a general or any other special hospital.

NRS 639.2806 Parenteral solutions: Limitation on sale and dispensing. A parenteral solution which is used by a patient in his or her home or in a facility for the dependent or a medical facility, other than a hospital as defined in NRS 449.012, may only be sold or dispensed:

1. By a pharmacy licensed in this state or a practitioner;
2. If the date of expiration is on its label; and
3. If a practitioner, registered pharmacist and a registered nurse are available at all times for immediate assistance to the patient in case of any pharmaceutical problems encountered in its use.

(Added to NRS by 1985, 867; A 1995, 295)

NRS 639.2807 Parenteral solutions: Compounding, packaging and labeling; regulations.

DRAFT

1. Any parenteral for use in a home or a facility for the dependent or a medical facility, other than a hospital as defined in NRS 449.012, must be compounded, packaged and labeled:

(a) By a registered pharmacist in a pharmacy or a practitioner licensed in this state. The practitioner shall ensure that the parenterals are delivered to the patient and are not available for use after the date of expiration.

(b) Pursuant to regulations adopted by the Board.

2. To maintain the stability of parenteral solutions, to prevent their contamination and that of the personnel of the practitioner and to ensure the quality and continuity of care for patients, the Board shall adopt regulations, to include:

(a) The procedures for the compounding, packaging, replacement and disposal of parenteral solutions;

(b) The conditions under which those solutions must be prepared, stored and delivered;

(c) The equipment required for the preparation, sterilization and storage of those solutions and the maintenance and cleaning of that equipment;

(d) The procedures for the proper disposal of any material used in the preparation of those solutions;

(e) The procedures for maintaining records and clinical monitoring of patients;

(f) The education and training of persons employed by practitioners; and

(g) The requirements for the education of patients relating to the use of parenterals.

(Added to NRS by 1985, 867; A 1989, 1123; 1995, 295)

NAC 639.476 Prepackaging of drugs. (NRS 639.070, 639.071, 639.072)

1. A pharmacy may prepackage drugs in quantities suitable for distribution within the facility or institution. The prepackaging may be performed only by a pharmacist or a pharmaceutical technician.

2. The label of a prepackaged unit must include:

(a) The generic or trade name of the drug, its strength and the dosage form;

(b) The lot number;

(c) The expiration date of the drug; and

(d) The quantity of the drug if the unit dose does not equal the unit of use.

3. A record of a prepackaged drug must be maintained that includes:

(a) The generic or trade name of the drug, its strength and the dosage form;

(b) The pharmacy's lot number;

(c) The name of the manufacturer;

(d) The manufacturer's lot number;

(e) The manufacturer's expiration date for the drug;

(f) The quantity per package, if more than one tablet or capsule is in a unit dose package;

(g) The number of packages;

(h) The date it was packaged and the assigned expiration date; and

(i) The initials of the responsible pharmacist.

4. Stock packages, prepackaged units and control records must be inspected by the pharmacist before the drugs may be included in regular stock.

(Added to NAC by Bd. of Pharmacy, eff. 3-27-90; A 9-12-91; 11-15-93)

NAC 639.515

1. A facility for skilled nursing or a facility for intermediate care may maintain a stock of the following drugs for emergency treatment for inpatients:

Analgesic-CII
Analgesic-non CII
Anesthetics, local
Antiarrhythmics
Antibiotics
Oral

DRAFT

Intravenous
Anticholinergic
Antidiarrheal
Antihistamine
Antihypertensive
Antinauseants
Antipsychotic
Bronchodilators
Calcium injectable
Dextrose injection
Diazepam
Digoxin
Diuretic injectable
Epinephrine
Glucagon
Heparin
Insulin
Intravenous solutions
Magnesium sulfate
Muscle relaxant
Naloxone
Nitroglycerin tablets
Normal saline
Phenobarbital
Phenytoin
Potassium chloride
Pressor amine
Protamine
Sodium bicarbonate
Steroids
Vitamin K
Water for injection

2. The quantity of each drug stocked must not exceed 20 units of each drug at each nursing station in the facility.

3. All drugs must be stored and maintained in unit dosages, if manufactured in that form.

DRAFT

14B

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop – December 5th 2024

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~*omitted material*~~] is language to be omitted, and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 639.070; NRS 639.2177; NRS 639.2327

Amendment of Nevada Administrative Code (NAC) Chapter 639. The proposed amendments allow a Dispensing Practitioner to mail certain prescriptions to a patient's physical location.

Section 1. NAC 639.742 is hereby amended to read as follows:

NAC 639.742 Dispensing of controlled substances or dangerous drugs for human consumption: Application by practitioner for certificate of registration at each site; application by facility required under certain circumstances; duties of dispensing practitioner, facility and federally-qualified health center vehicle relating to drugs; authority of dispensing practitioner and technician. (NRS 639.070**,** 639.0727**)**

1. Except as otherwise provided in NAC 639.7421 and 639.7423, a practitioner who wishes to dispense controlled substances or dangerous drugs, or both, for human consumption must apply to the Board on an application provided by the Board for a certificate of registration to dispense controlled substances or dangerous drugs. A practitioner must submit a separate application for each site of practice, including, without limitation, a telepharmacy, remote site or satellite consultation site, from which the practitioner wishes to dispense controlled substances or dangerous drugs, or both, for human consumption. A certificate of registration to dispense controlled substances or dangerous drugs, or both, for human consumption is a revocable privilege, and no holder of such a certificate of registration acquires any vested right therein or thereunder.

2. Except as otherwise provided in NAC 639.7421, 639.7422 and 639.7423, if a facility from which the practitioner intends to dispense dangerous drugs or controlled substances, or both, for human consumption is not wholly owned and operated by the practitioner, the owner or owners of the facility must also submit an application to the Board on a form provided by the Board.

3. Except as otherwise provided in this section and NRS 639.23277 and NAC 639.395, 639.648, 639.719 and 639.7423, the dispensing practitioner and, if applicable, the owner or owners of the facility and any federally-qualified health center vehicle, shall ensure that:

(a) All drugs are ordered by the dispensing practitioner;

(b) All drugs are received and accounted for by the dispensing practitioner;

(c) All drugs are stored in a secure, locked room or cabinet to which the dispensing practitioner has the only key or lock combination;

(d) All drugs are dispensed in accordance with NAC 639.745;

(e) No prescription is dispensed to a patient unless the dispensing practitioner is on-site at the facility or federally-qualified health center vehicle, as applicable;

(f) All drugs are dispensed only to the patient ***or to the agent of the ultimate user of the drugs*** personally at the facility or federally-qualified health center vehicle ***or mailed to the patient at the address of record***, as applicable;

(g) The price of each drug dispensed to a patient is separately itemized on any bill or statement provided to the patient;

(h) All drugs are dispensed only for medically necessary purposes and according to prevailing standards of care for practitioners practicing in the specialty claimed or practiced by the dispensing practitioner; and

(i) The certificate for each dispensing technician employed at the facility is displayed in the room or cabinet in which drugs are stored.

4. Except as otherwise provided in NAC 639.648, 639.719, 639.7423 and 639.7424, with regard to the filling and dispensing of a prescription at a facility, only the dispensing practitioner or a dispensing technician may:

(a) Enter the room or cabinet in which drugs are stored;

(b) Remove drugs from stock;

(c) Count, pour or reconstitute drugs;

(d) Place drugs into containers;

(e) Produce and affix appropriate labels to containers that contain or will contain drugs;

(f) Fill containers for later use in dispensing drugs; or

(g) Package or repackage drugs.

5. Except as otherwise provided in NAC 639.7423, a dispensing practitioner may compound drug products if he or she complies with the provisions of NAC 639.661 to 639.690, inclusive, as if:

(a) He or she were a pharmacist;

(b) His or her practice site was a pharmacy; and

DRAFT

(c) Any dispensing technician involved in the compounding was a pharmaceutical technician.

6. Except as otherwise provided in subsection 6 of NAC 639.746, the dispensing practitioners of an oncology group practice or a group of practitioners practicing at a reproductive healthcare center registered pursuant to NAC 639.746 are jointly responsible for ensuring that the requirements of subsection 3 are met.

(Added to NAC by Bd. of Pharmacy by R034-02, eff. 5-30-2003; A by R035-06, 9-18-2008; R037-10, 10-15-2010; R098-13, 3-28-2014; R146-17 & R015-18, 5-16-2018; R004-19, 12-30-2019; R007-21, 6-13-2022; R087-22, R178-22, R180-22 & R181-22, 12-29-2022)

NAC 639.708 Counseling of patients: Duties of pharmacy or dispensing practitioner. (NRS 639.070**,** 639.0727**,** 639.266**)** To facilitate counseling regarding a prescription, a pharmacy or dispensing practitioner shall:

1. Maintain a record of medication for each patient to whom a prescription has been dispensed by that pharmacy or dispensing practitioner, as applicable. The record must:

(a) Be retrievable for use by the pharmacist or dispensing practitioner;

(b) Be maintained for at least 2 years after the most recent entry;

(c) List all prescriptions dispensed to the patient at that pharmacy or by the dispensing practitioner; and

(d) Include all data required to be placed on the prescription.

2. Make a reasonable effort to obtain and retain in the record of medication the:

(a) Telephone number or numbers, if any, of the patient;

(b) Gender of the patient;

(c) Age or date of birth of the patient;

(d) History of the patient, including allergies, reactions to particular drugs and any medications or medical devices used by the patient; and

(e) Any comments relevant to the drug therapy of the patient, including any other information which is specific to the patient or drug.

3. Ensure that a pharmacist or dispensing practitioner who has access to the medical records of the patient is available by telephone during business hours and, for a pharmacy that routinely delivers prescriptions outside of the trade area covered by local telephone service, provide a toll-free telephone number.

4. Include with each prescription container of a pharmacy that is delivered or distributed by a public carrier:

(a) The local, and if applicable toll-free, telephone numbers of the pharmacy ***or dispensing practitioner***;

(b) The hours during which the patient may contact the pharmacy ***or dispensing practitioner*** by telephone; and

(c) A written notice in substantially the following form:

Written information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist ***or dispensing practitioner*** is available between the hours of ..... and ..... to answer your questions.

5. Maintain the confidentiality of each patient's records, including prescriptions, pursuant to NRS 449A.112 or 639.238, as applicable. A pharmacist or dispensing practitioner shall not divulge the contents of a patient's records, except as authorized by NRS 639.238 or any other applicable provision of law.

6. Make available to a practitioner, upon request, all information relating to a prescription that is provided to a patient of that practitioner by the pharmacist, an intern pharmacist or a dispensing practitioner.

7. Ensure that counseling is conducted in a confidential manner to prevent disclosure of information to any person other than the patient or the person caring for the patient.

(Added to NAC by Bd. of Pharmacy, eff. 11-15-93; A by R180-22, 12-29-2022)

DRAFT

David and Mui,

I wanted to share some exciting news regarding H.R. 5526, the Seniors' Access to Critical Medications Act of 2024. This legislation aims to amend the Stark Law to clarify that delivering medications by mail, courier, or via a family member by a dispensing practitioner will no longer be considered a violation. On September 23, 2024, the House of Representatives unanimously approved an amended version of the bill, which will soon be passed to the Senate, where it is expected to be adopted and signed into law. CCS has been a strong supporter of this initiative at the federal level, and it represents a significant advancement for cancer patients.

Below are some key provisions outlined within the bill:

- Starting January 1, 2025 through December 31, 2029, physician dispensing to Medicare patients via in-office, mail, or courier will be allowed.
- Will be allowed only if the patient had an in-person visit with the doctor within the last year and has an ongoing relationship with that doctor.
- Requires the Department of Health and Human Services to report back to Congress within three years on how many patients received drugs under this rule, how much it cost Medicare, what drugs were involved, and whether drug prices were impacted.

Given the federal allowance for medication delivery by dispensing practitioners, we need to take action to request that the Nevada Pharmacy Board revise NAC 639.742, which currently prohibits practitioners from mailing prescriptions. Many rural patients in Nevada face significant barriers, often needing to travel to Reno or Las Vegas for oral cancer medications or relying on pharmacy benefit managers, which can lead to delays in care.

We have garnered support from the Nevada State Medical Society, Washoe County Medical Society, and Clark County Medical Society, along with endorsements from Senators Catherine Cortez Masto and Jacky Rosen, as well as Congressman Mark Amodei.

I am optimistic that our request will be straightforward for the Pharmacy Board to process, ultimately helping to remove barriers for rural patients in need of medications.

Thank you in advance for your guidance and consideration,

--

Wesley Falconer, MBA/MHA

President and Chief Executive Officer

Cancer Care Specialists

Pronouns: he/him/his

Stark Law & Mailing Physician-Dispensed Prescriptions: From COVID-19 Waivers to Federal Legislative Action

by: Linda Mack of Squire Patton Boggs (US) LLP - *Triage*

Friday, September 27, 2024



Related Practices & Jurisdictions

- Health Law Managed Care
- Litigation Trial Practice
- Administrative Regulatory
- Coronavirus News
- D.C. Circuit (incl. bankruptcy)

PrintMailDownload/>i

In August 2024, a federal district court dismissed a lawsuit filed by the Community Oncology Alliance ("COA"), holding that the "in-office ancillary services" exception to the Stark Law does not permit physicians to dispense medications through the physician's office and then mail prescriptions to the patient's home. *COA v. Becerra, Case No. 23-cv-2168, Doc. 40, United States District Court for the District of Columbia (Aug. 30, 2024)*.

COA sued the Secretary of Health and Human Services (the "Secretary") and CMS challenging the policies presented under certain of CMS's Stark Law "Frequently Asked Questions" ("FAQs") as violating the Medicare Act and Administrative Procedure Act. COA alleged that prior to the COVID-19 pandemic, the regulations regarding the "in-office ancillary services" exception permitted mailing prescription drugs to patients. In September 2021 and May 2023, CMS published FAQs taking the position that the "in-

office ancillary services" exception does not apply when a patient receives an item outside the physician's office, including prescriptions delivered by mail, as the prescription would not be dispensed to the patient in the physician's office. COA argued the FAQs violated the Administrative Procedure Act by not following required rule-making procedures. COA also alleged that if physicians are prohibited from mailing prescriptions to patients such regulation would violate the Tenth Amendment of the U.S. Constitution by preventing states from regulating how physicians may dispense cancer drugs to patients.

From March 2020 to May 11, 2023, in response to the COVID-19 pandemic, the Secretary suspended penalties and issued waivers for certain referrals that would otherwise violate the Stark Law. One of the waivers applied to the "in-office ancillary services" exception and permitted physicians to mail "medically necessary" drugs and devices to a patient's home.

The Stark Law prohibits physicians from making referrals for "designated health services" including outpatient prescription drugs, to an entity in which the physician has a financial relationship (including the physician's own group practice) if such services are reimbursed by Medicare, unless an exception applies. 42 U.S.C. § 1395nn, *et seq*. The Stark Law aims to prevent Medicare abuse through self-dealing and the overutilization of health services. Congress created the "in-office ancillary services" exception in part to permit physicians to refer designated health services to their own group practices. The Stark Law also empowers the Secretary to promulgate regulations to further define how and when the statutory exceptions apply, and to also enact regulations for other exceptions for "any other financial relationship which the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse." *Id*. § 1395nn(b)(4).

COA alleged that mailing prescription drugs to a patient's home was permitted as the health care service (dispensing of medication) was "furnished" "in the location where the service is actually performed upon a patient" and where the drugs are "dispensed to a patient in a manner that is sufficient to meet the applicable Medicare payment and coverage rules." 42 C.F.R. § 411.355(b)(5). Because Medicare payment and coverage rules permit mailing prescription drugs, COA argued that the "in-office ancillary service" is met with physicians mailing drugs to a patient's home. Although the Court noted that "[t]here is something to [COA's] argument" it ultimately denied COA's Administrative Procedural Act claim, holding that the FAQs are consistent with preexisting requirements of the Stark Law and implementing regulations. The Court was persuaded by the "most natural reading of the regulation" which requires an "in-person" dispensing of medications and prohibits mailing of prescription drugs. Thus, because the FAQs did not alter preexisting requirements, CMS did not need to comply with notice and procedural act requirements when it issued the "interpretive" FAQs.

The Court also denied COA's Tenth Amendment claim. COA alleged that prohibiting physicians from mailing prescription drugs regulates the practice of medicine which is reserved to the police power of the states. The Court disagreed, holding that the Stark Law and the FAQs do not restrict the practice of medicine—"they only place conditions on physicians seeking Medicare payments." Further, because Congress possesses broad powers to "attach conditions on the receipt of federal funds," there is no Tenth Amendment violation.

Although COA was unsuccessful in its judicial challenge to the Secretary's interpretation of the "in-office ancillary services" exception to the Stark Law, COA and other physicians may obtain the relief they seek from Congress. In September 2023, House Bill 5526, titled "*Seniors' Access to Critical Medications Act of 2024"* was introduced with bi-partisan House of Representatives sponsorship, with 39 Republicans and

28 Democrats supporting the bill. As currently drafted, House Bill 5526 adds a prescription drug specific sentence to the statutory "in-office ancillary services" exception to the Stark Law which eliminates the requirement for the drugs to be furnished in a "building in which the referring physician … furnishes physicians' services unrelated to the furnishing of designated health services." Thus, H.R. 5526 essentially provides that delivering medicines by mail, courier, or other methods and allowing a family member to pick up medicines on behalf of a patient would not violate the Stark Law, so long as the prescriber as an ongoing preexisting relationship with the patient (not including telehealth). H.R. 5526 as currently proposed would be effective January 1, 2025. On September 23, 2024, the House of Representatives passed H.R. 5526, the bill was read twice in the Senate and referred to the Committee on Finance. During Congressional debate, Representative Dr. Larry Bucshon (Ill.) urged passing of H.R. 5526 and stated: "a silver lining of the COVID-19 pandemic, if there is one, was the proliferation of new, effective ways to deliver healthcare."

© Copyright 2024 Squire Patton Boggs (US) LLP

14C

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop December 5, 2024

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~*omitted material*~~] is language to be omitted, and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 453.146; NRS 453.221; NRS 639.070

A REGULATION relating to controlled substances adding ethylphenidate and 2-methyl AP-237 to the controlled substances listed in Schedule I; and providing other matters properly relating thereto.

NAC 453.510 is hereby amended to read as follows:

1. Schedule I consists of the drugs and other substances listed in this section by whatever official, common, usual, chemical or trade name designated

2. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including, without limitation, their isomers, esters, ethers, salts and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation:

Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide);

Acetylmethadol;

Acryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide) (some trade or other names: acryloylfentanyl);

Allylprodine;

Alpha' -methyl butyryl fentanyl (2-methyl-N-(1-phenethylpiperidin-4-yl)-phenylbutanamide);

Alphacetylmethadol (except levo-alphacetylmethadol, commonly referred to as levo-alpha-

acetylmethadol, levomethadyl acetate or “LAAM”);

Alphameprodine;

Alphamethadol;

Alphamethylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);

Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);

Benzethidine;

Betacetylmethdol;

Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropanamide);

Beta-hydroxy-3-methylfentanyl (other name: N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide);

Beta-hydroxythiofentanyl (trade or other names: N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide; N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide);

Betameprodine;

Betamethadol;

Betaprodine;

Butyryl fentanyl (trade or other names: N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide; N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide);

Clonitazene;

Cyclopentylfentanyl(N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide);

Cyclopropylfentanyl(N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide);

Dextromoramide;

Diampromide;

2',5'-dimethoxyfentanyl (N *-(1-(2,5 dimethoxyphenethyl)piperidin-4-yl)* N*-phenylpropionamide);*

Diethylthiambutene;

Difenoxin;

Dimenoxadol;

Dimepheptanol;

Dimethylthiambuten;

Dioxaphetyl butyrate;

Dipipanone;

Ethylmethylthiambutene;

Etonitazene;

Etoxeridine;

Eutylone (bk-EBDB, 1-(1,3-Benzodioxol-5-yl)-2-(ethylamino)butan-1-one, b-keto-ethylbenzodioxolylbutanamine);

Fentanyl carbamate (Ethyl-(1-phenethylpiperidin-4-yl)(phenyl)carbamate);

Fluoro furanyl fentanyl;

Fluoroacryl fentanyl;

Fluorobutyryl fentanyl;

Fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]propanamide);

Fluoroisobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide);

Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide);

DRAFT

3-furanyl fentanyl (N *-(1-phenethylpiperidin-4-yl)-* N *-phenylfuran-3-carboxamide);*

Furethidine;

Hydroxypethidine;

Isobutyryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide);

Isovaleryl fentanyl (3-methyl-N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide);

Isotonitazene;

Ketobemidone;

Levomoramide;

Levophenacylmorphan;

Meta -fluorofentanyl (N -(3-fluorophenyl)- N -(1-phenethylpiperidin-4-yl)propionamide);

Meta -fluoroisobutyryl fentanyl (N -(3-fluorophenyl)- N -(1-phenethylpiperidin-4-yl) isobutyramide);

Methoxyacetyl fentanyl***;***

Methyl acetyl fentanyl;

2-Methyl-AP-237 (some trade or other names: 1-(2-methyl-4-(3- phenyl-2-propen-1-yl)-1-piperazinyl)-1-butanone; 2-MAP);

Methyl methoxyacetyl fentanyl (some trade or other names: 2-methoxy-N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide (ortho-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl));

Methylfentanyl;

Methylthiofentanyl;

Morpheridine;

MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);

Noracymethadol;

DRAFT

Norlevorphanol;

Normethadone;

N-(1-(2-fluorophenethyl)piperidin-4-yl)-N-(2-fluorophenyl)propionamide (2'-fluoro ortho-fluorofentanyl; 2'-fluro 2'-fluorofentanyl);

Norpipanone;

Ocfentanil (N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl)acetamide;

Ortho -fluorofuranyl fentanyl (N -(2-fluorophenyl)- N -(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

Para-chloroisobutyryl fentanyl (N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide);

Para-fluorobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide);

Para-methoxybutyryl fentanyl (N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)butyramide);

Para -methoxyfuranyl fentanyl (N -(4-methoxyphenyl)- N -(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

Para -methylcyclopropyl fentanyl (N -(4-methylphenyl)- N -(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide);

PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine);

Phenadoxone;

Phenampromide;

Phenomorphan;

Phenoperidine;

Phenyl fentanyl (some trade or other names: benzoyl fentanyl);

DRAFT

Phenylpropanoyl fentanyl;

Piritramide;

Proheptazine;

Properidine;

Propiram;

Racemoramide;

Tetrahydrofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide);

Tianeptine;

Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide);

Thiofuranyl fentanyl (some trade or other names: thiophene fentanyl);

Tilidine;

Trimeperidine; or

Valeryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylpentanamide).

3. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

Acetorphine;

Acetyl fentanyl;

Acetyldihydrocodeine;

Benzylmorphine;

Codeine methylbromide;

Codeine-N-Oxide;

Cyprenorphine;

Desomorphine;

Dihydromorphine;

Drotebanol;

Etorphine (except hydrochloride salt);

Heroin;

Hydromorphinol;

Methyldesorphine;

Methyldihydromorphine;

Morphine methylbromide;

Morphine methylsulfonate;

Morphine-N-Oxide;

Myrophine;

Nicocodeine;

Nicomorphine;

Normorphine;

Pholcodine; or

Thebacon.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following hallucinogenic substances, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

DRAFT

ADB–BUTINACA (some trade or other names: N -(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butyl-1 H -indazole-3-carboxamide

ADB-4en-PINACA (some trade or other names: N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1H-indazole-3-carboxamide)

Adinazolam (some trade or other names: 8-chloro-1-((dimethylamino)methyl)-6-phenyl-4H-s-triazlo(4,3-a)(1,4)benzodiazepine; adinazolamum; Deracyn);

Alpha-ethyltryptamine (some trade or other names: ET, Trip);

Alpha-methyltryptamine (some trade or other names: AMT);

Alpha -PiHP (some trade or other names: 4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one)

Bromazolam (some trade or other name: 8-bromo-1-methyl-6-phenyl H[1,2,4]triazolo[4,3a][1,4]benzodiazepine; XLI-268);

1,4-Butanediol (some trade or other names: 1,4-butyleneglycol, dihydroxybutane, tetramethylene glycol, butane 1,4-diol, SomatoPro, Soma Solutions, Zen);

~~3~~-bromo-2,5-dimethoxyamphetamine (some trade or other names: 4-bromo-2,5-dimethoxy-alpha-methylphenethylamine; 4-bromo-2,5-DMA);

4-bromo-2,5-dimethoxyphenethylamine (some trade or other names: Nexus, 2C-B);

1-Butyl-3-(1-naphthoyl)indole-7173 (some trade or other names: JWH-073);

2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-C);

4-(2-chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine (some trade or other names: Etizolam);

Clonazolam (some trade or other names: 6-(2-chlorophenyl)-1-methyl-8-nitro-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; clonitrazolam);

1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (some trade or other names: SR-18; BTM-8; RCS-8);

CUMYL-PEGACLONE (some trade or other names: SGT-151; 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one; 2,5-dihydro-2-(1-methyl-1-phenylethyl)-5-pentyl-1H-pyrido[4,3-b]indol-1-one)

Diclazepam (some trade or other names: 7-chloro-5-(2-chlorophenyl)-1,3-dihydro-1-methyl-2H-1,4-benzodiazepine-2-one; 7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2H-benzo[e][1,4]diazepin-2-one; 2'-chlorodiazepam; Chlorodiazepam; Ro 5-3448);

2,5-dimethoxyamphetamine (some trade or other names: 2,5-dimethoxy-alpha-methylphenethylamine; 2,5-DMA);

2,5-dimethoxy-4-ethylamphet-amine (some trade or other names: DOET);

2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (some trade or other names: 2C-E);

2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (some trade or other names: 2C-D);

2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (some trade or other names: 2C-N);

2,5-Dimethoxy-N-(2-methoxybenzyl) phenethylamine (NBOMe) and any derivative thereof (some trade or other names: 2C-X-NBOMe; N-benzylated phenethylamines; N- o-methoxybenzyl analogs; NBOMe; 25H-NBOMe; 25B-NBOMe; 25C-NBOMe; 25D-NBOMe; 25E-NBOMe; 25I-NBOMe; 25N-NBOMe; 25P-NBOMe; 25T2-NBOMe; 25T4-NBOMe; 25T7-NBOMe);

2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (some trade or other names: 2C-P);

2,5-dimethoxy-4-(n)-propylthiophenethylamine (some trade or other names: 2C-T-7);

2-(2,5-Dimethoxyphenyl)ethanamine (some trade or other names: 2C-H);

3-[(2-Dimethylamino)ethyl]-1H-indol-4-yl acetate (some trade or other names: 4-acetoxy- N, N-dimethyltryptamine;4-AcO-DMT; psilacetin; O-acetylpsilocin; 4-acetoxy-DMT);

5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7297 (some trade or

other names: CP-47,497);

5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7298 (some trade or other names: cannabicyclohexanol; CP-47,497 C8 homologue);

Ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-EDMB-PINACA);

4-ethylnaphthalen-1-yl-(1-pentylindol-3-yl)methanone (some trade or other names: (4- ethyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone; JWH-210);

2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-2);

4F-MDMB-BUTICA (some trade or other names: 4F-MDMB-BICA; Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate; N-[[1-(4-fluorobutyl)-1H-indol-3-yl]carbonyl]-3-methyl-L-valine, methyl)

5F-EDMB-PICA (some trade or other names: 5F-EDMB-2201; Ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate; N-[[1-(5-fluoropentyl)-1H-indol-3-yl]carbonyl]-3-methyl-L-valine, ethyl ester)

Flualprazolam (some trade or other names: 8-chloro-6-(2-fluorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; 8-chloro-6-(2-fluoro-phenyl)-1-methyl-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine; 2'-fluoro alprazolam; ortho-fluoro alprazolam);

Flubromazepam (some trade or other names: 7-bromo-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; 7-Bromo-5-(2-fluorophenyl)-1H-benzo[e][1,4]diazepin- 2(3H)-one; 7-bromo-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one);

Flubromazolam (some trade or other names: 8-bromo-6-(2-fluorophenyl)-1-methyl-4H-(1,2,4)triazolo(4,3-a)(1,4)benzodiazepine);

DRAFT

Flunitrazolam (some trade or other names: 6-(2-fluorophenyl)-1-methyl-8-nitro-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine);

(1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: FUB-144);

2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (Some trade or other names: FUB-AMB; MMB-FUBINACA);

[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (some trade or other names: THJ-2201; 5-fluoro THJ 018; AM2201 indazole analog; fluorpentyl JWH-018 indazole);

[1-(5-fluoropentyl)-1H-indol-3-yl]-1-naphthalenyl-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(1-naphthoyl)indole; AM-2201);

[1-(5-fluoropentyl)-1H-indol-3-yl]-(2-iodophyenyl)-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole; AM-694);

(1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: XLR-11);

1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (some trade or other names: 5F-CUMYL-PINACA; SGT-25);

1-(5-fluoropentyl)-N-(tricyclo[3.3.1.13,7]dec-1-yl)-1H-indazole-3-carboxamide (some trade or other names: N-((3s,5s,7s)-adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide; APINACA 5-fluoropentyl analog; 5F-AKB48; 5-Fluoro-AKB48; 5F-APINACA; 5-Fluoro-APINACA;

1-(5-fluoropentyl)-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1-(5-fluoropentyl)-1H-indole-3-carboxylic acid 8-quinolinyl ester; 5-Fluoro-PB-22; 5F-PB-22);

Flutoprazepam (some trade or other names: 7-chloro-1-(cyclopropylmethyl)-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one);

2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-I);

2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-4);

1-hexyl-3-(1-naphthoyl)indole (some trade or other names: JWH-019);

MDMB-4en-PINACA (some trade or other names: Methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1H-indazole-3-carboxamido)butanoate)

Meclonazepam (some trade or other names: (3S)-5-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one; Ro 11-3128);

Methoxetamine (some trade or other names: MXE; 2-(3-methoxyphenyl)-2-(ethylamino)cyclohexanone)

3–MMC (some trade or other names: 3-methylmethcathinone; 2-(methylamino)-1-(3-methylphenyl)propan-1-one)

4-methoxyamphetamine (some trade or other names: 4-methoxy-alpha-methylphenethylamine; para-methoxyamphetamine; PMA);

(4-methoxy-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other names: JWH-081);

5-methoxy-3,4-methylenedioxyamphetamine (some trade or other names: MMDA);

5-methoxy-N, N-diisopropyltryptamine (some trade or other names: 5-meO-DIPT);

4-methyl-2,5-dimethoxyamphetamine (some trade or other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine; “DOM”; “STP”);

(4-methyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other

names: JWH-122);

Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-ADB; 5F-MDMB-PINACA);

Methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-MDMB-PICA);

Methylenedioxyamphetamine (some trade or other names: MDA);

Methylenedioxymethamphetamine (MDMA);

Methylenedioxy-N-ethylamphetamine (commonly referred to as N-ethyl-alpha-methyl-3,4(methylenedioxy) phenethylamine, N-ethyl MDA, MDE, MDEA);

1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole-7200 (some trade or other names: JWH-200);

MMB-FUBICA ester (some trade or other names: Methyl 2-(1-(4-fluorobenzyl)-1H-indole-3-carboxamido)-3-methyl butanoate; N-[[1-[(4-fluorophenyl)methyl]-1H-indol-3-yl]carbonyl]-L-valine, methyl ester

N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (some trade or other names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-fluorobenzyl);

N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: 1-pentyl-N-tricyclo[3.3.1.13,7]dec-1-yl-1H-indazole-3-carboxamide; APINACA; AKB48);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (trade or other names: ADB-CHMINACA; MAB-CHMINACA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (trade or other name: ADB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: AB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (trade or other name: AB-FUBINACA);

N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (trade or other name: AB-CHMINACA);

N-hydroxy-3,4-methylenedioxyamphetamine (commonly referred to as N-hydroxy-alpha-methyl-3,4(methylenedioxy) phenethylamine, N-hydroxy MDA);

2-(2-methoxyphenyl)-1-(1-pentylindol-3-yl)ethanone (some trade or other names: 1-(1-pentyl-1H-indol-3-yl)-2-(2-methoxyphenyl)-ethanone; 1-pentyl-3-(2-methoxyphenylacetyl)indole; JWH-250);

Nifoxipam (some trade or other names: 5-(2-fluorophenyl)-1,3-dihydro-3-hydroxy-7- nitro-2H-1,4-benzodiazepin-2-one; 1,3-Dihydro-5-(2-fluorophenyl)-3-hydroxy-7-nitro- 2H-1,4-benzodiazepin-2-one; 3-hydroxydesmethylflunitrazepam; DP 370);

Nitrazolam (some trade or other names: 1-methyl-8-nitro-6-phenyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine);

Norflurazepam (some trade or other names: 7-chloro-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; nor-Flurazepam; N-Desalkylflurazepam; Desalkylflurazepam; Ro 5-3367);

1-Pentyl-3-(2-chlorophenylacetyl)indole (some trade or other names: JWH-203);

1-Pentyl-3-(4-cholor-1-naphthoyl)indole (some trade or other names: JWH-398);

1-Pentyl-3-[(4-methoxy)-benzoyl]indole (some trade or other names: SR-19; BTM-4; RCS-4);

1-Pentyl-3-(1-naphthoyl)indole-7118 (some trade or other names: JWH-018; AM678);

(1-pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: UR-144);

1-pentyl-N-(tricyclo[3.3.1.1^{3,7}]dec-1-yl-1H-indole-3 carboxamide (some trade or other names: APICA; JWH-018 adamantyl carboxamide; 2NE1; SDB-001);

1-pentyl-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1-pentyl-1H-indole-3-carboxylic acid 8-quinolinyl ester; PB-22; QUPIC);

Phenazepam (some trade or other names: 7-bromo-5-(2-chlorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; 7-bromo-5-(2-chlorophenyl)-1,2-dihydro-3H-1,4-benzodiazepin- 2-one; BD 98; Fenazepam; Elzepam; Phezipam; Phenorelaxan; Phenzitat);

Pyrazolam (some trade or other names: 8-bromo-1-methyl-6-(2-pyridinyl)-4H-(1,2,4)triazolo(4,3-a)(1,4)benzodiazepine; 8-bromo-1-methyl-6-(pyridin-2-yl)-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine; Pirazolam);

3,4,5-trimethoxyamphetamine;

Bufotenine (some trade or other names: 3-(beta-dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethyl-aminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N, N-dimethyltryptamine; mappine);

Diethyltryptamine (some trade or other names: DET; N,N-Diethyltryptamine);

Dimethyltryptamine (some trade or other names: DMT; N,N-DMT; N,N-Dimethyltryptamine);

Fluorophenylpiperazine (some trade or other names: FPP, pFPP, 2-fluorophenylpiperazine, 3-fluorophenylpiperazine, 4-fluorophenylpiperazine);

Gamma butyrolactone (some trade or other names: GBL, Gamma Buty Lactone, 4-butyrolactone, dihydro-2(3H)-furanone, tetrahydro-2-furanone, Gamma G, GH Gold);

Gamma hydroxy butyric acid (some trade or other names: GHB);

Ibogaine (some trade or other names: 7-ethyl-6, 6 beta, 7, 8, 9, 10, 12, 13-octahydro-2-methoxy-6, 9-methano-5H-pyrido (1',2':1,2) azepino (5,4-b) indole; *Tabernanthe iboga*);

Lysergic acid diethylamide;

Marijuana;

Mescaline;

Methoxyphenylpiperazine (some trade or other names: MeOPP, pMPP, 4-MPP, 2-MeOPP, 3-MeOPP, 4-MeOPP);

Parahexyl (some trade or other names: 3-Hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran; Synhexyl);

Peyote (meaning all parts of the plant presently classified botanically as *Lophophora williamsii Lemaire*, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant, its seeds or extracts);

N-benzylpiperazine (some trade or other names: BZP, 1-benzylpiperazine);

N-ethyl-3-piperidyl benzilate;

N-methyl-3-piperidyl benzilate;

Psilocybin;

Psilocin;

Salvinorin A (some trade or other names: Divinorin A; Methyl (2S,4aR,6aR,7R,9S,10aS,10bR)-9-(acetyloxy)-2-(furan-3-yl)-6a,10b-dimethyl-4,10-dioxododecahydro-2H-benzofisochromene-7-carboxylate);

Ethylamine analog of phencyclidine (some trade or other names: N-ethyl-1-phenylcyclohexylamine; (1-phenylcyclohexyl) ethylamine; N-(1-phenylcyclohexyl)

ethylamine; cyclohexamine; PCE);

Pyrrolidine analog of phencyclidine (some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine; PCPy; PHP);

1-(1-(2-thienyl)-cyclohexyl)-pyrrolidine (some trade or other names: TCPy);

Thiophene analog of phencyclidine (some trade or other names: 1-(1-(2-thienyl)-cyclohexyl)-piperidine; 2-thienyl analog of phencyclidine; TPCP; TCP); or

Trifluoromethylphenylpiperazine (some trade or other names: 1-(3-trifluoromethylphenyl)piperazine; 3-trifluoromethylphenylpiperazine; TFMPP).

 For the purposes of this subsection, "isomer" includes, without limitation, the optical, position or geometric isomer.

5. All parts of the plant presently classified botanically as Datura, whether growing or not, the seeds thereof, any extract from any part of such plant or plants, and every compound, manufacture, salt derivative, mixture or preparation of such plant or plants, its seeds or extracts, unless substances consistent with those found in such plants are present in formulations that the Food and Drug Administration of the United States Department of Health and Human Services has approved for distribution.

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of phencyclidine, mecloqualone or methaqualone having a depressant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation.

7. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers:

Alpha-PBP (some trade or other names: 1-phenyl-2-(pyrrolidin-1-yl)butan-1-one, alpha- pyrrolidinobutiophenone);

Alpha-PVP (some trade or other names: 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone, alpha- pyrrolidinopentiophenone, alpha-pyrrolidinovalerophenone, O-2387);

Alpha-pyrrolidinoheptaphenone (some trade or other names: PV8);

Alpha-pyrrolidinohexanophenone (some trade or other names: alpha-PHP);

Aminorex;

Butylone (some trade or other names: 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1- one, β-keto-N-methylbenzodioxolylpropylamine, bk-MBDB);

Cathinone (some trade or other names: 2-amino-1-phenyl-1-propanone; alpha- aminopropiophenone; 2-aminopropiophenone; norephedrone);

4-chloro-alpha-pyrrolidinovalerophenone (some trade or other names: 4-chloro-a-PVP);

Dimethylone (some trade or other names: 3,4-methylenedioxy-N,Ndimethylcathinone; N,N-dimethyl MDCATH; N,N-dimethyl-3,4- methylenedioxycathinone; N,N-dimethylβ-keto-3,4-methylenedioxyamphetamine; 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)propan-1-one; bk-MDDMA);

N-ethylhexedrone;

Ethylone (some trade or other names: N-ethyl-3,4-methylenedioxycathinone; 1-(1,3- benzodioxol-5-yl)-2-(ethylamino)propan-1-one; MDEC; bk-MDEA);

DRAFT

N-ethylpentylone (1-(1,3-benzodioxol-5-yl)-2-ethylamino)-pentan-1-one) (some trade or other names: ephylone);

Ethylphenidate (some trade or other names: ethyl 2-phenyl-2-(piperidin-2-yl)acetate);

Fenethylline;

Fluoroamphetamine (some trade or other names: 2-fluoroamphetamine, 3-fluoroamphetamine, 4-fluoroamphetamine, 2-FA, 3-FA, 4-FA, PFA);

Fluoromethcathinone (some trade or other names: 4-Fluoro-N-methylcathinone, 1-(4-fluorophenyl)-2-(methylamino)propan-1-one, 4-Fluoromethcathinone (Flephedrone), 4- FMC, 3-Fluoro-N-methylcathinone, 1-(3-fluorophenyl)-2-2(methylamino)propan-1- one, 3-Fluoromethcathinone, 3-FMC, 2-Fluoro-N-methylcathinone, 1-(2-fluorophenyl)- 2-(methylamino)propan-1-one, 2-FMC);

Mephedrone (some trade or other names: Methylmethcathinone, 4-Methylmethcathinone, 4-MMC, 4-Methylephedrone);

Methamphetamine;

Methcathinone (some trade or other names: N Methylcathinone,cat);

Methedrone (some trade or other names: Methoxymethcathinone, 4-Methoxymethcathinone, bk-PMMA, methoxyphedrine);

4-methyl-alpha-ethylaminopentiophenone (some trade or other names: 4-MEAP);

4'-methyl-alpha-pyrrolidinohexiophenone (some trade or other names: MPHP);

4-methyl-alpha-pyrrolidinopropiophenone (some trade or other names: 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)-propan-1-one, 4-MePPP);

(±)cis-4-methylaminorex ((+)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine);

Methylenedioxypyrovalerone (some trade or other names: 3,4-

Methylenedioxypyrovalerone, MDPV);

Methylethcathinone (some trade or other names: 2-(ethylamino)-1-(4-methylphenyl)propan-1-one, 4-MEC, 4-methyl-N-ethylcathinone);

Methylone (some trade or other names: Methylenedioxy-N-methylcathinone, Methylenedioxymethcathinone, 3,4-Methylenedioxy-N-methylcathinone, bk-MDMA);

N,N-dimethylamphetamine (commonly referred to as N,N-alpha-trimethyl-benzeneethanamine; N,N-alpha-trimethylphenethylamine);

N-ethylamphetamine;

Naphyrone (some trade or other names: 1-(naphthalen-2-yl)-2(pyrrolidin-1-yl)pentan-1-one, naphthylpyrovalerone, naphpyrovalerone, NRG-1, O-2482);

Pentedrone (some trade or other names: 2-(methylamino)-1-phenylpentan-1-one, α- methylaminovalerophenone); or

Pentylone (trade or other names: 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one; beta-keto-methylbenzodioxolylpentanamine; bk-MBDP; bk-methyl-K).

8. Unless specifically listed in another schedule, coca leaves, cocaine base or free base, or a salt, compound, derivative, isomer or preparation thereof which is chemically equivalent or identical to such substances, and any quantity of material, compound, mixture or preparation which contains coca leaves, cocaine base or cocaine free base or its isomers or any of the salts of cocaine, except decocainized coca leaves or extractions which do not contain cocaine or ecgonine.

9. Unless specifically listed in another schedule, Tetrahydrocannabinols (natural or synthetic equivalents of substances contained in the plant, or in the resinous extractives of

DRAFT

Cannabis, sp. or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity such as the following:

Delta 9 cis or trans tetrahydrocannabinol, and their optical isomers, also known as Delta 1 cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 8 cis or trans tetrahydrocannabinol, and their optical isomers, also known as Delta 6 cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 3, 4 cis or trans tetrahydrocannabinol, and its optical isomers;

Tetrahydrocannabinols contained in the genus Cannabis or in the resinous extractives of the genus Cannabis;

Synthetic equivalents of tetrahydrocannabinol substances or synthetic substances, derivatives and their isomers with a similar chemical structure; and

Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered).

10. Unless specifically listed in another schedule and except as otherwise provided in subsection 11, any material, compound, mixture or preparation which contains any quantity of CBD (natural or synthetic equivalents of the substances contained in the plant or in the resinous extractives of Cannabis sp. or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity).

11. A drug product which:

(a) Has been approved by the United States Food and Drug Administration;

(b) Contains CBD derived from any plant in the genus Cannabis or the resinous extractives thereof; and

(c) Contains not more than 0.1 percent residual THC by weight,

➥ is not a controlled substance.

DRAFT

as SBSEF–FIN–QTR, SBSEF–FIN–QTR/A, SBSEF–FIN–REQ, and SBSEF–FIN–REQ/A submissions, respectively.[4]

Addition of XBRL Taxonomy for Cybersecurity Disclosures

EDGAR will be updated to allow filers to use the appropriate XBRL Taxonomy for cybersecurity disclosures required to be included in Forms 6–K, 8–K, 10–K, and 20–F (and the variants 10–KT, 10–K/A, 10–KT/A, 20–F/A, 8–K/A, and 6–K/A).[5]

Removal of the Index From Volume II of the EDGAR Filer Manual

Volume II of the Filer Manual will be updated to remove the Index. Filers may continue to use the Table of Contents which links directly to chapters and topics, and the document search function of this online manual.

III. Amendments to Rule 301 of Regulation S–T

Along with the adoption of the updated Filer Manual, we are amending Rule 301 of Regulation S–T to provide for the incorporation by reference into the Code of Federal Regulations of the current revisions. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

The updated EDGAR Filer Manual is available at *https://www.sec.gov/edgar/filerinformation/current-edgar-filer-manual.*

IV. Administrative Law Matters

Because the Filer Manual and rule amendments relate solely to agency procedures or practice and do not substantially alter the rights and obligations of non-agency parties, publication for notice and comment is not required under the Administrative Procedure Act (''APA'').[6] It follows that the amendments do not require analysis under requirements of the Regulatory Flexibility Act[7] or a report to Congress under the Small Business Regulatory Enforcement Fairness Act of 1996.[8]

The effective date for the updated Filer Manual and related rule amendments is October 22, 2024. In accordance with the APA,[9] we find that there is good cause to establish an effective date less than 30 days after publication of these rules. The Commission believes that establishing an effective date less than 30 days after publication of these rules is necessary to coordinate the effectiveness of the updated Filer Manual with the related system upgrades.

V. Statutory Basis

We are adopting the amendments to Regulation S–T under the authority in sections 6, 7, 8, 10, and 19(a) of the Securities Act of 1933,[10] sections 3, 12, 13, 14, 15, 15B, 23, and 35A of the Securities Exchange Act of 1934,[11] section 319 of the Trust Indenture Act of 1939,[12] and sections 8, 30, 31, and 38 of the Investment Company Act of 1940.[13]

List of Subjects in 17 CFR Part 232

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

Text of the Amendments

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 1. The general authority citation for part 232 continues to read as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78c(b), 78*l,* 78m, 78n, 78n–1,78*o*(d), 78w(a), 78*ll,* 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, 7201 *et seq.;* and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

■ 2. Section 232.301 is revised to read as follows:

§ 232.301 EDGAR Filer Manual.

Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets forth the technical formatting requirements for electronic submissions. The requirements for becoming an EDGAR Filer and updating company data are set forth in the EDGAR Filer Manual, Volume I: ''General Information,'' Version 41 (December 2022). The requirements for filing on EDGAR are set forth in the updated EDGAR Filer Manual, Volume II: ''EDGAR Filing,'' Version 71 (September 2024). All of these provisions have been incorporated by reference into the Code of Federal Regulations, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You must comply with these requirements in order for documents to be timely received and accepted. The EDGAR Filer Manual is available for inspection at the Commission and at the National Archives and Records Administration (NARA). The EDGAR Filer Manual is available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Operating conditions may limit access to the Commission's Public Reference Room. For information on the availability of the EDGAR Filer Manual at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations.html* or email *fr.inspection@nara.gov.* The EDGAR Filer Manual may also be obtained from *https://www.sec.gov/edgar/filerinformation/current-edgar-filer-manual.*

By the Commission.

Dated: September 16, 2024.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–24355 Filed 10–21–24; 8:45 am]

BILLING CODE 8011–01–P

[4] Security-Based Swap Execution and Registration and Regulation of Security-Based Swap Execution Facilities, Release No. 34–98845 (Nov. 2, 2023) [88 FR 87156 (Dec. 15, 2023)].

[5] Cybersecurity Risk Management, Strategy, Governance, and Incident Disclosure, Release No. 33–11216 (July 26, 2023) [88 FR 51896 (Aug. 4, 2023)].

[6] 5 U.S.C. 553(b)(A).

[7] 5 U.S.C. 601 through 612.

[8] 5 U.S.C. 804(3)(c).

[9] 5 U.S.C. 553(d)(3).

[10] 15 U.S.C. 77f, 77g, 77h, 77j, and 77s(a).

[11] 15 U.S.C. 78c, 78*l,* 78m, 78n, 78*o,* 78*o*–4, 78w, and 78*ll.*

[12] 15 U.S.C. 77sss.

[13] 15 U.S.C. 80a–8, 80a–29, 80a–30, and 80a–37.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1142]

Schedules of Controlled Substances: Placement of Ethylphenidate in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places ethylphenidate (chemical name: ethyl 2-phenyl-2-(piperidin-2-yl)acetate), including its salts, isomers, and salts of isomers, in schedule I of the Controlled Substances Act. This action is being taken, in part, to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. When finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import,

export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle ethylphenidate.

DATES: *Effective date:* November 21, 2024.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), Feb. 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2)–(4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention indicating that a drug or other substance has been added to a schedule specified in the notification, the Secretary of Health and Human Services (Secretary),[1] after consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the Controlled Substances Act (CSA) and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance.[2] In the event that the Secretary did not so consult with the Attorney General, and the Attorney General did not issue a temporary order, as provided under 21 U.S.C. 811(d)(4), the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) control.

Pursuant to 21 U.S.C. 811(a)(1) and (2), the Attorney General (as delegated to the Administrator of the Drug Enforcement Administration (DEA) pursuant to 28 CFR 0.100) may, by rule, and upon the recommendation of the Secretary, add to such a schedule or transfer between such schedules any drug or other substance, if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug or other substance is to be placed.

Background

Ethylphenidate is a central nervous system stimulant and shares structural and pharmacological similarities with other schedule II stimulants, such as methylphenidate. On April 21, 2017, the Secretary-General of the United Nations advised the Secretary of State of the United States that, during its 60th session on March 16, 2017, the Commission on Narcotic Drugs (CND) voted to place ethyl 2-phenyl-2-(piperidin-2-yl)acetate (ethylphenidate) in Schedule II of the 1971 Convention (CND Dec/60/7). Because the procedures in 21 U.S.C. 811(d)(3) and (4) for consultation and issuance of a temporary order for ethylphenidate were not followed, as discussed above in the legal authority section, DEA is utilizing the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) to control ethylphenidate. Permanently scheduling ethylphenidate satisfies the United States' international obligations.

DEA and HHS Eight Factor Analyses

In a letter dated October 26, 2020, in accordance with 21 U.S.C. 811(b), and in response to DEA's April 3, 2019 request, HHS provided to DEA a scientific and medical evaluation and scheduling recommendation for ethylphenidate. DEA reviewed the scientific and medical evaluation and scheduling recommendation for schedule I placement provided by HHS, and all other relevant data, pursuant to 21 U.S.C. 811(b) and (c), and conducted its own analysis under the eight factors stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 811(b)(1), that this substance warrants control in schedule I. Both DEA and HHS Eight-Factor analyses are available in their entirety under the tab Supporting Documents of the public docket for this action at *https://www.regulations.gov* under docket number DEA–1142.

Notice of Proposed Rulemaking To Schedule Ethylphenidate

On September 22, 2023, DEA published a notice of proposed rulemaking (NPRM) to permanently control ethylphenidate in schedule I.[3] Specifically, DEA proposed to add ethylphenidate to the list of stimulant substances under 21 CFR 1308.11(f). The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before October 23, 2023. DEA did not receive any requests for such a hearing. The NPRM also provided an opportunity for interested persons to submit comments on or before November 21, 2023.

Comments Received

DEA received ten comments in response to the notice of proposed rulemaking for the placement of ethylphenidate into schedule I of the CSA. The submissions were from individuals or anonymous commenters. Five commenters provided support for the notice of proposed rulemaking, four commenters were against the placement of ethylphenidate in schedule I of the CSA, and one commenter expressed statements that were neither for nor against the proposed rule.

DEA received five comments in support of the placement of ethylphenidate in schedule I.

DEA Response: DEA appreciates these comments in support of this rulemaking.

DEA received four comments against the placement of ethylphenidate in schedule I of the CSA. The following are DEA's responses to the individual comments against the proposed rulemaking.

DEA received a comment asserting that methylphenidate is already controlled under schedule II of the CSA, thus, ethylphenidate is considered controlled under the Controlled Substances Analogue Act due to their similarities. This commenter concluded that the government should not dictate what researchers may study for legitimate scientific use.

DEA Response: DEA appreciates this comment and would like to provide further clarification regarding the control of ethylphenidate. Ethylphenidate has been placed under international control. In order to comply with treaty obligations, DEA must place ethylphenidate under the most appropriate schedule, taking into consideration all appropriate scientific data. This is true even if this substance could be treated under the Controlled Substances Analogue provision. Additionally, as set forth in the NPRM, ethylphenidate has no currently accepted medical use in treatment in the United States. Therefore, ethylphenidate must be placed in schedule I of the CSA along with other substances which have no currently accepted medical use, lack

[1] As discussed in a memorandum of understanding entered into by the FDA and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518 (Mar. 8, 1985). The Secretary has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. *Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law 91–513, As Amended; Delegation of Authority,* 58 FR 35460 (July 1, 1993).

[2] 21 U.S.C. 811(d)(3).

[3] *Schedules of Controlled Substances: Placement of Ethylphenidate in Schedule* I, 88 FR 65330 (Sept. 22, 2023).

accepted safety for use under medical supervision, and possess a high potential for abuse. With respect to scientific research, the placement of substances in schedule I of the CSA does not preclude academic research on these substances. DEA registrants wishing to conduct research on schedule I substances may apply for permission to do so through the schedule I researcher registration program.[4]

DEA received a comment comparing ethylphenidate to methylphenidate. The commenter questioned the reasonable nature of placing ethylphenidate in schedule I of the CSA considering it is a weaker substance when compared to methylphenidate, a schedule II substance.

DEA Response: DEA appreciates this comment and asserts the following: Ethylphenidate belongs to the stimulant class of drugs and possesses abuse liability similar to that of methylphenidate; however, unlike methylphenidate, ethylphenidate has no currently accepted medical use in treatment in the United States. A qualification for placing substances in schedules II thorough IV of the CSA is that they must have a currently accepted medical use in treatment in the United States. Thus, DEA asserts that the placement of ethylphenidate in schedule I of the CSA is warranted.

DEA received a comment with statements against the NPRM placing ethylphenidate in schedule I of the CSA. The commenter stated that, in the NPRM, DEA failed to provide a reason for the placement of ethylphenidate in a more restrictive schedule (here, schedule I) than methylphenidate, considering the two drugs share significant pharmacological similarities and are considered analogues of one another. The commenter further stated that because ethylphenidate is an analog of methylphenidate, it may be possible in the future for ethylphenidate to be marketed as an alternative to methylphenidate. In particular, the commenter stated the placement of ethylphenidate in schedule I of the CSA would completely hamper future legitimate research regarding its medical efficacy. Thus, the commenter states, by imposing criminal sanctions on those who engage in research or chemical analysis of the drug, DEA would prevent the future discovery of its possible medical use.

DEA Response: DEA appreciates this comment and asserts the following: As stated above, ethylphenidate has been placed under international control. In order to comply with treaty obligations, DEA must place ethylphenidate under the most appropriate schedule, taking into consideration all appropriate scientific data. Additionally, a qualification for placing substances in schedules II thorough IV of the CSA is that they must have a currently accepted medical use in treatment in the United States. Ethylphenidate has no currently accepted medical use in treatment in the United States, lacks accepted safety for use under medical supervision, and possesses a high potential for abuse. Thus, DEA asserts that the placement of ethylphenidate in schedule I of the CSA is warranted. With respect to research, the placement of substances in schedule I of the CSA does not preclude research into this substance. DEA registrants wishing to conduct research on schedule I substances, including ethylphenidate, may apply for permission to do so through the schedule I researcher registration program.

DEA received a comment expressing that ethylphenidate should be categorized as a schedule II drug ''until further research has been conducted to prove its viability.''

DEA Response: DEA appreciates this comment and asserts the following: According to the CSA, schedule I substances are defined as drugs that have no known medical use in treatment in the United States, and have a high potential for abuse. Additionally, according to the CSA, schedule II substances also have a high potential for abuse but have a currently accepted medical use in treatment. Accordingly, DEA proposed to place ethylphenidate in schedule I of the CSA, due to its lack of a currently accepted medical use in treatment in the United States, its lack of accepted safety for use under medical supervision, and its high potential for abuse.

DEA received one comment that provided statements that were neither explicitly for nor against the proposed rule.

In this comment, the commenter suggested that instead of creating a new rule for the control of ethylphenidate, DEA should simply clarify the existing rule which controlled methylphenidate. According to this commenter, this suggested amendment would extend control to all derivatives of methylphenidate. The commenter also expressed an understanding of DEA's intent to schedule ethylphenidate but questioned whether a standard notice-and-comment procedure was needed for an action that could be addressed by clarifying existing rulemaking.

DEA Response: DEA appreciates this suggestion and asserts the following: Ethylphenidate was placed under international control on March 16, 2017, during the CND's 60th session. As a signatory to the 1971 Convention on Psychotropic Substances, it is incumbent upon DEA to place ethylphenidate in its most appropriate schedule under the CSA. Therefore, DEA proposed to place ethylphenidate in schedule I of the CSA because it has no currently accepted medical use in treatment in the United States, lacks accepted safety for use under medical supervision, and has an abuse potential similar to that of methylphenidate. As explained in the NPRM, because the procedures in 21 U.S.C. 811(d)(3) and (4) for consultation and issuance of a temporary order for ethylphenidate were not followed, DEA utilized the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) to control ethylphenidate, which required notice and an opportunity for hearing.

Scheduling Conclusion

After consideration of the public comments, scientific and medical evaluation and accompanying scheduling recommendation from HHS, and after its own eight-factor evaluation, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of ethylphenidate. As such, DEA is permanently scheduling ethylphenidate as a controlled substance under schedule I of the CSA. The permanent scheduling of ethylphenidate will fulfill the United States' obligations as a party to the 1971 Convention.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, II, IV, and V. The CSA also specifies the findings requires to place a drug or other substance in any particular schedule, 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Acting Assistant Secretary for Health of HHS and review of all other available data, the Administrator of DEA, pursuant to 21 U.S.C. 812(b)(1), finds that:

(1) Ethylphenidate has a high potential for abuse that is comparable to other scheduled substances, such as methylphenidate (a schedule II substance);

(2) Ethylphenidate has no currently accepted medical use in treatment in the United States. In HHS' 2020 recommendation to control ethylphenidate, it was noted there are no approved New Drug Applications for ethylphenidate and no known therapeutic applications for ethylphenidate in the United States. DEA is not aware of any other evidence suggesting that ethylphenidate has

[4] *https://apps.deadiversion.usdoj.gov/webforms2/spring/main?execution=e1s2.*

a currently accepted medical use in treatment in the United States.[5]

(3) There is a lack of accepted safety for use of ethylphenidate under medical supervision. Because ethylphenidate has no approved medical use and has not been investigated as a new drug, its safety for use under medical supervision has not been determined.

Based on these findings, the Administrator of DEA concludes that ethylphenidate, as well as its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, warrants control in schedule I of the CSA.

Requirements for Handling Ethylphenidate

Ethylphenidate is subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, import, export, engagement in research, conduct instructional activities or chemical analysis with, and possession of schedule I controlled substances, including the following:

[5] When placing a substance in schedule I, DEA must consider whether the substance has a currently accepted medical use in treatment in the United States. 21 U.S.C. 812(b)(1)(B) There is no evidence suggesting that ethylphenidate has a currently accepted medical use in treatment in the United States. To determine whether a drug or other substance has a currently accepted medical use, DEA has traditionally applied a five-part test to a drug or substance that has not been approved by the FDA: i. The drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. See *Marijuana Scheduling Petition; Denial of Petition; Remand,* 57 FR 10499 (Mar. 26, 1992), pet. for rev. denied, *Alliance for Cannabis Therapeutics* v. *Drug Enforcement Admin.,* 15 F.3d 1131, 1135 (D.C. Cir. 1994). DEA and HHS applied the traditional five-part test for currently accepted medical use in this matter. In a recent published letter in a different context, HHS applied an additional two-part test to determine currently accepted medical use for substances that do not satisfy the five-part test: (1) whether there exists widespread, current experience with medical use of the substance by licensed health care practitioners operating in accordance with implemented jurisdiction-authorized programs, where medical use is recognized by entities that regulate the practice of medicine, and, if so, (2) whether there exists some credible scientific support for at least one of the medical conditions for which part (1) is satisfied. On April 11, 2024, the Department of Justice's Office of Legal Counsel (OLC) issued an opinion, which, among other things, concluded that HHS's two-part test would be sufficient to establish that a drug has a currently accepted medical use. Office of Legal Counsel, Memorandum for Merrick B. Garland Attorney General Re: Questions Related to the Potential Rescheduling of Marijuana at 3 (April 11, 2024). For purposes of this final rule, there is no evidence that health care providers have widespread experience with medical use of ethylphenidate or that the use of ethylphenidate is recognized by entities that regulate the practice of medicine under either the traditional five-part test or the two-part test.

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, ethylphenidate must register with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Any person who currently handles ethylphenidate and is not registered with DEA must submit an application for registration and may not continue to handle ethylphenidate, unless DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity in a manner not authorized by the CSA is unlawful and those in possession of any quantity may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person unwilling or unable to obtain a schedule I registration must surrender or transfer all quantities of currently held ethylphenidate to a person registered with DEA before the effective date of a final scheduling action in accordance with all applicable Federal, State, local, and tribal laws. Ethylphenidate must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security.* Ethylphenidate is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.71–1301.76, as of the effective date of this final scheduling action. Non-practitioners handling ethylphenidate must comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of ethylphenidate must comply with 21 U.S.C. 825, and be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture ethylphenidate in accordance with a quota assigned pursuant to 21 U.S.C. 826, and in accordance with 21 CFR part 1303.

6. *Inventory.* Every DEA registrant who possesses any quantity of ethylphenidate must take an inventory of ethylphenidate on hand, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who registers with DEA must take an initial inventory of all stocks of controlled substances (including ethylphenidate) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including ethylphenidate) on hand every two years, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports for ethylphenidate, or products containing ethylphenidate, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1301.74(b) and (c), 1301.76(b), and parts 1304, 1312 and 1317. Manufacturers and distributors must submit reports regarding ethylphenidate to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* Every DEA registrant who distributes ethylphenidate must comply with the order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of ethylphenidate must comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR parts 1304 and 1312.

10. *Liability.* Any activity involving ethylphenidate not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 14094 (Modernizing Regulatory Review)

In accordance with 21 U.S.C. 811(a), this final scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles

reaffirmed in E.O. 13563. E.O. 14094 modernizes the regulatory review process to advance policies that promote the public interest and address national priorities.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995.[6] Also, this proposed rule would not impose new or modify existing recordkeeping or reporting requirements on state or local governments, individuals, businesses, or organizations. However, this proposed rule would require compliance with the following existing OMB collections: 1117–0003, 1117–0004, 1117–0006, 1117–0008, 1117–0009, 1117–0010, 1117–0012, 1117–0014, 1117–0021, 1117–0023, 1117–0029, and 1117–0056. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Regulatory Flexibility Act

The Administrator of DEA, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this final rule, and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

DEA is placing the substance ethylphenidate (chemical name: ethyl 2-phenyl-2-(piperidin-2-yl)acetate), including its salts, isomers, and salts of isomers, in schedule I of the CSA to enable the United States to meet its obligations under the 1971 Convention. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle ethylphenidate.

Based on the review of HHS's scientific and medical evaluation and all other relevant data, DEA determined that ethylphenidate has high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks accepted safety for use under medical supervision. DEA's research confirms that there is no legitimate commercial market for ethylphenidate in the United States. Therefore, this final rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the ''Regulatory Flexibility Act'' section above, DEA has determined pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.)* that this final rule would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year . . . .'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of the final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11:
■ a. Redesignate paragraphs (f)(6) through (f)(12) as (f)(7) through (f)(13); and
■ b. Add a new paragraph (f)(6)
The addition reads as follows:

§ 1308.11 Schedule I.

* * * * *

(f) * * *

*	*	*	*	*	*	*
(6) Ethylphenidate (ethyl 2-phenyl-2-(piperidin-2-yl)acetate)						1727
*	*	*	*	*	*	*

* * * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on October 10, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

[6] 44 U.S.C. 3501–3521.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2024–24083 Filed 10–21–24; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2024–0924]

Safety Zone: Fireworks Displays Within the Fifth Coast Guard District; The Wharf, Washington, DC

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone for a fireworks display at ''The Wharf DC,'' in Washington, DC, to provide for the safety of life on navigable waterways during this event. Our regulation, ''Safety Zones; Fireworks Displays within the Fifth Coast Guard District,'' identifies the precise location. During the enforcement period, vessels may not enter, remain in, or transit through the safety zone unless authorized to do so by the COTP or his representative, and vessels in the vicinity must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulation in 33 CFR 165.506 will be enforced for the location identified in line no. 1 of table 2 to 33 CFR 165.506(h)(2) from 8 p.m. until 9:30 p.m. on December 7, 2024, or if necessary, due to inclement weather, from 8 p.m. until 9:30 p.m. on December 8, 2024.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LCDR Kate M. Newkirk, Sector Maryland-NCR, Waterways Management Division, U.S. Coast Guard: telephone 410–576–2596, email *MDNCRMarineEvents@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone regulation for a fireworks display at The Wharf DC from 8 p.m. to 9:30 p.m. on December 7, 2024, or, if necessary due to inclement weather, from 8 p.m. until 9:30 p.m. on December 8, 2024. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation, ''Safety Zones; Fireworks Displays within the Fifth Coast Guard District,'' § 165.506, specifies the location of the safety zone for the fireworks show, which encompasses portions of the Washington Channel in the Upper Potomac River. As reflected in 33 CFR 165.23, vessels in the vicinity of the safety zone may not enter, remain in, or transit through the safety zone during the enforcement period unless authorized to do so by the COTP or his representative, and they must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and marine information broadcasts.

Dated: October 7, 2024.

Patrick C. Burkett,

Captain, U.S. Coast Guard, Captain of the Port, Sector Maryland-National Capital Region.

[FR Doc. 2024–24284 Filed 10–21–24; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51 and 52

[EPA–HQ–OAR–2024–0234; FRL–11945–01–OAR]

Prevention of Significant Deterioration (PSD): Paragraph Designation Corrections

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is amending its Prevention of Significant Deterioration (PSD) regulations to correct the fourth-level paragraph designations to conform with the Office of the Federal Register (OFR) requirements. This is a ministerial final rule action that involves minor technical corrections.

DATES: This rule is effective October 22, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2024–0234. All documents in the docket are listed on the *https://www.regulations.gov* website. Publicly available docket materials are available either electronically through *https://www.regulations.gov* or in hard copy at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding federal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Office of Air and Radiation Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Questions concerning this final rule should be addressed to Mr. Peter Keller, Air Quality Policy Division, Office of Air Quality Planning and Standards (C539–04), U.S. Environmental Protection Agency, Post Office Box 12055, Research Triangle Park, NC 27711; telephone number: (919) 541–2065; email address: *keller.peter@epa.gov.*

SUPPLEMENTARY INFORMATION: The information presented in this preamble is organized as follows:

I. Does this action apply to me?
II. Background and Rationale for This Action
III. Final Action
IV. Statutory and Executive Order Reviews
V. Statutory Authority
VI. Judicial Review

I. Does this action apply to me?

No entities will be affected by this final action. The EPA is amending its PSD regulations to correct the fourth-level paragraph designations from the Code of Federal Regulations (CFR) to conform with the OFR requirements. The EPA is responsible for making the required paragraph codification corrections in the EPA PSD regulations and communicating those corrections to stakeholders, including state, local, and Tribal (SLT) permitting authorities and regulated entities. SLT permitting authorities are not required to make corresponding corrections to any of their regulations implementing the PSD program including those approved by the EPA into a State Implementation Plan (SIP).

II. Background and Rationale for This Action

Part C of title I of the Clean Air Act (CAA), 42 U.S.C. 7470 *et seq.,* contains the requirements for a component of the major New Source Review (NSR) program known as the PSD program. This program sets forth procedures for the preconstruction review and permitting of new and modified stationary sources of air pollution located in areas meeting the National Ambient Air Quality Standards (NAAQS) (''attainment'' areas) and areas for which there is insufficient information to classify an area as either attainment or nonattainment (''unclassifiable'' areas). The EPA's PSD regulations are contained in 40 CFR

section 513(f)(2) of the act, is pending before the Food and Drug Administration, or

(ii) There is a predetermined change control plan (PCCP) cleared under section 515C of the act, provided that the change is consistent with the PCCP.

* * * * *

§ 807.87 [Amended]

■ 3. Amend § 807.87 by removing the phrase ''(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910–0281)'' that appears after paragraph (m).

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

■ 4. The authority citation for part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 360bbb–8b, 371, 372, 373, 374, 375, 379, 379e, 379k–1, 381.

■ 5. In § 814.39, revise paragraph (b) to read as follows:

§ 814.39 PMA supplements.

* * * * *

(b) An applicant may make a change in a device after FDA's approval of a PMA for the device without submitting a PMA supplement if the change does not affect the device's safety or effectiveness and the change is reported to FDA in post approval periodic reports required as a condition to approval of the device, *e.g.,* an editorial change in labeling which does not affect the safety or effectiveness of the device, or if the change is consistent with a predetermined change control plan (PCCP) approved under section 515C of the act.

* * * * *

Dated: March 11, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05473 Filed 3–14–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1245]

Schedules of Controlled Substances: Placement of 2-Methyl AP–237 in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final amendment; final order.

SUMMARY: With the issuance of this final order, the Administrator of the Drug Enforcement Administration is permanently placing 1-(2-methyl-4-(3-phenylprop-2-en-1-yl)piperazin-1-yl)butan-1-one (commonly known as 2-methyl AP–237), including its optical and geometric isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, in schedule I of the Controlled Substances Act. This scheduling action discharges the United States' obligations under the Single Convention on Narcotic Drugs (1961). This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research or conduct instructional activities with, or possess), or propose to handle 2-methyl AP–237.

DATES: Effective April 15, 2024.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The United States is a party to the 1961 United Nations Single Convention on Narcotic Drugs, March 30, 1961, 18 U.S.T. 1407, 570 U.N.T.S. 151 (Single Convention), as amended by the 1972 Protocol. Article 3, paragraph 7 of the Single Convention requires that if the Commission on Narcotic Drugs (Commission) adds a substance to one of the schedules of such Convention, and the United States receives notification of such scheduling decision from the Secretary-General of the United Nations (Secretary-General), the United States, as a signatory Member State, is obligated to control the substance under its national drug control legislation. Under 21 U.S.C. 811(d)(1) of the Controlled Substances Act (CSA), if control of a substance is required ''by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970,'' the Attorney General must issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by 21 U.S.C. 811(a) or 812(b), and without regard to the procedures prescribed by 21 U.S.C. 811(a) and (b). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the Drug Enforcement Administration (Administrator of DEA or Administrator). 28 CFR 0.100.

Background

In a letter dated November 24, 2022, the Director-General of the World Health Organization recommended to the Secretary-General of the United Nations that 2-methyl AP–237 be placed in Schedule I of the Single Convention, as this substance has an opioid mechanism of action and similarity to drugs that are controlled in Schedule I of the Single Convention (*i.e.,* 2-methyl AP–237 is similar to drugs such as isotonitazene) and has dependence and abuse potential. On May 17, 2023, the United States Government was informed by the Secretariat of the United Nations, by letter, that during its 66th session in March 2023, the Commission voted to place 2-methyl AP–237 in Schedule I of the Single Convention (CND Mar/66/1).

2-Methyl AP–237

2-Methyl AP–237 has a pharmacological profile similar to other classical opioids such as fentanyl (schedule II), morphine (schedule II) and heroin (schedule I), which act as mu-opioid receptor agonists. Because of the pharmacological similarities of 2-methyl AP–237 to the aforementioned opioids, 2-methyl AP–237 presents a high risk of abuse and has negatively affected users and communities. According to the DEA Toxicology Testing Program (DEA TOX) [1] and a recent publication,[2] the abuse of 2-methyl AP–237 has been associated with at least seven fatalities in the United States between February 2020 and July 2023. The identification of this substance in post-mortem cases is a serious concern to public safety.

In June 2019, 2-methyl AP–237 emerged on the United States illicit drug market as evidenced by its identification in drug seizures.[3] Law enforcement

[1] The DEA Toxicology Testing Program (DEA TOX) was initiated in response to the ongoing novel synthetic drug abuse epidemic. This program provides toxicology data on synthetic drugs from biological samples that may not be routinely identified, which are generated from drug overdose victims. Data queried on 8/7/2023.

[2] Fogarty, MF, Vandeputte, MM, Krotulski, AJ, Walton, SE, Stove, CP, and Logan, BK (2022). Toxicological and pharmacological characterization of novel cinnamylpiperazine synthetic opioids in humans and in vitro including 2-methyl AP–237 and AP–238. Archives of Toxicology 96:1701–1710.

[3] NFLIS represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS-Drug is a comprehensive

Continued

reports demonstrate that 2-methyl AP–237 is being illicitly distributed and abused. The illicit use and distribution of this substance is similar to that of heroin (schedule I) and prescription opioid analgesics. According to the National Forensic Laboratory Information System (NFLIS-Drug) database, which collects drug identification results from drug cases submitted to and analyzed by Federal, State, and local forensic laboratories, there have been 92 reports of 2-methyl AP–237 in the United States since 2019 (data queried July 17, 2023).

DEA is not aware of any claims or any medical or scientific literature suggesting that 2-methyl AP–237 has a currently accepted medical use in treatment in the United States. In addition, the Assistant Secretary for Health of the U.S. Department of Health and Human Services, by a letter to DEA dated December 22, 2022, stated that there are no investigational new drug applications or approved new drug applications for 2-methyl AP–237 in the United States; hence, there are no legitimate channels for this substance as a marketed drug product in the United States. Because 2-methyl AP–237 is not formulated or available for clinical use as an approved medicinal product, all current use of this substance by individuals is based on their own initiative, rather than on the basis of medical advice from a practitioner licensed by law to administer such a drug.

Therefore, consistent with 21 U.S.C. 811(d)(1), DEA concludes that 2-methyl AP–237 has no currently accepted medical use in treatment in the United States [4] and is most appropriately placed in schedule I of the CSA. Because control is required under the Single Convention, DEA will not be initiating regular rulemaking proceedings to permanently schedule 2-methyl AP–237 pursuant to 21 U.S.C. 811(a).

Conclusion

In order to meet the United States' obligations under the Single Convention and because 2-methyl AP–237 has no currently accepted medical use in treatment in the United States, the Administrator has determined that 2-methyl AP–237, including its optical and geometric isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, should be placed in schedule I of the CSA.

Requirements for Handling

Upon the effective date of the final order contained in this document, 2-methyl AP–237 will be permanently subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture of, distribution of, importation of, exportation of, engagement in research or conduct of instructional activities with, and possession of, schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research or conducts instructional activities with, or possesses), or who desires to handle, 2-methyl AP–237 must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of this substance in a manner not authorized by the CSA is unlawful and those in possession of any quantity of this substance may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* 2-Methyl AP–237 must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, state, local, and tribal laws.

3. *Security.* 2-Methyl AP–237 is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.71–1301.76. Non-practitioners handling 2-methyl AP–237 must comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

4. *Labeling and packaging.* All labels, labeling, and packaging for commercial containers of 2-methyl AP–237 must comply with 21 U.S.C. 825, and be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture 2-methyl AP–237 in accordance with a quota assigned pursuant to 21 U.S.C. 826, and in accordance with 21 CFR part 1303.

6. *Inventory.* Any person registered with DEA to handle 2-methyl AP–237 must have an initial inventory of all stocks of controlled substances (including this substance) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including 2-methyl AP–237) on hand every two years pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* DEA registrants must maintain records and submit reports with respect to 2-methyl AP–237 pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1301.74(b) and (c), 1301.76(b), and 1307.11 and parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding 2-methyl AP–237 to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* All DEA registrants who distribute 2-methyl AP–237 must comply with the order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of 2-methyl AP–237 must comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving 2-methyl AP–237 not authorized by, or in violation of the CSA, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

information system that includes data from forensic laboratories that handle the nation's drug analysis cases. NFLIS-Drug participation rate, defined as the percentage of the national drug caseload represented by laboratories that have joined NFLIS, is currently 98.5 percent. NFLIS includes drug chemistry results from completed analyses only. While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV; 76 FR 77330, 77332, December 12, 2011. NFLIS data was queried on July 17, 2023. Reports to NFLIS-Drug are still pending for 2023.

[4] Although, as discussed above, there is no evidence suggesting that 2-methyl AP–237 has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by the Food and Drug Administration, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated: i. the drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. 57 FR 10499 (Mar 26,1992), *pet. for rev. denied, Alliance for Cannabis Therapeutics* v. *Drug Enforcement Admin.,* 15 F.3d 1131, 1135 (D.C. Cir. 1994).

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review) and 14094 (Modernizing Regulatory Review)

This action is not a significant regulatory action as defined by Executive Order (E.O.) 12866 (Regulatory Planning and Review), section 3(f), as amended by E.O. 14094, section 1(b), and the principles reaffirmed in E.O. 13563 (Improving Regulation and Regulatory Review); and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988, Civil Justice Reform

This action meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This action does not have federalism implications warranting the application of E.O. 13132. This action does not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications warranting the application of E.O. 13175. The action does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Administrative Procedure Act

The CSA provides for an expedited scheduling action where control is required by the United States' obligations under international treaties, conventions, or protocols. 21 U.S.C. 811(d)(1). If control is required pursuant to such international treaty, convention, or protocol, the Attorney General, as delegated to the Administrator, must issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, and ''without regard to'' the findings and rulemaking procedures otherwise required for scheduling actions in 21 U.S.C. 811(a) and (b). *Id.*

In accordance with 21 U.S.C. 811(d)(1), scheduling actions for drugs that are required to be controlled by the United States' obligations under international treaties, conventions, or protocols in effect on October 27, 1970, shall be issued by order (as opposed to scheduling by rule pursuant to 21 U.S.C. 811(a)). Therefore, DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this scheduling action.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA or any other law. As explained above, the CSA exempts this final order from notice and comment. Consequently, the RFA does not apply to this action.

Paperwork Reduction Act of 1995

This order would modify an existing collection of information requirement under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501–3521. Pursuant to section 3507(d) of the PRA of 1995 (44 U.S.C. 3507(d)), DEA is adding new reporting and recordkeeping requirements for 1117–0003. This order also involves existing collection 1117–0004, but would not modify the existing collection of information requirement under the PRA. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information, unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be obtained at *http://www.reginfo.gov/public/do/PRAMain.*

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined and certifies that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year * * *.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This order is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, DEA is submitting reports under the CRA to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11:

■ a. Redesignate paragraphs (b)(59) through (b)(103) as follows:

Old paragraph	New paragraph
(b)(59) through (103)	(b)(60) through (104).

■ b. Add new paragraph (b)(59).

The addition reads as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

* * * * * * *

(59) 2-Methyl AP–237 (1-(2-methyl-4-(3-phenylprop-2-en-1-yl)piperazin-1-yl)butan-1-one) 9664

* * * * * * *

* * * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on March 8, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for

publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2024–05543 Filed 3–14–24; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF STATE

22 CFR Part 126

[Public Notice: 12306]

RIN 1400–AF80

International Traffic in Arms Regulations: Addition to List of Proscribed Countries

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is amending the International Traffic in Arms Regulations (ITAR) to add Nicaragua in the list of countries for which it is the policy of the United States to deny licenses or other approvals for exports and imports of defense services and defense articles, except as otherwise provided.

DATES: The rule is effective on March 15, 2024.

FOR FURTHER INFORMATION CONTACT: Ms. Maria Tatarska, Foreign Affairs Officer, Office of Defense Trade Controls Policy, U.S. Department of State, telephone (771) 205–7671; email *DDTCCustomerService@state.gov* ATTN: Regulatory Change, ITAR Section 126.1: Nicaragua.

SUPPLEMENTARY INFORMATION: Due to growing concerns regarding Nicaragua's continuing dismantling of democratic institutions, attacks on civil society, and increased security cooperation with Russia, to include support of Russia's full-scale invasion of Ukraine, the Under Secretary of State for Arms Control and International Security has determined that it is in the best interests of U.S. national security and foreign policy to restrict, with certain exceptions, the export and import of defense articles and defense services destined for or originating in Nicaragua. This policy reflects the U.S. government's opposition to the trade of arms with Nicaragua and its authoritarian government dominated by President Daniel Ortega Saavedra and his wife, Vice President Rosario Murillo Zambrana. Pursuant to this determination, the Department is adding Nicaragua to ITAR § 126.1 in paragraph (p). The policy of denial toward Nicaragua applies to licenses or other approvals for exports and imports of defense articles or defense services, except that a license or other approval may be issued on a case-by-case basis for non-lethal military equipment intended solely for humanitarian assistance, to include natural disaster relief. Further, in accordance with ITAR § 129.7, no broker, as described in ITAR § 129.2, may engage in or make a proposal to engage in brokering activities subject to the ITAR that involve Nicaragua without obtaining the approval of the Directorate of Defense Trade Controls. Consistent with ITAR § 129.7(d), the Department of State will apply the same policy of denial to such requests.

Regulatory Analysis and Notices

Administrative Procedure Act

This rulemaking is exempt from the rulemaking requirements of section 553 of the Administrative Procedure Act (APA) pursuant to 5 U.S.C. 553(a)(1) as a military or foreign affairs function of the United States.

Regulatory Flexibility Act

Since this rule is exempt from the notice-and-comment provisions of 5 U.S.C. 553, the rule does not require analysis under the Regulatory Flexibility Act.

Unfunded Mandates Reform Act of 1995

This rulemaking does not involve a mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions are deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

The Department does not believe this rulemaking is a major rule within the definition of 5 U.S.C. 804.

Executive Orders 12372 and 13132

This rulemaking does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this rulemaking.

Executive Orders 12866, 13563, and 14094

Executive Order 12866, as amended by Executive Orders 13563 and 14094, directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributed impacts, and equity). As a result of this change, certain exemptions to licensing requirements will not be available for exports, reexports, retransfers, and temporary imports destined for or originating in Nicaragua. However, a license or other approval may be issued on a case-by-case basis for non-lethal military equipment intended solely for humanitarian assistance, to include natural disaster relief. Because the scope of this rule does not impose significant additional regulatory requirements or obligations, the Department believes costs associated with this rule will be minimal. This rule has been designated a ''significant regulatory action'' by the Office and Information and Regulatory Affairs under Executive Order 12866.

Executive Order 12988

The Department of State has reviewed this rulemaking in light of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13175

The Department of State determined that this rulemaking will not have Tribal implications, will not impose substantial direct compliance costs on Indian Tribal governments, and will not preempt tribal law. Accordingly, Executive Order 13175 does not apply to this rulemaking.

Paperwork Reduction Act

This rulemaking does not impose or revise any information collections subject to 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Part 126

Arms and munitions, Exports.

For the reasons set forth above, title 22, chapter I, subchapter M, part 126 is amended as follows:

PART 126—GENERAL POLICIES AND PROVISIONS

■ 1. The authority citation for part 126 continues to read as follows:

Authority: 22 U.S.C. 287c, 2651a, 2752, 2753, 2776, 2778, 2779, 2779a, 2780, 2791, 2797; Sec. 1225, Pub. L. 108–375, 118 Stat. 2091; Sec. 7045, Pub. L. 112–74, 125 Stat.

15

16

Executive Secretary Report

A. Financial Report
B. Issuance of Temporary Licenses and Registrations
C. Change of Address Business List
D. Meetings with Other Health Care Regulatory Boards
E. Licensing Activities Report
F. Citations & Fines issued pursuant to NRS 632.2895
G. Licensing Update

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
NAC 639.870: APRN Dispensing License/pharmacy applicant appearance	06/02/22	06/02/22 – Dave revising language.	R086-22	06/29/22; 07/05/22: under Dave review; 10/12/23: Included in R100-23 (Executive Order Regs)				
NAC 453.310: DEA Registration	10/13/22	10/19/22	R197-22	05/12/23: to Dave/ Yenh; 05/26/23: Under review by Yenh/Peter; 05/30/23: Hold till final rule on state specific DEA registration requirement.	11/02/23	12/07/23	12/22/23	2/27/24
NAC 639.694: DME Administrator for DME Inventory at a Licensed Hospital	09/07/23	09/12/23	R058-23	10/09/23	11/02/23	12/07/23	12/22/23	2/27/24

NAC 639.520: Security of Pharmacies	09/07/23 Dave to meet with industry							
NAC 639: Administrative Fine in Lieu of Disciplinary Action	09/07/23	09/12/23	R057-23	10/09/23	11/02/23	12/07/23	12/22/23	2/27/24
NAC 639: Protocol for RPH to Treat OUD (AB156)	09/07/23	09/12/23	R059-23	10/19/23	11/02/23	12/07/23	12/22/23	2/27/24
Regulations relating to Governor Lombardo's Executive Order 003-2023. Changes in these Regulations streamline and clarify licensing requirements while ensuring public safety; and providing other matters properly relating thereto.	10/11/23	10/18/23	R100-23	3/6/24	3/14/24; 4/9/24	5/30/24	4/18/24 - Early Review Sent Inform and SBIMPACT to LCB 6/6/24	6/14/24
NAC 453: The proposed amendments relate to controlled substances adding synthetic cannabinoids to the controlled substances listed in Schedule I.	10/11/23	10/18/23	R101-23	11/08/23 - To Dave/ Yenh for review.	3/14/24	4/18/24	4/25/24	6/20/24
NAC 453: Add Zuranolone to Schedule IV	12/07/23	12/13/23	R144-23	01/03/24	2/6/24	3/7/24	3/18/24	4/19/24

NAC 639: The proposed amendment ensures proper and adequate safeguards for registered nurses who participate in certain public health programs or certain mental health services.	01/18/24	2/6/24	R013-24	2/26/24	3/14/24; 4/9/24	5/30/24	4/18/24 - Early Review Sent Inform and SBIMPACT to LCB 6/10/24	6/14/24
NAC 639: The proposed amendment removes various provisions relating to compounding which are in conflict with current United States Pharmacopeia compounding standards.	01/18/24 03/07/24	3/12/24	R053-24	5/13/24 – To Dave/Yenh for review	6/18/24	7/18/24: Dave to make revisions with LCB	10/8/24	11/15/24
NAC 453: The proposed amendments relate to controlled substances adding tianeptine, hallucinogenic substances and fentanyl related substances to the controlled substances listed in Schedule I.	3/7/24	3/12/24	R054-24	4/1/24	4/9/24	5/30/24	6/6/24	6/20/24

A REGULATION relating to pressurized stocking. Allowing pressurized stocking to be provided without a prescription in certain circumstances.	3/7/24	3/12/24	R052-24	4/1/24	4/9/24	5/30/24	6/10/24	6/20/24
The proposed amendments establishes the registration requirements for certified registered nurse anesthetist, under the supervision of a physician licensed pursuant to chapter 630 or 633 or NRS, to order, prescribe, possess, and administer controlled substances, poisons, dangerous drugs and devices to treat a patient under the care of a licensed physician in a critical access hospital in preparation for surgery or childbirth, during surgery or childbirth and while a patient recovers from surgery or childbirth.	3/7/24	3/12/24	R051-24	4/10/24	4/24/24	5/30/24	6/10/24	6/20/24
Amendment to Nevada Administrative Code (NAC) 639.708. The proposed amendments clarifies record keeping requirements of counseling by a pharmacy.	4/18/24	4/23/24	R085-24	6/03/24 – To Dave/Yenh for Review 6/25/24 – Sent revised version to Yenh/Dave	7/19/24	09/05/24	9/17/24	11/15/24

Amendment to Nevada Administrative Code (NAC). The proposed amendments establish the minimum staffing standards in a pharmacy and modify the number of pharmaceutical technicians and pharmaceutical technicians in training a pharmacist may supervise.	5/29/24	6/3/24	R113-24	6/25/24 – To Yenh/Dave for review 7/15/24 – sent revised version to Dave/Yenh		12/5/24		
Amendment to Nevada Administrative Code NAC 639.748. The proposed amendments revises the requirements concerning the documentation an employee of a pharmacy must obtain from a person before dispensing a controlled substance pursuant to a lawful prescription to the person.	7/18/24	7/19/24	R189-24	7/30/24	9/11/24	10/17/24	10/22/24	11/15/24
Amendment to the Nevada Administrative Code ("NAC") 639. The proposed amendments relate to the licensing requirements for facilities for treatment with narcotics and provide other matters properly relating thereto.	10/17/24	10/21/24	R197-24					

December 2024 – Out-of-State Temporary Business License

Original License Date	Business Name	License Number	License Status	License Expiration Date	Address	City, State and Zip
10/28/2024	3B Medical, Inc	WH03721	Temporary	12/13/2024	5101 Fruitville Rd, Suite 200	Sarasota, FL 34232

Citations & Fines issued pursuant to NRS 639.2895 (Since last Board Meeting)

- **Cease & Desist/Citation –**
  - **Unlicensed Practice: 4**
  - **Other: 3**
- **Citation & Fine –**
  - **Unlicensed Practice: 1**
  - **Misfill: 4**
  - **Other: 1**

17

18

19